Remuneration and regulation of community pharmacy

Literature review

Department of Health

November 2016
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<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACA</td>
<td>Affordable Care Act</td>
</tr>
<tr>
<td>ACO</td>
<td>Accountable Care Organization</td>
</tr>
<tr>
<td>AEMPS</td>
<td>Spanish Agency of Medicines and Medicinal Products</td>
</tr>
<tr>
<td>AHI</td>
<td>administration, handling and infrastructure</td>
</tr>
<tr>
<td>AIHW</td>
<td>Australian Institute of Health and Welfare</td>
</tr>
<tr>
<td>AUD</td>
<td>Australian dollars</td>
</tr>
<tr>
<td>BIG</td>
<td><em>Individual Health Care Professions Act 1993</em></td>
</tr>
<tr>
<td>CGMPs</td>
<td>Current Good Manufacturing Practices</td>
</tr>
<tr>
<td>CMM</td>
<td>Comprehensive Medication Management</td>
</tr>
<tr>
<td>CPAM</td>
<td>Community Pharmacy Anti-Coagulation Management</td>
</tr>
<tr>
<td>CPSA</td>
<td>Community Pharmacy Services Agreement</td>
</tr>
<tr>
<td>CSO</td>
<td>Community Service Obligation</td>
</tr>
<tr>
<td>DHB</td>
<td>District Health Board</td>
</tr>
<tr>
<td>DKR</td>
<td>Danish krones</td>
</tr>
<tr>
<td>DIS</td>
<td>Drug Information System</td>
</tr>
<tr>
<td>EFC</td>
<td>efficient funding of chemotherapy</td>
</tr>
<tr>
<td>EHR</td>
<td>electronic health record</td>
</tr>
<tr>
<td>ETP</td>
<td>Electronic Transfer of Prescriptions</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>GDP</td>
<td>gross domestic product</td>
</tr>
<tr>
<td>GP</td>
<td>general practitioner</td>
</tr>
<tr>
<td>HIE</td>
<td>health information exchange</td>
</tr>
<tr>
<td>HSE</td>
<td>Health Service Executive</td>
</tr>
<tr>
<td>INGESÁ</td>
<td>National Institute of Healthcare Management</td>
</tr>
<tr>
<td>IPHA</td>
<td>Irish Pharmaceutical Healthcare Association</td>
</tr>
<tr>
<td>IPU</td>
<td>Irish Pharmacy Union</td>
</tr>
<tr>
<td>LEEM</td>
<td>Les Entreprises du Médicament en France</td>
</tr>
<tr>
<td>MTA</td>
<td>Medicines Therapy Assessment</td>
</tr>
<tr>
<td>MTM</td>
<td>Medication Therapy Management</td>
</tr>
<tr>
<td>MUR</td>
<td>Medicine Use Review</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<tr>
<td>NAPRA</td>
<td>National Association of Pharmacy Regulatory Authorities</td>
</tr>
<tr>
<td>NGA</td>
<td>National Governors Association</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service</td>
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<tr>
<td>NOK</td>
<td>Norwegian Krone</td>
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<tr>
<td>NoMA</td>
<td>Norwegian Medicine Agency</td>
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<tr>
<td>NPFIT</td>
<td>National Programme for IT</td>
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<tr>
<td>NSW</td>
<td>New South Wales</td>
</tr>
<tr>
<td>NZePS</td>
<td>New Zealand ePrescription Service</td>
</tr>
<tr>
<td>OECD</td>
<td>Organisation for Economic Co-operation and Development</td>
</tr>
<tr>
<td>OTC</td>
<td>over-the-counter</td>
</tr>
<tr>
<td>PBAC</td>
<td>Pharmaceutical Benefits Advisory Committee</td>
</tr>
<tr>
<td>PBM</td>
<td>pharmacy benefits manager</td>
</tr>
<tr>
<td>PBS</td>
<td>Pharmaceutical Benefits Scheme</td>
</tr>
<tr>
<td>PCEHR</td>
<td>Personally Controlled Electronic Health Record</td>
</tr>
<tr>
<td>PHARMAC</td>
<td>Pharmaceutical Management Agency</td>
</tr>
<tr>
<td>PHIS</td>
<td>public health insurance system</td>
</tr>
<tr>
<td>PMPRB</td>
<td>Patented Medicine Prices Review Board</td>
</tr>
<tr>
<td>PPP</td>
<td>pharmacy purchase price</td>
</tr>
<tr>
<td>PSI</td>
<td>Pharmaceutical Society of Ireland</td>
</tr>
<tr>
<td>PSNC</td>
<td>Pharmaceutical Services Negotiating Committee</td>
</tr>
<tr>
<td>PSNZI</td>
<td>Pharmaceutical Society of New Zealand Incorporated</td>
</tr>
<tr>
<td>QRE</td>
<td>quality-related event</td>
</tr>
<tr>
<td>RPBS</td>
<td>Repatriation Pharmaceutical Benefits Scheme</td>
</tr>
<tr>
<td>RTPM</td>
<td>Real Time Prescription Monitoring</td>
</tr>
<tr>
<td>SEK</td>
<td>Swedish krona</td>
</tr>
<tr>
<td>SHI</td>
<td>statutory health insurance</td>
</tr>
<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>USA</td>
<td>United States of America</td>
</tr>
<tr>
<td>USD</td>
<td>United States of America dollars</td>
</tr>
<tr>
<td>VAT</td>
<td>value-added tax</td>
</tr>
<tr>
<td>VHI</td>
<td>voluntary health insurance</td>
</tr>
<tr>
<td>6CPA</td>
<td>Sixth Community Pharmacy Agreement</td>
</tr>
</tbody>
</table>
Executive summary

Deloitte Access Economics was commissioned by the Australian Government Department of Health to undertake a literature review of community pharmacy in Australia and 12 other countries: New Zealand, Japan, the United States of America (USA), Canada, France, Spain, the Netherlands, Denmark, Norway, Sweden, the United Kingdom (UK: limited to England, Scotland and Wales), and the Republic of Ireland.

The project is an input to the broader Review of Pharmacy Remuneration and Regulation, which will provide recommendations on remuneration and regulation of community pharmacy, and other arrangements that apply to pharmacy and wholesalers, to ensure that consumers have reliable and affordable access to medicines.

Health system context and expenditure

Each of the 13 countries (including Australia) have differing structures, policies and responsibilities within their health care systems. However, it is evident from this analysis that governments play an integral role in managing, delivering services and funding health care in all countries.

Of the 13 countries, 12 countries (excluding the USA) provide universal health care to their citizens, primarily funded by government. The USA does not have universal health care through the public system; health services are mainly financed and provided privately. Some countries, including Australia, offer one national health insurance system which provides reimbursement of defined health care services. Others provide universal health coverage through a national scheme, with some regional oversight. Private health insurance also plays a role, to varying degrees, in the different countries’ health systems. In general, private health insurance primarily supplements public health care, aiming to offer greater choice of providers, faster access and rebates for selected services. The exceptions are the USA, where private health insurance plays a major role in health care funding, and the Netherlands which mandates that health insurance be purchased from private providers.

Average per capita expenditure (in United States of America dollars ($USD)) on public and private health care ranged from $2,204 in Spain, up to $9,086 in the USA. In Australia, per capita health expenditure is $4,115. Australia’s per capita health expenditure is comparable to 7 of the 12 other countries reviewed. Total (public and private) pharmaceutical expenditure per capita (in $USD) ranged from $288 in Denmark, to $1,034 in the USA. This compares to $590 in Australia, which was higher than the majority of countries studied.

Remuneration and regulation

In general, four different types of regulated pharmacy margins (or mark-ups) were seen: regressive (a fixed percentage which decreases as the price to which it refers increases), progressive (a fixed percentage which increases as the price to which it refers increases), linear (an equation is applied to all price ranges) or flat fee (a flat percentage is applied to all price ranges), or a combination of these. The most common type of pharmacy margin was regressive; this was the case in France and Sweden, and a combination of regressive and fixed
is used in both Norway and Spain. Australia previously had a regressive pharmacy margin that was replaced in 2015 with the administration, handling and infrastructure fee – of a predominantly fixed type.

Pharmacy margins in the 13 countries ranged from 3% in Norway (for higher priced medicines as the margins are regressive), up to 27.9% in Spain, 25.5% in France and, on average, 21.3% in Sweden. Dispensing fees (converted to AUD) ranged from $0.73 per pack dispensed in France (for prescriptions with five or more medicines), up to $7.12 in Ireland. Australia was only slightly lower than the highest dispensing fees at $7.02. In general, where dispensing fees were higher (or absent), pharmacy margins were comparably lower. In both Spain and Sweden, dispensing fees are foregone while pharmacy margins are generally higher.

Consistent with the restrictions in Australia, ownership of pharmacies is limited to pharmacists in Spain and France. In Norway and Sweden, only doctors and the pharmaceutical industry are excluded from ownership. In New Zealand and Denmark, non-pharmacists can have part ownership in a pharmacy if a pharmacist is the majority owner. In contrast, there are no restrictions on ownership in Ireland, Canada, Japan, the Netherlands, the UK and the USA. In terms of pharmacy location, Australia, Denmark, France and Spain restrict the location of pharmacies on the basis of population serviced, and proximity to other pharmacies. The UK and Ireland also place restrictions on the location of pharmacies and approval is needed prior to opening a new pharmacy however this does not consider proximity to other pharmacies. There are no restrictions on location of pharmacies in Canada, Japan (although approval is needed), the Netherlands, Norway, New Zealand, Sweden and the USA.

**Scope of services, settings and distribution**

In addition to dispensing medicines, countries that remunerate pharmacists on a per service basis for additional patient services included Australia, Canada, Denmark, France, Japan, the Netherlands, New Zealand, Spain and the UK. The services that are remunerated in addition to standard remuneration varies between the countries. In contrast to Australia, pharmacists in Canada have a wide range of professional offerings including the ability to prescribe medicines to patients for minor ailments, initiate prescription medicine therapy, offer therapeutic substitution, order laboratory tests and administer medicines by injection. Pharmacist Prescribers in New Zealand are also able to modify, initiate or discontinue medicines for patients under a team care arrangement with prescribers.

Besides community pharmacies and hospital pharmacies, other settings in which prescription medicines may be dispensed to the community include dispensing doctors in rural areas in Australia, France, Ireland, Netherlands, Norway and the UK. Branch pharmacies – small outlets under the supervision of a pharmacy – can dispense medicines to the community in Denmark and Norway. In contrast to Australia, prescribers can dispense medicines directly to patients in Japan (although this is declining) and in the majority of states in the USA. Denmark, the Netherlands, Norway, Sweden and the UK allow the purchase of prescription medicines from internet sources (‘internet pharmacies’).
At 83 pharmacists and 23.1 pharmacies per 100,000 population, respectively, Australia is just below the 12 country average of 87 pharmacists per 100,000 population, and 24 pharmacies per 100,000 population. In comparison to the Netherlands, which had the lowest number of pharmacists per 100,000 population, Australia has around four times the number of pharmacists per 100,000 population and nearly twice as many pharmacies per 100,000 population. When compared to Japan, which had the highest density of pharmacists and pharmacies, Australia has approximately half as many pharmacists and pharmacies per 100,000 population. In Norway, deregulation of the community pharmacy sector in 2000 removed limitations on the ownership of pharmacies, and removed the limitations on establishing new pharmacies. This improved accessibility to medicines as it led to an increase in the number of pharmacies, and an increase in the opening hours of pharmacies.

**Wholesaler supply arrangements**

A number of countries allow direct commercial arrangements from pharmaceutical manufacturers to pharmacies. These include employing a restricted number of wholesalers as sole agents to distribute products directly to pharmacy, or, indeed, using wholesalers as logistics providers for the same purpose. While the majority of pharmacy sales continue to originate from (full-line) wholesalers, in a number of countries the proportion of pharmacy sales originating directly from the manufacturer is more than 10%. Direct to pharmacy distribution is not currently used in Japan, New Zealand, or Sweden. In these countries, the traditional model from manufacturers to pharmacies using wholesalers is used for the distribution of medicines throughout the supply chain.

Of the countries included in the analysis, most do not regulate wholesale margins. Australia, France and Spain have regulated wholesale margins, while the other countries do not. The regulated countries all use a combination of regressive and fixed margins for wholesale remuneration. For the unregulated countries, an official margin is not stipulated by the government and typically depends on private negotiations between the wholesaler and the pharmacy. As a result, the wholesale prices of medicines vary with individual pharmacies and hospitals.

**Adoption of technology**

Globally, there has been increased uptake of electronic technology within the health and pharmacy sectors. In particular, many countries have adopted, to varying degrees, electronic health records (EHR), e-prescription systems and other e-pharmacy interventions such as telemedicine.

Denmark is generally recognised as being at the forefront of eHealth initiatives. Technology is used at all levels of the health system. E-prescriptions are replacing paper-based prescriptions in both Australia and internationally. All countries included in this study utilise e-prescriptions, uptake of which varies between the countries. Uptake is greater than 90% in Sweden and Denmark.

In the same way as Australia, many countries (including Canada, Denmark, France, the Netherlands, Ireland, Spain, Sweden, the United Kingdom and the United States) use EHRs or EHR equivalents within their health system, with varying degrees of uptake.
Unique technological initiatives include prescription dispensing machines in Ontario, Canada. These machines, called PharmaTrust MedCentres, are remote dispensing systems and allow users to communicate with a pharmacist who might be located elsewhere via videoconferencing. They have been installed in rural communities and allow access to pharmacists in communities where pharmacies may be scarce. In Spain and the UK, a number of community pharmacies have begun to experiment with remote dispensing robots. These machines are placed in a community pharmacy and dispense the required medicines directly to the pharmacist, with no need for the pharmacist to locate the products.

**Reforms, incentives and learnings**

Global trends in pharmaceutical sector reform have focused on pricing reforms, increased use of generic medicines and expanding the role of the pharmacist. Australia recently began implementation of the 2015-2020 PBS Access and Sustainability Package, which includes a number of initiatives focused on controlling growing pharmaceutical expenditure. A number of countries have focussed on increasing the uptake of generic medicines and price referencing in an attempt to contain increasing medicine costs.

A number of other reforms have been implemented in the pharmacy sector in the countries reviewed. France has implemented reforms to reduce package wastage and low value care. In April 2016, Japan introduced the “family pharmacist” scheme, where a pharmacist is appointed by a patient as their pharmacist. This initiative aims to expand the role of community pharmacists, avoid duplication and reduce waste by establishing a single medicine gatekeeper.

The Irish *Pharmacy Act 2007* introduced the requirement for the management and administration of the sale and supply of medicines to be under the personal control of the superintendent pharmacist. The superintendent pharmacist model was introduced as a measure to ensure that the management and administration of the sale and supply of medicines in retail pharmacies in Ireland is firmly under the control of a senior pharmacist with a defined minimum level of experience. The superintendent pharmacist is the person who is in overall control of professional and clinical management, while the supervising pharmacist is the pharmacist who is responsible for day-to-day management of the pharmacy.

**Country profiles**

The following tables summarise the key findings of this inter-country analysis. Table i provides an overview of the 13 countries’ health systems, as well as key data on health expenditure, pharmacy and pharmaceutical expenditure and distribution of pharmacies and pharmacists. Table ii provides a comparison of the 13 countries’ pharmacy remuneration and regulation arrangements including scope of services provided by pharmacists and the delivery settings for prescription medicines. Table iii compares the wholesale remuneration and distribution arrangements for each of the 13 countries, as well as the current state of technological advance in e-health and an overview of key pharmaceutical sector reforms.
## Table i: Health system context and key statistics

<table>
<thead>
<tr>
<th>Country</th>
<th>Health system context</th>
<th>Health expenditure</th>
<th>Pharmaceutical expenditure</th>
<th>Distribution</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Australia</strong></td>
<td>Universal public health insurance (&quot;Medicare&quot;) is primarily funded by government. Services are funded under Medicare Benefits Scheme. State and local governments also administer public hospitals, community health services and mental health services. The Pharmaceutical Benefits Scheme is the nationally subsidised program which provides prescription medicines to Australians.</td>
<td>9.4%; $4,115</td>
<td>$590</td>
<td>83.0; 23.1</td>
</tr>
<tr>
<td><strong>Canada</strong></td>
<td>Universal public health Insurance (&quot;Medicare&quot;) is primarily funded by government. Medicare covers physician, diagnostic imagining and other medically necessary services. Medicare does not cover prescription medicines. This is covered by province and territories own health insurance plans. Delivery of health services is primarily delegated to the province and territory governments. Private health insurance is also an option for Canadians.</td>
<td>10.7%; $4,569</td>
<td>$761</td>
<td>92.0; 26.7</td>
</tr>
<tr>
<td><strong>Denmark</strong></td>
<td>Universal health care system is primarily funded by government. Services are primarily managed and delivered through local municipalities. Voluntary insurance is also common, which covers statutory co-payments—mainly for pharmaceuticals and dental care.</td>
<td>11.1%; $4,847</td>
<td>$288</td>
<td>50.0; 3.9</td>
</tr>
<tr>
<td><strong>France</strong></td>
<td>The French health care system is funded by the government. Statutory Health Insurance (SHI) is Universal to the resident population and covers listed medicines. Most voluntary health insurance (VHI) complements SHI, covering mainly the co-payments for usual care, balance billing, and vision and dental care.</td>
<td>11.1%; $4,367</td>
<td>$656</td>
<td>106.0; 34.0</td>
</tr>
<tr>
<td><strong>Ireland</strong></td>
<td>The Irish public health system is universal and is provided and funded by government. The Health Services Executive is responsible for the budget and management of health services. A majority of the population also have VHI which provides semi-state private insurance coverage.</td>
<td>8.0%; $4,157</td>
<td>$765</td>
<td>114.0; 37.5</td>
</tr>
<tr>
<td><strong>Japan</strong></td>
<td>The Japanese government provide a universal Public Health Insurance System (PHIS). Enrolment in one of the PHIS plans is mandatory and the government determines the benefits package that is provided by all plans. This package covers approved medicines amongst other services. The majority of the population also hold private insurance.</td>
<td>10.2%; $3,713</td>
<td>$756</td>
<td>161.0; 45.0</td>
</tr>
<tr>
<td><strong>Netherlands</strong></td>
<td>SHI is purchased from private insurers, and is mandatory for all Dutch residents. Standard benefits package includes general practitioners (GPs), hospitals, specialists, dental, prescription</td>
<td>11.1%; $5,131</td>
<td>$397</td>
<td>21.0; 11.7</td>
</tr>
</tbody>
</table>
medicines, basic ambulatory and mental health care. Most of the population also purchases VHI, which covers dental care, alternative medicine, physiotherapy, spectacles and lenses, contraceptives and the full cost of co-payments.

<table>
<thead>
<tr>
<th>Country</th>
<th>System Description</th>
<th>2014 %</th>
<th>2015 %</th>
<th>2012 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Zealand</td>
<td>New Zealand has a universal public health system funded by government. Services include hospital, mental health and dental services. District Health Boards are responsible for managing health services within their regions. A government organisation decides which pharmaceuticals will receive a government subsidy.</td>
<td>11.0%</td>
<td>$3,855</td>
<td>$420</td>
</tr>
<tr>
<td>Norway</td>
<td>Norway has a universal public health system that is primarily funded by government. Local municipalities are responsible for providing primary health care, whilst the state is responsible for specialist care.</td>
<td>9.4%</td>
<td>$6,170</td>
<td>$437</td>
</tr>
<tr>
<td>Spain</td>
<td>The Spanish Nation Health System provides virtually universal health coverage offering a comprehensive benefits package. Private VHI is held by only a small number of the population.</td>
<td>9.0%</td>
<td>$2,062</td>
<td>$489</td>
</tr>
<tr>
<td>Sweden</td>
<td>The Swedish universal health care is primarily funded by government. The health care system is largely regionally based and publicly operated. County councils and local municipalities are responsible for delivery of services.</td>
<td>11.5%</td>
<td>$5,153</td>
<td>$496</td>
</tr>
<tr>
<td>UK</td>
<td>The UK universal health care system is primarily funded by government. Each country within the UK has a National Health Service that is responsible for managing the health care system within each jurisdiction. Services are delivered through public providers and have devolved purchasing responsibilities to local bodies (primary care trusts in England, Health Boards in Scotland, Local Health Boards in Wales and Primary care partnerships in Northern Ireland). Within the UK there is a low uptake of private health insurance.</td>
<td>8.8%</td>
<td>$3,364</td>
<td>$471</td>
</tr>
<tr>
<td>USA</td>
<td>The USA does not have a universal public health care system. Eligible residents are able to get government health insurance from Medicare, Medicaid or the Children’s Health Insurance Program. Services covered by these programs vary. Other options include private health insurance or employer-covered insurance.</td>
<td>17.1%</td>
<td>$9,086</td>
<td>$1,034</td>
</tr>
</tbody>
</table>

Notes: ^ per 100,000 population. 1 2014 figure. 2 2015 figure. 3 2012 figure.
<table>
<thead>
<tr>
<th>Country</th>
<th>Remuneration</th>
<th>Regulation*</th>
<th>Scope of remunerated services^ (other than dispensing)</th>
<th>Supply of prescription medicines*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Non-pharmacist ownership</td>
<td>Number of pharmacies per owner</td>
<td>Location</td>
</tr>
<tr>
<td>Australia</td>
<td>Dispensing fees, AHI fee (replaces pharmacy margin). Chemotherapy compounding</td>
<td>✓</td>
<td>✓</td>
<td>Professional service programs,</td>
</tr>
<tr>
<td></td>
<td>additional fees per service</td>
<td></td>
<td>✓</td>
<td>counselling and immunisations</td>
</tr>
<tr>
<td>Canada</td>
<td>Varies by province</td>
<td>X</td>
<td>X</td>
<td>Prescribing, therapeutic substitution;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td>order and interpret lab tests;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>administer injections</td>
</tr>
<tr>
<td>Denmark</td>
<td>Dispensing fees, Flat mark-up</td>
<td>~</td>
<td>✓</td>
<td>Unused medicine disposal, dose</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td>dispensing, counselling</td>
</tr>
<tr>
<td>France</td>
<td>Dispensing fees, plus price-based (regressive) margin</td>
<td>✓</td>
<td>✓</td>
<td>Counselling about appropriate use of</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td>medicines and smoking cessation</td>
</tr>
<tr>
<td>Ireland</td>
<td>Flat fee and dispensing fee, plus margin in some situations</td>
<td>X</td>
<td>X</td>
<td>Repeat dispensing, vaccination,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>testing services, aged care services</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>and smoking cessation</td>
</tr>
<tr>
<td>Japan</td>
<td>Dispensing fees, Pharmacy margins negotiated privately</td>
<td>X</td>
<td>X</td>
<td>Home health care, health promotion,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>medicine guidance and generic</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>switching</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Dispensing fees, no fixed mark-up</td>
<td>X</td>
<td>X</td>
<td>Guidance, device instruction,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>medicine review, counselling.</td>
</tr>
<tr>
<td>New Zealand</td>
<td>Progressive margin plus dispensing fees</td>
<td>~</td>
<td>~</td>
<td>Medicine management services,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>adherence programs and medicine</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>review</td>
</tr>
<tr>
<td>Norway</td>
<td>Combination of regressive margin and fixed margin, no dispensing fees</td>
<td>~</td>
<td>✓</td>
<td>Medicine review, smoking cessation,</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td>disease management programs.</td>
</tr>
<tr>
<td>Country</td>
<td>Remuneration</td>
<td>Regulation*</td>
<td>Scope of remunerated services^ (other than dispensing)</td>
<td>Supply of prescription medicines*</td>
</tr>
<tr>
<td>---------</td>
<td>--------------</td>
<td>-------------</td>
<td>------------------------------------------------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>Spain</td>
<td>Combination of regressive margin and fixed margin, no dispensing fees</td>
<td>✓ ✓ ✓</td>
<td>Adherence programs, vaccinations, medicine therapy reviews, remote pharmacy reviews, health promotion and health education.</td>
<td>Internet pharmacies</td>
</tr>
<tr>
<td>Sweden</td>
<td>Regressive margin, no dispensing fees</td>
<td>~ X X</td>
<td>Medicine waste disposal, medicine review services and blood pressure testing.</td>
<td>Internet pharmacies</td>
</tr>
<tr>
<td>UK</td>
<td>Dispensing fees and pool of retained margins</td>
<td>X X ✓</td>
<td>Anticoagulation monitoring, emergency contraception, minor ailment scheme, smoking cessation, advanced services (remunerated)</td>
<td>Internet pharmacies</td>
</tr>
<tr>
<td>USA</td>
<td>Pharmacies are remunerated either directly by the consumer or the consumer and their insurer</td>
<td>~ X X</td>
<td>Medication reviews, disease management, immunisations and anticoagulation management.</td>
<td>GPs are legally able to dispense medicines in 44 states. Nurses and GP assistants are allowed to dispense medicines in 38 states.</td>
</tr>
</tbody>
</table>

Notes: *A tick means the country has that regulation while a cross signifies that no regulation was found. A tilde signifies that the country has some form of that regulation, but not as extensive as Australia. ^ This is not restricted to government funded services. *This refers to dispensers other than pharmacies and hospital pharmacies. It should be noted that not all countries have hospital pharmacies.
<table>
<thead>
<tr>
<th>Country</th>
<th>Wholesaler distribution</th>
<th>Wholesaler remuneration</th>
<th>Technology adoption</th>
<th>Recent reforms and innovations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Three primary methods to distribute medicines: use of community service obligation (CSO) and non-CSO wholesalers and manufacturer to pharmacy distribution</td>
<td>Mark-ups for CSO wholesalers are regulated by the government</td>
<td>My Health Record is the Australian EHR system. Uptake of e-prescribing is not known.</td>
<td>Recent reforms include removal of some over-the-counter medicines from the Pharmaceutical Benefits Scheme, pharmacist option to discount patient co-payment by $1 and changes to pharmacy remuneration.</td>
</tr>
<tr>
<td>Canada</td>
<td>Use of wholesalers and direct manufacturer to pharmacy distribution.</td>
<td>Wholesalers negotiate privately with manufacturers. Rebates and margins vary by jurisdiction.</td>
<td>In 2010 pharmacists reported that 40% of prescriptions they received were generated from e-prescriptions.</td>
<td>Policy debate has focused on whether or not to provide a universal pharmaceutical care plan and expansion of the scope of pharmacists’ services.</td>
</tr>
<tr>
<td>Denmark</td>
<td>Two wholesalers distribute medicines to all pharmacies. Direct distribution of manufacturers to pharmacies exists but is not common.</td>
<td>Wholesaler profits are negotiated between the manufacturers or importers and wholesalers.</td>
<td>Recognised as being at the forefront of e-health initiatives. Technology is used at all levels of the health system.</td>
<td>Changes include creation of personal electronic medicine profiles, national interaction database and a reporting system for errors and adverse medicine events</td>
</tr>
<tr>
<td>France</td>
<td>59% of medicines are distributed by wholesalers. 15% are sold directly to retail pharmacies.</td>
<td>Combination of regressive and fixed</td>
<td>Approximately 0.8% of the population has an EHR. Currently implementing a high-level EHR project across the country.</td>
<td>Recent reforms include measures to increase access to generic medicines, reduce package wastage and reduce low value care.</td>
</tr>
<tr>
<td>Ireland</td>
<td>Increasingly focused on direct to pharmacy methods</td>
<td>The wholesaler’s margin is not regulated by government</td>
<td>e-pharmacy program was developed in 2015.</td>
<td>Changes to supply models to promote increased uptake of generic medicines and requirement to have a superintendent pharmacist.</td>
</tr>
<tr>
<td>Japan</td>
<td>Manufacturers distribute solely through wholesalers to patients via retailers. Four wholesaler companies account for 90% of the distribution market.</td>
<td>Prices are negotiated between wholesalers and pharmaceutical companies.</td>
<td>EHRs and e-prescriptions are only used as experiments in Japan.</td>
<td>The new scheme of the “family pharmacist” aims to expand roles of community pharmacies.</td>
</tr>
</tbody>
</table>

Table iii: Wholesale arrangements. technology adoption and reforms
<table>
<thead>
<tr>
<th>Country</th>
<th>Wholesaler distribution</th>
<th>Wholesaler remuneration</th>
<th>Technology adoption</th>
<th>Recent reforms and innovations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Netherlands</td>
<td>There are five full line wholesalers that account for over 90% of the market share.</td>
<td>Wholesale margins are not set by law.</td>
<td>Most GPs (50-80%) are already registering their prescriptions electronically.</td>
<td>Since 2005, insurers have used a ‘preferential pricing policy’ to designate specific medicines for reimbursement.</td>
</tr>
<tr>
<td>New Zealand</td>
<td>Manufacturers distribute through wholesalers to patients via pharmacies.</td>
<td>Margins are negotiated between wholesalers and pharmacies.</td>
<td>The uptake of e-prescription services started in March 2016.</td>
<td>The Pharmacy Action Plan 2016-2020 outlined plans for the expanded role of the pharmacist in the workplace.</td>
</tr>
<tr>
<td>Norway</td>
<td>Three primary wholesalers in the market. They are vertically integrated with their own pharmacy chain.</td>
<td>Margins are negotiated between wholesalers and manufacturers.</td>
<td>By 2013, approximately 80% of total reimbursed prescriptions claims were electronic.</td>
<td>In 2002 an international price referencing system was implemented to set a maximum price for new and existing medicines.</td>
</tr>
<tr>
<td>Spain</td>
<td>Wholesalers distribute 95% of medicines.</td>
<td>Combination of regressive and fixed EHRs and e-prescribing have been rolled out in most of the territories.</td>
<td>EHRs and e-prescribing have been rolled out in most of the territories.</td>
<td>Introduction of reference prices and aggressive generic use policies.</td>
</tr>
<tr>
<td>Sweden</td>
<td>Two wholesalers make up 95% of the market. Wholesalers have exclusive right to distribute medicines for a manufacturer.</td>
<td>Wholesale margins are negotiated directly with pharmaceutical companies.</td>
<td>Well-advanced; more than 90% of prescriptions dispensed are e-prescriptions</td>
<td>Low mark-ups in the distribution chain, no value-added tax for prescription medicines, mandatory generic substitution and pharmacists must dispense the cheapest medicine on the Swedish market.</td>
</tr>
<tr>
<td>UK</td>
<td>Use of wholesalers and direct manufacturer to pharmacy distribution.</td>
<td>The wholesaler’s margin is not regulated by government</td>
<td>Community pharmacies use EHRs and e-prescribing. Estimated 49% of prescriptions were electronic in 2016.</td>
<td>Some initiatives have aimed to improve quality of pharmacies and increase collaboration of GPs and pharmacists.</td>
</tr>
<tr>
<td>USA</td>
<td>Manufacturers sell medicines to wholesalers who then sell to pharmacies.</td>
<td>Margins vary depending on arrangements with pharmacy benefit managers, wholesalers, insurance companies, pharmacies and manufacturers.</td>
<td>Surescripts is the primary e-prescribing network. In 2013, 57% of prescriptions were sent electronically.</td>
<td>The Affordable Care Act was recently implemented. Impacts on the pharmacy sector include increased reporting requirements, demand and accountability.</td>
</tr>
</tbody>
</table>
1 Introduction

Deloitte Access Economics was commissioned by the Australian Government Department of Health to undertake a literature review of community pharmacy in Australia and 12 other countries: New Zealand, Japan, the United States of America (USA), Canada, France, Spain, the Netherlands, Denmark, Norway, Sweden, the United Kingdom (UK: limited to England, Scotland and Wales), and the Republic of Ireland.

The project is an input to the broader Review of Pharmacy Remuneration and Regulation (the Review), which will provide recommendations on remuneration and regulation of community pharmacy, and other arrangements that apply to pharmacy and wholesalers, to ensure that consumers have reliable and affordable access to medicines. The Review was announced during the development of the Sixth Community Pharmacy Agreement (6CPA) between the Australia Government and the Pharmacy Guild of Australia.

This chapter presents information on the scope of research for the literature review and the structure of the report, and an overview of the methods used for conducting the research.

1.1 Scope of research and structure of report

The terms of reference for this project identified twelve research questions for each of the 13 countries included in the project. These have been grouped into six topics, as follows:

- **Health system context and expenditure:**
  - Background and contextual information on the health system.
  - Government expenditure on community pharmacy, including trend analysis and comparison to total health expenditure.

- **Remuneration and regulation:**
  - Remuneration for community pharmacy for the dispensing of medicines.
  - Pharmacy regulation (including pharmacy location requirements, if any).
  - Regulatory and other arrangements or incentives in place to promote high standards of delivery and accountability among pharmacies, wholesalers and manufacturers.
  - The delivery settings, regulatory arrangements and remuneration for the extemporaneous preparation of infusions and injections for chemotherapy.

- **Scope of services, settings and distribution:**
  - Scope of professional services provided through community pharmacy and the funding model/s for the delivery of these professional services.
  - Pharmacy distribution (in urban, regional and remote areas) and analysis of the number of pharmacies in comparison to population data (for example, geographic and population density).
  - Various settings and arrangements for the dispensing of medicines and the delivery of pharmaceutical services, beyond community pharmacies.
• **Wholesaler supply arrangements:** wholesaler supply arrangements (including wholesaling, logistics and distribution of medicines from manufacturer to community pharmacy) and the level and structure of remuneration for wholesalers and pharmacies.

• **Adoption of technology:** adoption of electronic technology in pharmacies, including (but not limited to) e-health records for patients, telehealth, electronic/remote dispensing and online pharmacy.

• **Reforms, innovations and trials:** recent reforms, innovations or trials to improve access to, affordability and quality use of medicines.

For Australia only, the scope of research also included the predicted growth and distribution of demand for community pharmacy in the short, medium and long term, and analysis of these findings in the context of demographic and health care trends.

Chapters 2 to 5 present the findings from the research for the 13 countries. The chapters are structured as follows:

- Chapter 2 presents the findings for the Asia-Pacific region: Australia (Section 2.1), New Zealand (Section 2.2) and Japan (Section 2.3).
- Chapter 3 presents the findings for North America: the USA (Section 3.1) and Canada (Section 3.2).
- Chapter 4 presents the findings for continental Europe: France (Section 4.1), Spain (Section 4.2), the Netherlands (Section 4.3), Denmark (Section 4.4), Norway (Section 4.5), and Sweden (Section 4.6).
- Chapter 5 presents the findings for the UK (Section 5.1) and Ireland (Section 5.2).

Chapter 6 presents a comparative analysis of the international community pharmacy models with Australia’s current arrangements. The chapter is grouped into the six topics.

Throughout the report, some references to amounts in foreign currencies have been converted into either Australian dollars (AUD), USA dollars (USD), or euros. Exchange rates that were current as of October 2016 were used, and were sourced from www.oanda.com. Amounts in foreign currencies can be converted to AUD using the following average rates: Canadian dollars 1.01; Danish krones (DKR) 5.13; Euros 0.69; British pounds 0.62; Japanese yen 78.87; Norwegian krones (NOK) 6.21; New Zealand dollars 1.06; Swedish krona (SEK) 6.69; and USD 0.76.

### 1.2 Methodological approach to the research

There were three methods used for gathering literature to provide an evidence base for answering the research questions. The first two methods were a systematic search of peer-reviewed literature, and a desktop research of publicly-available grey literature. Following these searches, Deloitte offices in the UK, Spain, Canada, USA, New Zealand, Japan, and Denmark were engaged to check the accuracy and completeness of the findings, address information gaps, and provide insights and commentary on recent developments.

For the systematic search, a consultant medical librarian developed the search strategy for searching the Embase and Medline databases. As part of developing the search strategy, relevant search terms comprising indexed keywords (subject headings) along with free text terms appearing in titles and/or abstracts of records when needed were used to identify the
topic of interest, being community pharmacy terms AND-ed with remuneration / regulation terms AND-ed country terms. A full list of search topic terms is provided in Appendix A. Inclusion and exclusion criteria restricted the search to English language results, from the period 2010 to 2016. The search was carried out on 11 October 2016.

A total of 13 subsets of records were extracted from the databases, which represented 10,694 unique records. These are itemised in Table 1.1. Note that due to overlaps between the results for each country, the total number of papers retrieved was less than the sum of the results for each country. As can be seen in Table 1.1, the countries with the most results were Australia, the USA, Canada and the UK.

Table 1.1: Results of the systematic search

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of search results*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>1,287</td>
</tr>
<tr>
<td>USA</td>
<td>5,032</td>
</tr>
<tr>
<td>Canada</td>
<td>1,303</td>
</tr>
<tr>
<td>New Zealand</td>
<td>155</td>
</tr>
<tr>
<td>Japan</td>
<td>222</td>
</tr>
<tr>
<td>UK (England, Wales and Scotland)</td>
<td>2,148</td>
</tr>
<tr>
<td>Sweden</td>
<td>131</td>
</tr>
<tr>
<td>France</td>
<td>469</td>
</tr>
<tr>
<td>Spain</td>
<td>385</td>
</tr>
<tr>
<td>Netherlands</td>
<td>390</td>
</tr>
<tr>
<td>Denmark</td>
<td>105</td>
</tr>
<tr>
<td>Norway</td>
<td>76</td>
</tr>
<tr>
<td>Ireland</td>
<td>306</td>
</tr>
</tbody>
</table>

Note: * this is the number of results with duplicate results removed.

Using the results of the search, a targeted search of publications with publicly-available abstracts was undertaken to identify relevant literature. Full-text articles corresponding to the relevant abstracts were retrieved and included in the findings for each country.
2 Asia-Pacific

The following sections present information on the community pharmacy sector in Australia, New Zealand and Japan. The community pharmacy sector in these countries are compared with Australia in Chapter 6.

2.1 Australia

Information on Australia has been included in the report in more detail than for other countries, to provide an agreed base from which comparisons with other countries can be drawn.

2.1.1 Health system context and expenditure

Australia has a universal public health insurance program (“Medicare”) funded by the Federal Government. Medicare provides funding for health services, which are listed on the Medicare Benefits Scheme along with the fee that the government contributes towards the cost of the service. State governments administer public hospitals, community health services and mental health services. Local government also deliver health services such as community health services and other health programs (The Commonwealth Fund, 2016).

The Pharmaceutical Benefits Scheme (PBS) is a national program that provides subsidised prescription medicines to residents of Australia. The Pharmaceutical Benefits Advisory Committee (PBAC) makes recommendations on whether to list a medicine on the PBS based on the evidence of clinical effectiveness, safety and cost-effectiveness (value for money) compared with other treatments. The PBS is split into two formularies – F1 and F2. In general, F1 is a list of pharmaceuticals that are single brand medicines, while F2 is a list of pharmaceuticals with multiple brands, such as generics (Australian Government Department of Health, 2016f).

A similar scheme to the PBS is the Repatriation Pharmaceutical Benefits Scheme (RPBS). Under this scheme, veterans, war widows and widowers and dependents are able to access items on the PBS and access additional government subsidised pharmaceuticals that are listed on the RPBS. The RPBS subsidises a more comprehensive range of medicines and dressings than the PBS. Veterans are also able to access other pharmaceuticals not listed on the PBS or the RPBS if clinically justified. Eligibility for the RPBS is determined by the Department of Veterans’ Affairs (Australian Government Department of Health, 2016a).

IbisWorld (2016) estimates that almost 90% of community pharmacist proprietors are members of the Pharmacy Guild of Australia (the Guild), however it is important to note that Guild members represent less than 90% of script volumes in Australia. The Guild has an agreement with the Federal Government which sets out prices received by the community pharmacies for dispensing pharmaceuticals, as well as other terms and conditions. This agreement is called the Community Pharmacy Agreement, the first of which commenced in 1990. The most recent agreement, the 6CPA, began in July 2015.

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1 Note that single brand combination drugs are not included in either the F1 or F2 formulary.
Government expenditure in 2013 on health services was approximately 9.4% of gross domestic product (GDP). As specified in the 6CPA, the remuneration for community pharmacies over the five year term of the agreement is estimated to be $18.9 billion. This is comprised of $15.5 billion from the government and $3.4 billion from patient contributions. Pharmacies may also provide other government funded programs. These are discussed in more detail in section 2.1.3. The total estimated funding provided for these services as outlined in the 6CPA was $177.3 million. Overview statistics of the Australian health sector for 2013 are shown in Table 2.1.

Table 2.1: Health care system indicators, Australia

<table>
<thead>
<tr>
<th>Population, 2013</th>
<th>Total population (millions)</th>
<th>23.1</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Percentage of population &gt;65 years</td>
<td>14.4%</td>
</tr>
<tr>
<td>Expenditure, 2013</td>
<td>Percentage of GDP spent on health care</td>
<td>9.4%</td>
</tr>
<tr>
<td></td>
<td>Health care expenditure per capita</td>
<td>$4,115</td>
</tr>
<tr>
<td></td>
<td>Average annual growth rate of real health care expenditure per capita, 2009-2013</td>
<td>2.4%</td>
</tr>
<tr>
<td></td>
<td>Out-of-pocket health care expenditure per capita</td>
<td>$771</td>
</tr>
<tr>
<td></td>
<td>Hospital expenditure per capita</td>
<td>$1,645</td>
</tr>
<tr>
<td></td>
<td>Expenditure on pharmaceuticals per capita</td>
<td>$590</td>
</tr>
</tbody>
</table>

Note: for consistency throughout the report, amounts in this table are expressed in USD.

2.1.2 Remuneration and regulation

Fees for pharmaceutical dispensing under the PBS are set by the Federal Government, and are shown in Table 2.2. Fees include dispensing fees, preparation fees, and additional fees for preparation of dangerous medicines (Australian Government Department of Health, 2016b).

Table 2.2: Dispensing and additional related fees, Australia

<table>
<thead>
<tr>
<th>Type of fee</th>
<th>Type of medicine</th>
<th>Amount per dispensed item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dispensing fees:</td>
<td>Ready-prepared</td>
<td>$7.02</td>
</tr>
<tr>
<td></td>
<td>Dangerous medicine fee</td>
<td>$2.91</td>
</tr>
<tr>
<td></td>
<td>Extemporaneously-prepared</td>
<td>$9.06</td>
</tr>
<tr>
<td></td>
<td>Allowable additional patient charge*</td>
<td>$4.33</td>
</tr>
<tr>
<td>Additional fees (for safety net prices):</td>
<td>Ready-prepared</td>
<td>$1.19</td>
</tr>
<tr>
<td></td>
<td>Extemporaneously-prepared</td>
<td>$1.55</td>
</tr>
</tbody>
</table>

*The allowable additional patient charge is a discretionary charge to general patients if a pharmaceutical item has a dispensed price for maximum quantity less than the general patient co-payment. The pharmacist may charge general patients the allowable additional fee but the fee cannot take the cost of the prescription above the general patient co-payment for the medicine. This fee does not count towards the safety net threshold. Source: Australian Government Department of Health (2016b).
In addition to the fees in Table 2.2, the 6CPA introduced administration, handling and infrastructure (AHI) fees for pharmacists that replaces the previous pharmacy margin. This varies according to the listed brand price of the medicine as shown in Table 2.3 (6CPA, 2015).

<table>
<thead>
<tr>
<th>Listed brand price</th>
<th>Value of payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than $180</td>
<td>$3.54 per dispense</td>
</tr>
<tr>
<td>$180 to $2,089.71</td>
<td>$3.54, plus 3.5% of the amount by which the price to pharmacists exceeds $180, per dispense</td>
</tr>
<tr>
<td>More than $2,089.71</td>
<td>$70.00 per dispense</td>
</tr>
</tbody>
</table>


When a patient purchases a medicine under the PBS, they pay the patient co-payment. Patients either pay the concessional co-payment, if they have a concession card, or they pay the general co-payment. The difference between the patient co-payment and the actual cost of the medicine, as set out in the PBS, is paid by the Federal Government. Currently, patient co-payments for medicines are $38.30 for general patients, and $6.20 for concessional patients (Australian Government Department of Health, 2016b).

A safety net helps patients who have high pharmaceutical costs. If a household’s co-payments reach the safety net threshold and they are general patients, they then pay the concession rate for any additional pharmaceutical goods PBS medicines purchased in that same calendar year. If a household’s co-payments reach the safety net threshold and they are concessional patients, then they do not pay any co-payments on additional pharmaceutical goods. This means that the entire cost of any additional medicines is covered by the Federal Government. Maximum expenditure by patients is capped at $1,475.70 for general patients, and $372.00 for concession card holders (Australian Government Department of Health, 2016b).

Pharmacy location rules exist in Australia and in the 6CPA were extended to 30 June 2020. These rules were created to ensure the proper distribution of pharmacies across Australia. There rules broadly cover the following topics:

- **distance** to other pharmacies when establishing a new pharmacy and distance from the existing premise when seeking relocation;
- **public need for pharmaceutical services** in the new location or in the area to be vacated, with exemptions granted for rural and remote communities;
- **specifications of co-located services**, including:
  - shopping centre that satisfies a set of minimum parameters on size or capacity, and size of the co-located supermarket;
  - private hospitals with a certain number of beds; and
  - medical centres and aged care facilities;
- **time limit on subsequent relocations**; and
- **other conditions, such as**:
  - receipt of closure and amalgamation payment (in the First and Second CPAs); and
Pharmacy ownership is restricted to pharmacists, and non-pharmacists may not own a pharmacy. In addition to the ownership and location rules, there are a number of regulations around licensing, dispensing, labelling, storing goods, and advertising goods. The states have restrictions on the number of pharmacies a pharmacist may own, while the territories have no restrictions. The maximum allowable number of pharmacies per pharmacist in each state is:

- Western Australia and Tasmania: four;
- Queensland, New South Wales (NSW) and Victoria: five; and
- South Australia: six (Hattingh, 2011).

There are also a number of regulations that pharmacists must adhere to. Pharmacists must be registered with the Pharmacy Board of Australia in order to practice in Australia. To become registered, a number of standards must be met, which include:

- criminal history registration standard;
- professional indemnity insurance arrangements;
- continuing professional development;
- recency of practice;
- supervised practice arrangements;
- examinations for eligibility for general registration; and
- pharmacy English language skills registration (Pharmacy Board of Australia, 2016).

To manufacture medicines a licence from the Therapeutic Goods Administration (TGA) is required. Laws such as the Therapeutics Goods Act 1989 and Therapeutic Goods Regulations 1990 provide legislation and regulations that manufacturers must adhere too. These requirements ensure that products which are manufactured by licence holders are safe and of a high degree of quality. TGA licenced compounders face a high level of regulation and compliance standards which they must adhere to. Examples of requirements include air handling, multiple daily bacterial cultures, product stability testing and auditing (Department of Health and Ageing, 2013).

Chemotherapy preparation is provided by a relatively small number of pharmacies, with fewer than 50 pharmacies providing 70% of chemotherapy infusions. Unlike other PBS pharmaceuticals, chemotherapy medicines need to be prepared by the pharmacist prior to being dispensed. As a result, dispensing of these medicines is subject to different arrangements than other PBS listed medicines. The funding arrangements for chemotherapy medicines is called the efficient funding of chemotherapy (EFC) measure (Australian Government Department of Health, 2016c).

Although chemotherapy compounding pharmacies essentially act as manufacturers when preparing extemporaneous infusions, pharmacies are not required to obtain a TGA licence, through specific exemptions set out in the Therapeutic Goods Regulation 1990. Amongst the exemption listings in this regulation is an exemption provided for pharmacists for “the manufacture of therapeutic goods, other than biologicals, produced by the pharmacist in a..."
pharmacy where the pharmacist practices and the pharmacy is open to the public” (Department of Health and Ageding, 2013).

Pharmacists may still choose to obtain a TGA licence as having a TGA licence does come with some benefits. Compounders licensed by the TGA receive $60 per eligible EFC claim while compounders not licensed by the TGA receive $40 per eligible EFC claim. Other chemotherapy fees paid to pharmacists include:

- distribution fee ($25.29);
- diluent fee ($5.07);
- preparation fee ($82.67); and
- ready prepared dispensing fee ($7.02) (Australian Government Department of Health, 2016c).

Despite the exemptions listed above, compounded medicines are not exempted from meeting the quality standards or advertising requirements set out in the Therapeutic Goods Act 1989. Additionally, pharmacists cannot lawfully compound medicines at a community pharmacy for supply by wholesale, unless their premises are licensed by the TGA (Pharmacy Board of Australia, 2015). Pharmacists are also expected to comply with all relevant professional practice standards and guidelines, and guidance published by the Pharmacy Board of Australia (Pharmacy Board of Australia, 2015). The updated Guidelines on Compounding of Medicines took effect from April 2015.

2.1.3 Scope of services, settings and distribution

Other than dispensing medicines, pharmacies partake in Community Pharmacy Programs which are funded by the Federal Government. To receive funding from the Federal Government for providing these services a pharmacy must apply through the Department of Health. The broad categories of programs listed within the 6CPA are listed below.

- **Medication adherence programs**: aim to support medicine compliance.
- **Medication management programs**: focus on preventing adverse medicine events and ensuring quality use of medicines. Some of these programs are delivered outside of the community pharmacy and involve a pharmacist making home visits, or going to an aged care facility.
- **Aboriginal and Torres Strait Island specific programs**: some programs within this category aim to ensure the provision of medicines to Aboriginal and Torres Strait Islander populations. Other programs included in this category aim to encourage Aboriginal and Torres Strait Islander pharmacy workforce participation.
- **Rural support programs**: these programs aim to improve the access to medicines for people living in rural or remote regions.
- **E-health**: supports pharmacies that use e-prescription technology (6CPA, 2015).

Other services that pharmacists may provide and receive government funding for are also listed on the MBS. These services are listed as Category 1 – Professional Attendances services. These services involve a pharmacist undertaking medicine management and reviews with patients, and in some cases providing immunisations (Australian Government Department of Health, 2016d).
In addition to providing these services, pharmacies in Australia also sell over-the-counter medicines and supply other health and wellbeing products. According to IBISWorld (2016), industry revenue was comprised of 61.0% prescription medicine, 16.0% scheduled non-prescription medicine, 15.5% other general retail products and 7.5% cosmetics and beauty products.

An Australian community pharmacy based intervention study examined the uptake and effectiveness of pharmacist-initiated interventions for 1,483 patients with asthma not currently well-managed. The pharmacists were randomised, by pharmacy, to perform either a mailed (34.4%) or face-to-face (32.4%) intervention (33.2% controls), whereby these patients received educational material and a referral to their general practitioner (GP) for an asthma management review. There were significant improvements in the preventer-to-reliever ratio after the intervention period (P<0.0001) in each group (Bereznicki et al, 2013).

Another pharmacy-based intervention in Australian community pharmacies evaluated the efficacy of trained pharmacists providing behavioural interventions such as stimulus control and sleep restriction to patients with insomnia, in improving insomnia severity. The overall decrease in Insomnia Severity Index from baseline to the 3-month follow-up in the intervention group, was significantly greater than for the control group. However, when cluster effects were taken into account, the difference was non-significant. The study authors concluded that reductions in insomnia severity can be gained from behavioural interventions provided by trained pharmacists (Fuller et al, 2016).

As at 30 June 2015, there were 5,511 pharmacies in Australia. In terms of distribution across states and territories, NSW had the most pharmacies with 33.2% of pharmacies in Australia being in NSW, while the Northern Territory had the least (0.6%). By remoteness, the number of pharmacies per 100,000 population in urban areas in 2011-12 was 29.1 while in rural areas it was 12.6. In addition to this, it was estimated that only 16% of pharmacists were thought to work in rural and remote regions (Australian Government Department of Health, 2016c; Deloitte, 2016; IBISWorld, 2016; Boyce and Frewin, 2015).

When compared to other countries, Australia is above the Organisation for Economic Co-operation and Development (OECD) average of the number of pharmacists per 100,000 population, but below the OECD average of pharmacies per 100,000 per population. Australian figures compared to the OECD average in terms of pharmacists and pharmacies per 100,000 population are shown in Table 2.4 (OECD, 2015).

<table>
<thead>
<tr>
<th>Number of practising pharmacists per 100,000 population</th>
<th>Australia</th>
<th>OECD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of pharmacies per 100,000 population</td>
<td>23.1</td>
<td>25.1</td>
</tr>
</tbody>
</table>


Community pharmacies employ the majority of pharmacists in Australia; however, pharmacists also work in hospital pharmacies. Other than community pharmacies, hospital pharmacies are allowed to distribute prescription medicines. Hospital pharmacies supply medicines to inpatients when discharged, in emergency departments and in outpatient clinics. In some cases medical practitioners are also allowed to supply medicines when there
is no pharmacy located nearby, this is allowed under the National Health Act 1953. Nurse practitioners and midwives\(^2\) are also able to prescribe some medicines in certain circumstances (Hoti et al, 2013; National Rural Health Alliance, 2014; Raven, 2012).

2.1.4 Wholesaler supply arrangements

There are approximately 140 manufacturing firms in Australia, the majority of which are foreign owned. These firms make (and on some occasions package) medicines, for sale to wholesalers, and also some retailers. There are currently four wholesale firms in Australia: Australian Pharmaceutical Industries, Sigma Pharmaceuticals, Symbion Pharmacy Services, and Friendly Society Medical Association Limited (Moore et al, 2015). An overview of the Australian pharmaceutical sector supply chain is shown in Figure 2.1.

![Figure 2.1: Wholesale supply arrangements, Australia](source: Moore et al (2015))

Under the traditional model of pharmaceutical distribution, manufacturers sell their medicines to wholesalers, who then sell these to retailers (pharmacies). The Community Service Obligation (CSO) was introduced to help ensure the timely supply of PBS medicines to all parts of Australia. Wholesalers that receive CSO funding are required to deliver any high volume PBS medicine within 72 hours and other PBS medicines within 24 hours, along with other requirements, such as reducing their margins. Funding for CSOs specified within the 6CPA is defined as being up to $195.22 million (Moore et al, 2015; 6CPA, 2015).

Some manufacturers use exclusive, or direct-to-pharmacy distribution channels. Under a direct delivery arrangement, medicines are distributed from pharmaceutical manufacturers to retailers, essentially bypassing the traditional role of wholesalers. Manufacturers may use a restricted number of wholesalers as sole agents to distribute products directly to pharmacy, or, indeed, use wholesalers as logistics providers for the same purpose. (Moore et al, 2016; Transport and Logistics news, 2014).

\(^2\) Excluding the Northern Territory.
Wholesale mark-ups permitted by wholesalers are shown in Table 2.5. A percentage mark-up applies up to $930.06, and a flat fee applies after this point (Department of Human Services, 2016).

Table 2.5: Wholesale mark-up, Australia

<table>
<thead>
<tr>
<th>Cost of medicine from manufacturer</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to and including $930.06</td>
<td>7.52%</td>
</tr>
<tr>
<td>$930.06 +</td>
<td>$69.94</td>
</tr>
</tbody>
</table>

Source: Department of Human Services (2016)

2.1.5 Adoption of technology

In 2010, the Department of Health launched the Personally Controlled Electronic Health Record (PCEHR), now known as My Health Record. PCEHR is an electronic health record (EHR) for an individual which may be accessed by medical practitioners, hospitals, pharmacists and other health care providers. The PCEHR contains information such as discharge summaries, medical history, immunisations and medicines information. The PCEHR is controlled by the patient and they are able to grant access to designated health professionals. The 6CPA contains an arrangement to encourage pharmacists to drive uptake of these records. Funding allocated to support PCEHR initiatives in community pharmacy was valued to be approximately $12.7 million in year one of the 6CPA and $48.3 million for years two to five (Australian Digital Health Agency, 2016; Mooranian et al, 2013).

Another e-health initiative in community pharmacy is the Electronic Transfer of Prescriptions (ETP). ETP enables prescription information to be electronically transferred between the prescriber and the pharmacist. The electronic transfer of information is in addition to the usual paper prescription which the GP issues the patient (Avant Mutual Group Limited, 2016). The Federal Government is actively encouraging pharmacies to use e-prescriptions by providing a support payment for each transaction, which is currently $0.15 per transaction. Within this system information is transferred between prescribers and dispensers (IBISWorld, 2016). Information on the number of prescriptions that are e-prescriptions is not readily available. However, data indicate that 87% of pharmacists and 72% of GPs have one of the two available prescription exchange services which administer e-prescribing in 2014 (eRx, 2014).

Pharmacies in Australia are also beginning to increase their online presence. According to IBISWorld (2016) there has been a significant development in the number of online pharmacies in Australia. These pharmacies are able to fill prescriptions online and deliver the medicines to the patient’s home (Doctus, 2016).

Another technology initiative that has been recently introduced in Tasmania (and imminently in Victoria) is the Real Time Prescription Monitoring (RTPM) system. Currently, pharmacists may record prescription information in a system but this information is not shared with prescribers or other pharmacies. The RTPM system has been demonstrated to reduce the misuse of prescription medicines and consequent adverse events (such as deaths from overdose), by allowing doctors and pharmacists to check a patient’s prescription information to minimise script-shopping for some potentially addictive medicines. Within this system,
prescription information is transferred to a database where pharmacists and doctors are able to access the information (Department of Health and Human Services, 2015).

2.1.6 Reforms, incentives and learnings

A major recent reform in the pharmacy sector in Australia has included the PBS Access and Sustainability Package, which was proposed to be implemented over the 2015-2020 period. Some of the measures proposed in the package took effect from 1 January 2016. Included within this package were a number of reforms, and these are discussed below.

- **The removal of selected over-the-counter (OTC) medicines listed on the PBS**: under this change it was announced that the PBAC will review PBS OTC medicines and provide advice as to which ones should be removed. Some medicines that were recommended for removal cost less than the co-payment; therefore the removal of these items would decrease costs for patients. This change would also decrease costs for the government as pharmacies would no longer be remunerated for dispensing these medicines.

- **Options for pharmacists to discount the PBS co-payment by $1**: pharmacists are able to offer a $1 discount on the co-payment for some patients. It was anticipated that this would deliver the government $400 million in efficiencies over five years due to increased competition amongst pharmacies.

- **Introduction of the AHI fee**: this initiative aims to restore remuneration to average levels provided under the Fifth CPA. The AHI fee replaced the pharmacy mark-up which was in place in prior community pharmacy agreements. The mark-up differs from the AHI fee as the mark-up tended to be a percentage of the pharmaceutical price. Because the AHI fee offers a set base fee and in some cases a percentage of the price on top of the base fee, it separates remuneration from pharmaceutical price.

- **Changes to price disclosure arrangements for pharmaceuticals classified as F2**: the price disclosure changes were thought to result in a decrease in prices for F2 medicines. This is expected to deliver approximately $2 billion worth of efficiencies from 2016 to the end of the 6CPA.

- **Decrease in price for F1 medicines**: under this change F1 medicines would receive a reduction in price of 5% after they have been listed on the PBS for at least five years. The 5% reduction applies to the ex-manufacturers price. This is expected to result in efficiencies worth about $41 billion (Australian Government Department of Health 2016e, 2015, 2016g).

- **Biosimilar medicines**: includes an investment of $20 million over 2015-18 to improve awareness and confidence in biosimilar medicines and support the introduction of appropriate market access policies. With the introduction of multiple brands of a biologic medicine, in some cases (where a biosimilar has been deemed substitutable) unless a patient or prescriber has specifically requested a particular brand, a pharmacist can offer the choice. As such, community pharmacies are increasingly becoming involved in supply of these medicines (Australian Government Department of Health, 2016h). Due to the increased level of attention that biosimilar policy is receiving in Australia, information on biosimilar policies in other countries has been included in the report.

Biosimilar policy in Australia has received much recent attention. From a regulatory perspective, in Australia, biosimilars are not considered to be identical to the originator biologic medicine due to natural variability resulting from the complex, biological methods of producing these medicines (Australian Government Department of Health, 2016i). In
order for a biosimilar to be approved for use, comparability to the reference product must be demonstrated through clinical study. From a reimbursement perspective, when the PBAC recommends a biosimilar for listing on the PBS, it will also consider whether the biosimilar and its reference medicine should be substitutable at the pharmacy level (i.e. whether a pharmacist can offer the choice of brand to a patient). The PBAC will only recommend that substitution be allowed where the clinical evidence supports this. This is done on a case by case basis (Australian Government Department of Health, 2016). Where the PBAC determines that substitution of a biosimilar is allowed, the pricing consequence will be consistent with the first listing of a generic medicine on the PBS, including a 16% statutory price reduction of the originator biologic medicine.

2.1.7 Demand projections

This section presents analysis on the predicted growth and distribution of demand for community pharmacy in Australia, and discusses this analysis in the context of other demographic and health care trends in Australia and overseas. The “demand for community pharmacy” is considered to represent the demand for community pharmacies, the demand for community pharmacists, and the demand for prescription medications which are dispensed through community pharmacies.

The growth and distribution of demand for community pharmacy in Australia is hard to accurately forecast, given the current market dynamics and the existing regulations which limit the supply of community pharmacy below optimal levels. For example, existing pharmacies in urban areas may be able to expand to meet increased demand (but new entrants are restricted), however new entrants can enter the market in areas of new urban development and in some rural areas. Another example is provided through prior analysis undertaken by Deloitte Access Economics (2016), which shows that the population-to-pharmacy ratio and population-to-prescription ratios are not consistent across Australia. Thus, forecasts of the number of pharmacies, number of pharmacists, and number of prescriptions are unlikely to provide an estimate of the “true” demand for community pharmacy in Australia. Given the current regulations in Australia, these metrics likely serve to provide an upper bound on the true demand for community pharmacy into the future.

According to forecasts contained in the 6CPA, estimated PBS and RPBS prescription volumes of listed brands are expected to increase over the period 2015-16 to 2019-20. As shown in Table 2.6, estimated prescription volumes are expected to increase to 349.84 million in 2019-20 (6CPA, 2015).

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>PBS and RPBS prescription volumes (m)</td>
<td>227.07</td>
<td>232.47</td>
<td>238.05</td>
<td>243.73</td>
<td>248.75</td>
</tr>
<tr>
<td>Prescriptions under the Maximum Co-Payment (m)</td>
<td>74.57</td>
<td>80.99</td>
<td>87.71</td>
<td>94.48</td>
<td>101.09</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>301.63</strong></td>
<td><strong>313.47</strong></td>
<td><strong>325.76</strong></td>
<td><strong>338.21</strong></td>
<td><strong>349.84</strong></td>
</tr>
</tbody>
</table>

Estimated prescription volumes in 2018-19 (two years from 2016-17) were considered to be representative of short run growth in Australia. Estimated prescription volumes over the medium run (five years from 2016-17) and long run (ten years from 2016-17) were calculated based on a simple linear extrapolation of existing trends over the period 2015-16 to 2019-20:

- **Short run** (2018-19) volume of prescriptions: 338.21 million.
- **Medium run** (2021-22) volume of prescriptions: 374.25 million.
- **Long run** (2026-27) volume of prescriptions: 434.83 million. This is a 39% increase in the volume of prescriptions in Australia over this time period.

Table 2.7 presents the results of analysis from IBISWorld which estimates the expected growth in the number of people employed by the pharmacy sector in Australia over the period 2016-17 to 2021-22. Total employed people in the sector is currently 62,700 and is expected to increase to 68,705. However, the number reported here includes all staff employed by the pharmacy industry and is not an indicator of the number of pharmacists (IBISWorld, 2016).

<table>
<thead>
<tr>
<th>Year</th>
<th>Employment</th>
<th>Growth (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016-17</td>
<td>62,700</td>
<td></td>
</tr>
<tr>
<td>2017-18</td>
<td>64,000</td>
<td>2.1</td>
</tr>
<tr>
<td>2018-19</td>
<td>65,120</td>
<td>1.8</td>
</tr>
<tr>
<td>2019-20</td>
<td>66,440</td>
<td>2.0</td>
</tr>
<tr>
<td>2020-21</td>
<td>67,450</td>
<td>1.5</td>
</tr>
<tr>
<td>2021-22</td>
<td>68,705</td>
<td>1.9</td>
</tr>
</tbody>
</table>

Source: IBISWorld (2016).

The estimated number of people employed by pharmacies in 2018-19 (two years from 2016-17) was considered to be representative of short run growth in Australia. The estimated number of people employed by pharmacies over the medium run (six years from 2016-17) and long run (ten years from 2016-17) were calculated based on a simple linear extrapolation of existing trends over the period 2016-17 to 2021-22:

- **Short run** (2018-19) number of people employed by pharmacies: 65,120 people.
- **Medium run** (2021-22) number of people employed by pharmacies: 68,705 people.
- **Long run** (2026-27) number of people employed by pharmacies: 74,670 people. This is a 19% increase in the number of employees in Australia, from 2016-17 levels.

Data from the Australian Government provide an indication of the number of pharmacists in Australia in the future. These data estimate that the number of pharmacists in 2020 will be approximately 30,100. In 2015 the number of pharmacists in Australia was estimated to be 25,100. Therefore, there is an expected 5,000 person increase in the number of pharmacists in Australia over the 2015 to 2020 period, which is approximately 1,000 pharmacists per year (Department of Employment, 2015).

Estimates of the expected growth in the number of pharmacies over the period 2016-17 to 2021-22 are provided in Table 2.8. The number of pharmacies in 2016-17 is estimated to be 5,635, and is expected to grow to 6,063 in 2021-22 (IBISWorld, 2016).
Table 2.8: Growth of pharmacies and people employed by pharmacies

<table>
<thead>
<tr>
<th>Year</th>
<th>Pharmacies</th>
<th>Growth (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016-17</td>
<td>5,635</td>
<td></td>
</tr>
<tr>
<td>2017-18</td>
<td>5,725</td>
<td>1.6</td>
</tr>
<tr>
<td>2018-19</td>
<td>5,811</td>
<td>1.5</td>
</tr>
<tr>
<td>2019-20</td>
<td>5,892</td>
<td>1.4</td>
</tr>
<tr>
<td>2020-21</td>
<td>5,975</td>
<td>1.4</td>
</tr>
<tr>
<td>2021-22</td>
<td>6,063</td>
<td>1.5</td>
</tr>
</tbody>
</table>

Source: IBISWorld (2016).

The estimated number of pharmacies in 2018-19 (two years from 2016-17) was considered to be representative of short run growth in Australia. The estimated number of pharmacies over the medium run (five years from 2016-17) and long run (ten years from 2016-17) were calculated based on a simple linear extrapolation\(^3\) of existing trends over the period 2016-17 to 2021-22:

- **Medium run** (2021-22): 6,063 pharmacies.
- **Long run** (2026-27): 6,487 pharmacies. This is a 15% increase in the number of pharmacies in Australia from 2016-17 levels.

Thus, these three metrics for assessing the demand for community pharmacy in Australia place an upper bound of 15%-39% over the next ten years. It is important to analyse the demand for community pharmacy within the context of underlying health expenditure growth (as pharmaceuticals play a key role in managing ill health), and changing demographics including the ageing population and population growth.

The forecasted growth in prescription volumes, pharmacies and pharmacists in Australia is consistent with broader demographic and health care trends in Australia. Health expenditure in Australia has been increasing for a number of years. The most recent release by the Australian Institute of Health and Welfare (AIHW) (2016a) calculated Australian health expenditure in 2014-15 to be $161.63 billion, with real growth of 2.80% from the previous year. Historic health expenditure and real growth is shown in Table 2.9.

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\(^3\) As discussed previously, the existing regulations on ownership and location mean that a linear extrapolation of existing trends may not appropriately capture the future growth of the number of pharmacies in Australia. However, a more complex forecast of this variable is beyond the scope of this analysis.
Expenditure on health care in Australia is expected to increase due to the ageing population, which is consistent with demographics profiles in most developed economies around the world. Australians are living longer; during 2000 to 2002 the average life expectancy for males was 77 years and for females it was 83 years. In the 2012 to 2014 period, males were expected to live until 80 years while females were expected to live until 84 years (AIHW, 2016b).

As well as living longer, our population demographics are shifting. In 2010, Australians aged 65 years or older comprised 13.5% of the population. By 2050, this share is projected to rise to 22.6%. The share of those aged 85 years or older is projected to increase even more rapidly, from 1.8% to 5.1%. The ageing of the Australian population is shown in Figure 2.2, and will translate into increased demand for pharmaceutical and health care services (ABS, 2015).

**Figure 2.2: Ageing population of Australia - 1971, 2011 and 2051 projected**

Source: ABS (2015)

### 2.2 New Zealand

#### 2.2.1 Health system context and expenditure

The New Zealand health system is funded primarily by the central government through the Ministry of Health. All permanent residents are able to access publicly funded health services including hospital services, mental health services and dental services. In addition to the Ministry of Health, there are 20 District Health Boards (DHBs) which have responsibility over providing and managing health services in their regions, including operating hospitals and providing community services. The DHBs have service agreements with a number of medical practitioners, including pharmacists, who deliver health services. Private health insurance is
also available which often covers specialist appointments and elective surgery (The Commonwealth Fund, 2016).

The Pharmaceutical Management Agency (PHARMAC) is a government organisation that decides which pharmaceuticals will receive a government subsidy. PHARMAC encourages price competition through the use of competitive processes such as tendering for supply and reference pricing (PHARMAC 2016). If a pharmaceutical is approved by PHARMAC it will be listed on the Pharmaceutical Schedule. PHARMAC has a monopsony power over the pharmaceutical industry in New Zealand and negotiates with pharmaceutical companies for lower prices of medicines (The Commonwealth Fund, 2016).

In 2013, PHARMAC spent $734 million on pharmaceuticals, while total health expenditure was 11% of GDP. For the 2016-17 financial year, the PHARMAC budget was increased to $850 million. Table 2.10 presents data on other New Zealand health system characteristics (Coleman, 2016; The Commonwealth Fund, 2016).

### Table 2.10: Health care system indicators, New Zealand

<table>
<thead>
<tr>
<th></th>
<th>New Zealand</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population, 2013</td>
<td>4.5</td>
</tr>
<tr>
<td>Total population (millions)</td>
<td></td>
</tr>
<tr>
<td>Percentage of population &gt;65 years</td>
<td>14.2%</td>
</tr>
<tr>
<td>Expenditure, 2013</td>
<td></td>
</tr>
<tr>
<td>Percentage of GDP spent on health care</td>
<td>11.0%</td>
</tr>
<tr>
<td>Health care expenditure per capita</td>
<td>$3,855</td>
</tr>
<tr>
<td>Average annual growth rate of real health care expenditure per capita, 2009-2013</td>
<td>0.8%</td>
</tr>
<tr>
<td>Out-of-pocket health care expenditure per capita</td>
<td>$420</td>
</tr>
</tbody>
</table>

Note: for consistency throughout the report, amounts in this table are expressed in USD.

#### 2.2.2 Remuneration and regulation

DHBs have contracts with each pharmacy within their district, these agreements are called Community Pharmacy Service Agreements (CPSAs). Within these agreements, the DHBs agree to pay the community pharmacies for dispensing pharmaceuticals listed on PHARMAC’s New Zealand Pharmaceutical Schedule, which is updated monthly (PHARMAC, 2016).

The original 2012 CPSA for community pharmacies in New Zealand involved four stages, with the 2015-16 year being the first of a two year renewal period. The CPSA funding envelope for community pharmacies in the financial year 2015-16 was $380.90 million. Under stage four of the CSPA which commenced on 1 August 2014, pharmacies have received service fees for core and Long Term Conditions pharmacy services which are funded through the Case Mix Service Fees plus a $1.00 handling fee. Additionally, pharmacies receive funding for other services (see section 2.2.3) including a Long Term Conditions fee of $20 per month for each registered patient ($240 per annum) (Centraltas, 2016; CPSA, 2012).

The fees that pharmacies are reimbursed are shown in Table 2.11. The service fees are based on initial and repeat items for Long Term Conditions and core pharmacy services delivered to patients. Table 2.11 shows the service fee for 1-3 initial items of $4.38. The fee increases
based on a relative value unit which increases with the number of initial items dispensed by that pharmacy to that patient on that day. For repeat items Table 2.11 shows the service fee for 2-3 repeat items ($3.00). The value of the relative value unit for repeat items decreases as the repeat sequence number increases to discourage unnecessary repeats and reflects the estimated clinical input with each dispensing, while recognising the costs of providing necessary repeats. Pharmacists receive different remuneration for extemporaneously compounded medicines. Instead of the $1.00 handling fee, they receive a $7.95 handling fee (Centraltas, 2014; CPSA, 2012).

<table>
<thead>
<tr>
<th>Fee item</th>
<th>Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>For dispensing</strong></td>
<td></td>
</tr>
<tr>
<td>Handling fee</td>
<td>$1.00</td>
</tr>
<tr>
<td>For initial item</td>
<td>$4.38</td>
</tr>
<tr>
<td>For repeat</td>
<td>$3.00 per repeat</td>
</tr>
<tr>
<td><strong>For procurement and stockholding</strong></td>
<td></td>
</tr>
<tr>
<td>List price of pharmaceutical</td>
<td></td>
</tr>
<tr>
<td><strong>Margin</strong></td>
<td></td>
</tr>
<tr>
<td>Pharmaceutical less than $150</td>
<td>4%</td>
</tr>
<tr>
<td>Pharmaceutical equal to or greater than $150</td>
<td>5%</td>
</tr>
</tbody>
</table>


When accessing medicines listed on the Pharmaceutical Schedule, New Zealand residents pay a co-payment of $5.00. Once a family has accessed over 20 items per year, all of their remaining PHARMAC approved pharmaceutical costs are paid by the government. If a resident wanted to access a medicine not subsidised by PHARMAC they would have to pay the full cost of the medicine; however, if the prescriber prescribes a medicine not listed on the schedule, they may be able to apply to PHARMAC for funding for that particular patient. As a result, the majority of the reimbursement for distribution of pharmaceuticals is from the government (Ministry of Health, 2015a).

Pharmacies may also provide other services for which they receive compensation from the government. Services that a pharmacy may provide are the Medicine Management Service, Medicine Use Review (MUR), Medicines Therapy Assessment (MTA) and the Long Term Conditions service. A pharmacy is required to provide the Long Term Conditions service while other services are not compulsory (Kinsey et al, 2015). These services are discussed in more detail in section 2.2.3.

To be an intern pharmacist, pharmacist or pharmacist prescriber the person must be registered and hold an Annual Practising Certificate which is obtained through the Pharmacy Council of New Zealand and requires a minimum of 450 hours practice over the preceding three years. Ongoing requirements for registered pharmacists are described in the Health Practitioners Competence Assurance Act 2003, which specifies that a registered pharmacist

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4 Pharmacist prescribers work in a team care arrangement with other health professionals to optimise a patient’s medication therapy. A pharmacist prescriber can assess the effectiveness of a patient’s current medicine, review and interpret test results and make a prescribing decision to modify dosage, initiate a new medicine or discontinue an unnecessary medicine (Pharmacy Council of New Zealand, 2013).
is required to be ‘fit to practise’ (Pharmacy Council of New Zealand, 2015). Pharmacists which sell over the internet need to have an Internet Pharmacy Accreditation (Pharmaceutical Society of New Zealand Incorporated (PSNZI), 2004; PSNZI, 2001).

To open a pharmacy requires a licence from the Ministry of Health; however, there are a number of restrictions on pharmacy ownership. A relevant piece of legislation is the Medicines Act 1981. Under this Act, a non-pharmacist can own up to 49% of the share of capital of a pharmacy company while the majority must be owned by a pharmacist. Pharmaceutical companies are prohibited from owning an equity stake in pharmacies, which effectively prevents vertical integration in the New Zealand community pharmacy sector. Pharmacists are also restricted to having a majority share in up to five pharmacies (Norris et al, 2014). The Government is preparing to introduce the Therapeutic Products Bill, which would replace the Medicines Act. This is discussed in further detail in section 2.2.6.

There are no pharmacy location requirements in New Zealand; however, in the Pharmacy Action Plan 2016-2020, it was noted that there were some areas that did not have a pharmacy while other areas had multiple pharmacies. As a result, one of the actions from this plan was to review districts’ needs and develop and implement plans to ensure medicines are accessible to the population (Ministry of Health, 2016a).

2.2.3 Scope of services, settings and distribution

In addition to dispensing, storing and handling pharmaceuticals, pharmacies may provide a number of other services which receive some form of government funding. These services require different qualifications and have additional regulations that pharmacists and pharmacies must adhere to. These services are listed below.

- Long Term Conditions: this is a compulsory service which community pharmacies must provide as per the CPSA. This program targets patients with Long Term Conditions and those with adherence issues. Patients must be assessed and meet certain eligibility criteria prior to accessing the Long Term Conditions service. Under this program the pharmacist will develop a Medicines Management Plan to help the patient with adherence. Funding for this service is provided under the CPSA in similar arrangements to the funding structure set out in Table 2.11.

- Community Pharmacy Anti-Coagulation Management (CPAM) Service: this service aims to help patients who are taking the medicine warfarin. A patient who takes warfarin must have regular blood tests to ensure the correct warfarin dosage. Usually a patient will go to a laboratory to have blood tests performed. Under the CPAM service, a GP will refer a patient to a community pharmacy who will administer the test. There are currently 153 community pharmacies who provide this service. Funding for this service is set out within the CPSA and is currently $540 per user per year with a one-off payment of $1,600 for establishment costs (Centraltas, 2016).

- MUR: this service has the same aim as the Long Term Conditions service; however, it is more comprehensive and requires a systematic evaluation of the patient. To deliver this service, a pharmacist must have standards-based MUR training and accreditation. The MUR service funding does not fall under the CPSA, instead a different agreement is made between the pharmacy and the DHB.

- MTA: under this service, all medicines taken by a patient are reviewed to mitigate any medicine related problems. The funding agreement for the provision of MTA services
is not within the CPSA but requires a different agreement between the pharmacy and the DHB.

- **Clozapine dispensing**: through this service a pharmacy, prior to dispensing clozapine, will perform blood test monitoring as well as collaborate with prescribers to discuss the blood test results. Funding for this service is through the CPSA; instead of the $1.00 handling fee, there is a $10.60 handling fee paid to pharmacists, all other fees are the same as Table 2.11.

- **Age related residential care, community residential care and co-dispensed opioid services**: under these arrangements a pharmacy will provide pharmacy services to age related residential care users. When providing these services, the handling fee is $5.30 instead of $1.00 and funding is set out within the CPSA (PSNZI, 2014).

An evaluation of MUR services provided by pharmacists in New Zealand was undertaken to identify the types of drug-related problems and interventions provided during MURs. In total, 353 consultation records from 5 MUR providers were included in the analysis. A total of 886 medicine-related problems were identified, which resulted in 844 interventions. Most commonly, problems with health literacy and non-adherence to medicines were reported. The most common interventions provided were patient counselling and recommendations regarding medicine adjustments (Hatah et al, 2014).

Of all pharmacists in New Zealand in 2015, it was estimated that 13.2% of them worked in hospitals, 74.6% worked in community pharmacies and the rest worked in other fields such as teaching or research. The number of pharmacists and pharmacies per 100,000 population in New Zealand compared to the OECD average is shown in Table 2.12 (Pharmacy Council of New Zealand, 2015).

### Table 2.12: Number of pharmacies and pharmacists, New Zealand

<table>
<thead>
<tr>
<th></th>
<th>New Zealand</th>
<th>OECD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of pharmacists per 100,000 population (2013)</td>
<td>75.0</td>
<td>80.0</td>
</tr>
<tr>
<td>Number of pharmacies per 100,000 population</td>
<td>20.8</td>
<td>25.1</td>
</tr>
</tbody>
</table>

Source: OECD (2015) and Deloitte Access Economics calculations

Currently there are approximately 980 community pharmacies across New Zealand. (Ministry of Health, 2016). Norris et al (2014) analysed the geographic locations of pharmacies across New Zealand, and how far away the population live from pharmacies. In 2010, approximately 13% of the population lived 5 kilometres from a pharmacy, while 1-2% lived more than 25 kilometres away.

In New Zealand, access to pharmacy services is facilitated through extended opening hours. A survey conducted by Horsfield et al (2014) of 251 pharmacies found that 24.4% of the pharmacies opened late at least one evening a week and that 15% stayed open after 6 pm every week day. On weekends, 79.8% of pharmacies were open on Saturday with about 39.8% of the total pharmacies interviewed remaining open all day. On Sundays, 27.5% of the surveyed pharmacies were open and of those open on Sunday, 85.2% were open all day.
2.2.4 Wholesaler supply arrangements

An overview of the New Zealand pharmaceutical supply chain is shown in Figure 2.3. Wholesalers purchase the pharmaceuticals from the manufacturers at the agreed PHARMAC prices. The wholesalers will then sell the pharmaceuticals to the pharmacies. The wholesale margin is not regulated and is negotiated with retail pharmacies. Analysis by Deloitte (2015) found that a weighted average across the industry of wholesale margins was 3.5%.

![Wholesaler supply arrangements, New Zealand](image)


2.2.5 Adoption of technology

Some pharmacies and GPs in New Zealand use e-prescriptions. The system that manages these prescriptions is called the New Zealand ePrescription Service (NZePS). This system allows for electronic dispensing and prescribing and can exchange information between GPs and pharmacists. Paper prescriptions are still commonly used, with the focus of the system being to reduce the risk of misinterpretation and provide prescribers with better information (such as being able to track scripts) (National Health IT Board, 2015).

The uptake of e-prescriptions started in various districts from March 2016. As at July 2016, the Ministry of Health has received more than 140 applications from practices to use the e-prescribing service, with 41 practices currently using the service. The pricing structure has now been settled with an activation fee for the NZePS of $450 and a monthly maintenance fee for practices starting from $75 for practices from 1 October (Lee, 2016).

2.2.6 Reforms, innovations and trials

A major initiative for the New Zealand community pharmacy sector is the Pharmacy Action Plan 2016-2020. Within the plan are actions and focus areas which aim to develop pharmacist health services. The four focus areas in the plan are discussed below.

- **Population and personal health**: there is a rising prevalence of long term conditions and chronic conditions in the New Zealand population. Pharmacists are presented with opportunities to deliver services that provide information for the population such
as sexual health information, smoking cessation services and to also provide immunisations.

- **Medicines management services**: pharmacists should play a greater role in medicine management and collaborate with other health providers. This aims to have pharmacists working with a variety of health care providers, such as through the provision of MTA, MUR, Long Term Conditions and CPAM services.

- **Minor ailments and referral**: this area aims to provide cost-effective treatment and referral for minor ailments. Pharmacists are intended to play a bigger role in the treatment of minor ailments to reduce the demand for other health services that can then prioritise other higher needs patients.

- **Dispensing and supply services**: using technology and other initiatives to make the dispensing process more efficient. This aims to ensure that medicine is accessible to the entire population and use technology to facilitate the dispensing process (Ministry of Health, 2016a).

In 2015, an evaluation of the CPSA policy was undertaken to determine whether it had met five policy objectives (Sapere, 2015):

- **Incentivise a patient-centred approach to medicines management through the development of services that enhance the level of advice and support to high-needs patients**: while the CPSA introduced the Long Term Condition and CPAM services, uptake was mixed and depended on the pharmacist. Changes in pricing signals indicated that pharmacists reacted more strongly to the pricing signal than the professional incentive. Pharmacists were able to identify the correct patients for the services, but an improvement in health outcomes was not observed.

- **Enhance the professional satisfaction of community pharmacists through shifting the focus from dispensing to the provision of professional advice and support**: clear evidence of enhanced professional satisfaction was found.

- **Facilitate the increased collaboration of the patient’s multi-disciplinary team in medicine management and adherence**: the CPSA did not increase collaboration with GPs, and the rare instances of good integration with GPs were not due to the CPSA.

- **Support the sector goal for sustainable community pharmacy services, whilst delivering value for money for the DHBs**: the CPSA supported pharmacies through considerable change to their income structures, and resolved the problem of an unsustainable rate of growth of expenditure on dispensing.

- **Adjust the funding model to ensure that funding incentives align with services that improve medicine adherence, and ensure that expenditure on community pharmacy stays within a growth path acceptable to individual DHBs**: while the CPSA achieved this aim, price signals have become too dominant.

As noted in Section 2.2.2, the New Zealand Government is preparing to introduce the Therapeutic Products Bill, which would replace the Medicines Act. The Bill will be introduced later in 2016, following consultation on a draft. Key legislative changes include that (Ministry of Health, 2016b):

- pharmacies would no longer be restricted to physical locations;
- pharmacies could be owned by non-pharmacists; and
- a new regulator will be established.
As part of the CPSA, community pharmacies across New Zealand were allocated $750,000, which was apportioned between DHBs based on their population shares. The intent of the expenditure was to support pharmacists to develop additional patient-centric services. However, as of May 2016 most DHBs had not decided which initiatives to spend their funding on, and most of the DHBs which had chosen the additional services lacked detailed implementation plans (New Zealand Doctor, 2016).

2.3 Japan

2.3.1 Health system context and expenditure

Public health care in Japan is delivered through a universal public health insurance system (PHIS). The PHIS, which is highly regulated by the government, provides universal primary coverage to Japanese citizens and resident non-citizens. It is mandatory to enrol in one of the PHIS plans based on employment status and/or place of residence. There are more than 3,400 insurance providers. While the majority of the population also holds private insurance, this mostly plays only a supplementary role (The Commonwealth Fund, 2016).

While insurance premiums vary between providers, the Japanese government determines the benefits package that is provided by all PHIS plans. The benefits package covers hospital, primary, and specialist ambulatory and mental health care, approved prescription medicines, home care services by medical institutions, hospice care, physiotherapy, and most dental care. Cancer screenings are separately delivered by municipalities (The Commonwealth Fund, 2016).

Co-payments for services received vary between 10%, for those aged 75 and over with lower incomes, up to the general co-payment rate of 30%. In 2012, out-of-pocket payments accounted for 14% of total health expenditure. A monthly out-of-pocket threshold (‘safety net’) that varies according to age and income is stipulated. Subsidies are also available for people with disabilities, mental illness, and specified chronic conditions in low-income households. Catastrophic coverage sets out a monthly out-of-pocket threshold, which varies according to age and income. There is a ceiling for low-income people, who do not pay more than ¥35,400 ($422 AUD) a month, and an annual household health and long-term care out-of-pocket payments ceiling, which varies between ¥340,000 ($4,054 AUD) and ¥1.26 million ($15,024 AUD) per person according to income and age, above which such payments can be reimbursed (The Commonwealth Fund, 2016; Ministry of Health, Labour and Welfare, 2014a).

As shown in Table 2.13, in 2013 estimated total health expenditure amounted to approximately 10% of GDP, 83% of which was publicly financed, mainly through the PHIS. Expenditure on pharmaceuticals was $756 per capita (The Commonwealth Fund, 2016).
Table 2.13: Health care system indicators, Japan

<table>
<thead>
<tr>
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<th>Japan</th>
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<tbody>
<tr>
<td><strong>Population, 2013</strong></td>
<td></td>
</tr>
<tr>
<td>Total population (millions)</td>
<td>127.3</td>
</tr>
<tr>
<td>Percentage of population &gt;65 years</td>
<td>25.1%</td>
</tr>
<tr>
<td><strong>Expenditure, 2013</strong></td>
<td></td>
</tr>
<tr>
<td>Percentage of GDP spent on health care</td>
<td>10.2%</td>
</tr>
<tr>
<td>Health care expenditure per capita</td>
<td>$3,713</td>
</tr>
<tr>
<td>Average annual growth rate of real health care expenditure per capita, 2009-2013</td>
<td>3.8%</td>
</tr>
<tr>
<td>Out-of-pocket health care expenditure per capita (2012)</td>
<td>$503</td>
</tr>
<tr>
<td>Hospital expenditure per capita (2012)</td>
<td>$1,673</td>
</tr>
<tr>
<td>Expenditure on pharmaceuticals per capita</td>
<td>$756</td>
</tr>
</tbody>
</table>

Note: for consistency throughout the report, amounts in this table are expressed in USD.

Expenditure on prescription medications (including dispensing fees and the cost of medications) accounts for 5.3% of the national medical expenditure or 7.3 trillion yen in 2014, which is an increase from 4.6 trillion yen in 2005 with annual growth rate of 5.3%. The public sector funded 38.8% of the national medical expenditure, 25.8% from the national and 13% from local governments, with remaining amount covered by health insurance premiums and out-of-pocket payments (Ministry of Health, Labour and Welfare, 2014a).

2.3.2 Remuneration and regulation

Community pharmacies in Japan derive the majority of their income from dispensing fees that are paid to pharmacies through the health insurance programs. In 2015, 93.9% of community pharmacy revenue was from dispensing fees (Ministry of Health, Labour and Welfare, 2016a; Yamamura et al, 2006; The Commonwealth Fund, 2016). Dispensing fees are categorised by both the type of service and the size of the pharmacy and vary according to the number of prescription dispensed per month and the type of service provided. The dispensing fees include the technical fees of pharmacists for dispensing the medicines and fees for the provision of medicine guidance and information to patients. Some technical fees are added based on the number of medicines included in the prescription and the packaging of the medicines. An incentive for generic substitution is also available and community pharmacies receive ¥180 ($2.27 AUD) or ¥220 ($2.78 AUD) per prescription if the substitution rate reaches 65% or 75% (Yamamura et al, 2006; Ministry of Health, Labour and Welfare, 2016b).

A basic dispensing fee of ¥150-¥410 ($1.89 AUD - $5.17 AUD) is paid to pharmacists, as well as ¥380-¥500 ($4.79 - $6.30) for the provision of medicine guidance and patient information. These fees are subject to a premium which is based on several criteria such as the number of prescriptions dispensed per month and the type of service provided (Ministry of Health, Labour and Welfare, 2016b). An official pharmacy margin is not stipulated by the government and depends on private negotiations between the wholesaler and the pharmacy. Pharmacies derive profits from both the technical fee for the dispensing service that is paid by the insurance program and the difference between the wholesale and reimbursement price of the medicine.
The Pharmaceutical and Medical Device Act of Japan, revised from Pharmaceutical Affairs Law 1960 defines the term “pharmacy” as: the place where a pharmacist dispenses medicines for distribution or selling and excludes dispensaries in hospitals, clinics, or veterinary clinics. To establish a pharmacy in Japan, approval is required from the governor of the prefecture where it is to be located and this approval needs to be renewed every six years. Currently, there is no regulation that imposes restrictions on the locations where pharmacies are established. Pharmacy ownership is not restricted to pharmacists; a person who is not a pharmacist can own a pharmacy in Japan (Yamamura et al, 2006; OECD, 2014a).

The community pharmacy retail market in Japan is highly fragmented, with the share held by the five largest chains varying from 4.1% to 24.5%, depending on the prefecture. The three largest chains include Ain Holdings, Nihon Chouzai and Kraft (Drug Magazine, 2016).

The Pharmacist Act of Japan that was implemented in 1960 prohibits pharmacists from dispensing medicines without prescriptions from physicians or dentists, or dispensing medicines in places other than a pharmacy or other medical institutions, with some exceptions. Pharmacists are entitled to inquire about prescriptions but are not allowed to substitute the prescribed medicines without prior approval from the physician or dentist that wrote the prescription.

A pharmacy that engages in model community pharmacy practices is certified as an accredited pharmacy by the pharmaceutical society of the relevant prefecture. Such pharmacies are allowed to display a sign indicating their accreditation at the front of the establishment. Also, some premiums are available for community pharmacies that meet the criteria, including level of generic substitution and service offerings such as operating hours, product line-up and collaboration with other dispensing pharmacies in the region (Yamamura et al, 2006; Ministry of Health, Labour and Welfare, 2016b).

Given the increasing needs for home care, shared use of aseptic prescription laboratories became allowed by the ordinance that was issued in 2012 to amend the Pharmaceutical Affairs Law so that infusion and injections for chemotherapy can be prepared by pharmacies that do not have such laboratories (Ministry of Health, Labour and Welfare, 2014b).

### 2.3.3 Scope of services, settings and distribution

In addition to dispensing prescription medicines, community pharmacists in Japan, also participate in home health care, manage medicines, and promote overall health, thereby contributing to community health care. The following undertakings are considered to be model community pharmacy practices:

- labelling the dispensed medicine with a pharmacy label that includes the patient’s name, dosage, indication, and warnings;
- documenting past medical histories of patients to avoid adverse medicine reactions; and
- dispensing a patient information leaflet with the medicines (Inoue et al, 2016).

Medication reviews provided by 177 community pharmacists to 508 elderly participants in Japan under the ‘Brown Bag Program’ were investigated to understand medicine-use patterns, potential safety concerns and appropriateness of consultation provided to elderly individuals. This study identified 2 cases of contraindicated medicines, 3 of duplicate medicines and 327 cases of potentially inappropriate medicines. This evaluation identified
the usefulness of medication reviews in Japanese community pharmacies (Akazawa et al, 2012).

A cross-sectional survey of information provision was conducted for patients and pharmacists in community pharmacies in Fukuoka prefecture. In total, 407 patient-pharmacist pairs were included. The study simultaneously evaluated patient and pharmacist perceptions with the aim to clarify the perceptions of pharmacists and patients regarding information provision and the level of influence of those perceptions on patient satisfaction. This study found that found that the types of perceptions influencing patient satisfaction were not necessarily concordant between patients and pharmacists, suggesting that there are differences between the patient’s and the pharmacist’s perception with respect to pharmacists’ provision of information. Pharmacists’ perceived level of information provision concerning medication effects had a negative and significant association with patient satisfaction, while the patients’ perceived level of information provision by the pharmacist had a positive and significant association with patient satisfaction. Both pharmacist and patient perceptions of the information provision by pharmacists personalised to the patient had positive associations with patient satisfaction (Takaki et al, 2015).

In April 2016, the “family pharmacist guidance fees” were introduced. A pharmacist that is appointed by a patient as his/her “family pharmacist” can charge an additional fee of ¥700 ($8.83 AUD) every time they dispense medicines (Ministry of Health, Labour and Welfare, 2016b). The intention of this policy is to promote a change from pharmacies that specialise in dispensing medicines to pharmacies that serve as whole healthcare stations, providing pharmaceutical care based on patients’ medical history, including the intake of dietary supplements (Saito, 2016). Consumers are permitted to attend other pharmacies in addition to their family pharmacist.

Generic substitution policy in Japan is relatively new. Market share of generics by volume is comparatively low (20.2% in 2009). Reasons for this include concerns about quality and supply stability, as well as prescribing of medicines by brand name. To encourage the uptake of generic medicines, a new policy was introduced in 2008 allowing community pharmacists to switch to a generic of the prescribed medicine unless specifically stipulated by the prescriber (Iizuka and Kubo, 2011; Kobayashi et al, 2011; Kobayashi et al, 2011).

In response to increased demand for services due to Japan’s “super-aging population”, the government is promoting a shift from hospital-based to home-based provision of care. The role for pharmacists in home health care includes delivery of medicines, medicines checks where multiple medicines are used or there are leftover unused medicines, and provision of information and instruction on appropriate medicine use. For the purpose of remuneration, medical treatment payments are made for each of these home visits by pharmacists (Hasegawa et al, 2014; Hazama, 2010; Imai et al, 2012).

In Japan, both physicians and pharmacists have historically been permitted to dispense medicines. Primary care practices can dispense medicines which doctors can provide directly to patients. The proportion of prescriptions dispensed through community pharmacies out of the estimated total prescriptions issued by physicians and dentists is called the “bungyo rate”; bungyo refers to the separation of medicine prescribing and dispensing in hospitals and clinics. Use of community pharmacies, however, has been growing; 69% of prescriptions were filled at pharmacies in 2014, which is an increase from its level in 1990 (12%) (Yamamura et al, 2006; Drug Magazine, 2016). A study published in 2014 investigated the
association between medicine prices and the separation of dispensing and prescribing functions, which became optional in Japan in the 1960s. A significant negative correlation was observed between the expansion of the separation system and medicine cost in Japan (Yokoi and Tashiro, 2014).

Medicine stores, which do not require the services of pharmacists, can sell only non-prescription medicines with the exception that OTC medicines are required to be sold by pharmacists. These include OTC medicines, supplements, and herbal products that can be sold without a prescription (Yamamura et al, 2006).

In a comparison with five other countries (Thailand, Malaysia, UK, France and Germany), Japan had both the highest number of pharmacists and pharmacies. However, Japanese pharmacies offered fewer health promotion services. While this has increased in recent years, including blood glucose and hepatic functioning testing, the number of services offered was fewer. While in other countries this is a role for pharmacy assistants, pharmacists in Japan have duties of inventory control and medicine dispensing in addition to providing medicine advice to patients. Dispensing assistants (pharmacy technicians) do not exist in Japan (Inoue et al, 2015).

Table 2.14 shows the number of pharmacists and pharmacies in Japan, per 100,000 people. Compared to the OECD, Japan has almost twice as many pharmacies and pharmacists, on a per capita basis.

<table>
<thead>
<tr>
<th>Per 100,000 population</th>
<th>Japan</th>
<th>OECD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of practising pharmacists</td>
<td>161.0 (2012)</td>
<td>80.0 (2013)</td>
</tr>
<tr>
<td>Number of pharmacies (2015)</td>
<td>45.0</td>
<td>25.1</td>
</tr>
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In Japan, 23.5% of community pharmacies are concentrated in three prefectures of the three biggest cities in Japan: Tokyo, Osaka and Nagoya. However, the number of pharmacies per 100,000 population in those prefectures is in the same range of the national average of 45.0, at 47.9, 43.5 and 42.0, respectively. The highest rate is 63.2 in the Saga prefecture, which has the smallest population in the Kyushu Area (Ministry of Health, Labour and Welfare, 2013).

2.3.4 Wholesaler supply arrangements

The Japanese pharmaceutical market is the world’s second largest market next to the USA. The turnover of prescription medicines in the overall prescription medicine wholesale industry was ¥8,678.2 billion yen in 2011. Supply chain participants in Japan still follow a traditional route, whereby medicines manufactured by pharmaceutical companies are distributed solely through wholesalers to patients via retailers. As a result of the fact that wholesalers in Japan take greater roles compared to other developed markets, wholesalers distribute 97% of medicines (by value), with the remaining 3% considered to be generic medicines, that are sold directly to medical institutions. The roles of wholesalers in Japan include price negotiation with medical institutions, collection of receivables from medical institutions, and medicines information provision on behalf of representatives from
pharmaceutical companies (The Federation of Japan Pharmaceutical Wholesalers Association, 2012; OECD, 2014a; Global Business Intelligence Research, 2012).

As of March 2016, the Federation of Japan Pharmaceutical Wholesalers Association consisted of 79 member medicine wholesalers. The pharmaceutical distribution (wholesale) industry is an oligopoly, with the top four companies representing 90% of the Japanese pharmaceutical distribution market. Medicines are bought from wholesalers by five types of medical institutions: dispensing pharmacies and medicine stores (54% of sales in 2013), large hospitals (21%), clinics (18%), and small-medium sized hospitals (7%) (Global Business Intelligence Research, 2012).

There are few regulations on the wholesale pharmacy market in Japan. A wholesale license is required to sell prescription medicines to pharmacies. Wholesalers must not sell prescription medicines to parties other than pharmacies and medical institutions (OECD, 2014a).

An official wholesale margin is not stipulated by the government and depends on private negotiations between the wholesaler and the manufacturer. As a result, the wholesale prices of medicines vary with individual pharmacies and hospitals. The retail prices of prescription medicines covered by the health insurance system are set as official prices based on the medicine price standard. This effectively means that the official medicine prices function as the maximum wholesale prices of prescription medicines (OECD, 2014a). All key supply chain participants suffered losses from the National Health Insurance medicine prices review that occurs in every two years as the new National Health Insurance price of individual medicine is determined based on profit margins (Ministry of Health, Labour and Welfare, 2016a; Yamamura et al, 2006; The Commonwealth Fund, 2016).

Pharmaceutical manufacturers sell prescription medicines to wholesalers at wholesale prices and provide separate rebates or allowances depending on the volume of sales. Wholesalers negotiate the prices of medicines with pharmacies in consideration of the rebates from pharmaceutical companies and their own costs and profits. Recently, it is taking a longer time to determine the prices, as a result of complication of negotiations because wholesalers who aim to secure a minimum profit while pharmacies attempt to secure medicine price margins (OECD, 2014a).

2.3.5 Adoption of technology

To date, there has been limited adoption of technology in pharmacies in Japan. EHR networks have been developed only as experiments in selected areas, and interoperability between providers has not been generally established. Experiments are under way to make personal health information available to patients and providers via cloud computing. The Social Security and Tax Number System, a system of unique identifiers, will begin in 2016. It will be used for social security from its inception, and for health services, possibly including medical records, starting in 2018 (The Commonwealth Fund, 2016).

e-prescriptions and government-issued operational guidelines became available in April 2016, following trials of e-prescriptions such as in Kagawa. This system allows prescribers to send prescriptions, diagnoses and laboratory data to the community data centre server. In turn, pharmacists can access prescription information and input guidance and adverse event information. Patients can also view their dispensed medicines and input information on
allergies, adverse medicine reactions, and any OTC medicines they are taking. However, usage of the system is limited due to its recent introduction (Iihara and Kirino, 2014; Nikkei Digital Health, 2016).

In a pilot study conducted in Oita prefecture, the Healthcare Public Key Infrastructure – an e-certification of healthcare professionals approved by the Ministry of Health, Labour and Welfare – was used for storing e-prescriptions, which removed the need for paper prescriptions. However, the study concluded that paperless e-prescriptions were difficult due to existing procedures which requires paper prescriptions to have the seal of the requesting physician (Nikkei Digital Health, 2016).

Recently, electronic patient information leaflets have emerged in response to increases in smart phone usage. Community pharmacy chains are developing a leaflet app with value-added functions such as data transactions between connected devices, weight scales and pedometers (Nikkei Digital Health, 2016).

2.3.6 Reforms, innovations and trials

The new scheme of the “family pharmacist” implemented in April 2016 (see Section 2.3.3) is expected to expand roles of community pharmacies and quality of service through the incentives. The scheme aims to avoid duplication in prescriptions and reduce medicine waste by establishing a single gatekeeper (Japan Pharmaceutical Association, 2015). However, as this scheme has been recently introduced, no outcomes on the reform are available at the time this report was prepared.

To encourage continuing professional knowledge and skill development, the Council on Pharmacists’ Credentials was established in July 2004. The remit of this independent coordination and evaluation body is to increase the competence of pharmacists by improving the quality of their Continuing Education Credentialing Programs. Further, in an attempt to improve the ethical and academic level of pharmacists, the Japan Pharmaceutical Association has published “A Manual to Evaluate the Profession of Pharmacists in Pharmacies.” It functions as a guide for pharmacies and pharmacists to deliver high-quality health care services for patients and consumers (Yamamura et al, 2006). Analysis by the Japan Pharmaceutical Association (2016) suggests that the percentage of prescriptions which result in a pharmacist making an enquiry to the prescribing physician has remained relatively stable since 1998, at around 2-3% of all dispensed prescriptions. However, the amount of money that is saved as a result of the enquiries has increased, as the enquiries frequently result in generic medicines being prescribed in place of brand name medicines, and there are fewer duplicated prescriptions.

5 The process whereby the requesting physician places their seal on a prescription is similar to a requesting physician signing a prescription.
3 North America

The following sections present information on the community pharmacy sector in the USA and Canada. The community pharmacy sector in these countries are compared with Australia in Chapter 6.

3.1 United States of America

3.1.1 Health system context and expenditure

There are three primary oversight bodies in the USA health care system: government (local, state and federal), private insurers, and regulators. The Federal Government has two main roles; they regulate the providers of health care services and employers who provide private health insurance, and they fund public health insurance programs. State governments regulate marketplaces, pharmacies and private companies who provide private insurance, and in some cases will have their own state insurance health care programs. State and local governments provide other health services and play a role in operating public hospitals and other primary care services (Rice et al, 2013).

The two main programs for public health service delivery in the USA are Medicare and Medicaid. These programs provide some subsidised health care services to a specific population who meet eligibility criteria.

- **Medicare** is the largest public purchaser in the USA and is funded by the Federal Government. Only those who are over 65 years or have End-Stage Renal Disease or young people with specific disabilities are able to access Medicare (Rice et al, 2013).

- **Medicaid** is funded by both the state governments and the federal government. The eligibility requirements for Medicaid differ to Medicare and are primarily based on income. Low income families, pregnant women and children are eligible for Medicaid. Within Medicaid states run their own programs, as a result, services covered by Medicaid vary from state to state. States must adhere to guidelines provided by the Federal Government (The Commonwealth Fund, 2016).

Private insurance is available to the population and supplied by employers, marketplaces and private companies. Approximately 66.0% of USA residents had private voluntary health insurance (VHI) in 2014, while 19.5% had some form of public program. The most common form of insurance held by Americans was employer provided insurance with 55.4% of Americans having this type of insurance. However, within the health system it is possible for a person to have multiple forms of health insurance; for example, there is overlap in Medicare and Medicaid eligibility. Coverage of pharmaceuticals varies with each insurance plan. Within public health insurance programs, Medicare offers some coverage; however, this is only provided if the consumer decides to use it and pay particular fees (The Commonwealth Fund, 2016).

In addition to regulations imposed on health care service providers from the Federal Government, a number of other organisations also regulate health care service providers. Regulators include organisations such as the American Medicine Association, the Joint Commission and American Pharmacists Association (Rice et al, 2013).
Health system expenditure in the USA in 2013 was approximately 17.1% of GDP. Expenditure on pharmaceuticals per capita was $1,034 (The Commonwealth Fund, 2016). Other statistics on the USA health sector are shown in Table 3.1.

### Table 3.1: Health system indicators, USA

<table>
<thead>
<tr>
<th></th>
<th>USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population, 2013</td>
<td></td>
</tr>
<tr>
<td>Total population (millions)</td>
<td>316.1</td>
</tr>
<tr>
<td>Percentage of population &gt;65 years</td>
<td>14.10%</td>
</tr>
<tr>
<td>Expenditure, 2013</td>
<td></td>
</tr>
<tr>
<td>Percentage of GDP spent on health care</td>
<td>17.10%</td>
</tr>
<tr>
<td>Health care expenditure per capita</td>
<td>$9,086</td>
</tr>
<tr>
<td>Average annual growth rate of real health care expenditure per capita, 2009-2013</td>
<td>1.24%</td>
</tr>
<tr>
<td>Out-of-pocket health care expenditure per capita</td>
<td>$1,074</td>
</tr>
<tr>
<td>Hospital expenditure per capita</td>
<td>$2,964</td>
</tr>
<tr>
<td>Expenditure on pharmaceuticals per capita</td>
<td>$1,034</td>
</tr>
</tbody>
</table>

Note: for consistency throughout the report, amounts in this table are expressed in USD.

There is currently no publicly-available information which provides a complete picture of government expenditure on community pharmacy in the United States. Prescription medicine expenditure in 2014 was approximately $297.7 billion. The majority of this expenditure was attributed to health insurers ($250.9 billion) of which private health insurance was the biggest spender ($127.3 billion). Government expenditure, including federal, state and local expenditure, comprised the remaining $123.6 billion. Figure 3.1 shows prescription medicine expenditure by payer during the 2010 to 2014 period. Over this period, the majority of prescription medicine expenditure was funded through insurance programs. Expenditure increased in small increments over 2010-2013, but increased by a larger amount in 2014 (Centers for Medicare and Medicaid, 2015).
3.1.2 Remuneration and regulation

Because of the wide variation in insurance plans and the difference in remuneration for different types of medicines within those plans, there is no set structure for pharmacy remuneration. Pharmacies are remunerated either directly by the consumer or by the consumer and their insurer (which can be public and/or private insurance). When a consumer with no insurance purchases a medicine they will pay the full cost of the medicine. If the patient has insurance and the insurance covers the medicine they will either:

- pay a fixed contribution ("co-payment") towards the cost of the medicines; or
- pay a percentage ("co-insurance") of the cost of the medicine (Obamacare Facts, 2016).

Typical health insurance plans will require co-payments until the patient’s out-of-pocket expenses have reached a fixed amount (the “deductible”) over a specified time period, and then patients will pay co-insurance for any additional expenses after that amount. The remaining amount between the patient contribution and the cost of the medicine is paid by the health insurance provider. There are no national price regulations for medicines, however, in some cases the government will negotiate payment discounts such as for Medicaid, and pharmacy benefits managers (PBMs) will also negotiate prices (the role of these stakeholders is discussed in more detail in section 3.1.4). The patient contribution for medicines is typically divided into four tiers by health insurers (Obamacare Facts, 2016). The Affordable Care Act (ACA) caps cost-sharing for most private insurance plans at $6,600 for individuals and $13,200 for families per year in 2015 (Healthcare.gov, 2015).

Different states in the USA have different pharmacy regulations. There appears to be only one state with regulations around pharmacy ownership. In North Dakota it is a requirement that a pharmacist have majority ownership of a pharmacy. In addition to this ownership regulation, other regulations relating to pharmacy safety exist. Regulation of pharmacies and
wholesalers is done at the state level; however, there are some similar themes across all states. For example, all states have some form of regulation around secure storage, recordkeeping, the forms or pads used for patient prescriptions and purity. Most states have their own Boards of Pharmacy which regularly update these rules (Lowery, 2014; National Conference of State Legislatures, 2014).

To become a licensed pharmacist, all states require the participant to pass the North American Pharmacies Licensure Examination. Some states also require a pharmacist to pass another test called the Multistate Pharmacy Jurisprudence Examination. Pharmacists are also able to specialise – to obtain certification of their speciality they must have field experience and pass a test (National Governors Association (NGA), 2015). Additionally, guiding principles for post-licensure credentialing of pharmacists has been developed by the Council on Credentialing in Pharmacy which is intended to provide an credentialing and privileging system for pharmacists in the USA health care system (Burns et al, 2014).

In regards to chemotherapy regulations, chemotherapy delivered to Medicare eligible patients in a hospital outpatient setting requires the patient to pay a co-payment. This varies depending on the plan. If treatment is provided in a doctor’s office or clinic then the patient will pay 20% of the Medicare approved amount. This is the amount which a Medicare-eligible GP will accept (Centers for Medicare and Medicaid, 2016a).

For Medicaid, chemotherapy costs vary by state. In general, costs are composed of an ingredient cost and a dispensing fee. For example, in Hawaii Medicaid pays the ingredient cost of the wholesale acquisition cost and then a dispensing fee of $5 (Centers for Medicare and Medicaid, 2016b).

There are additional standards for chemotherapy compounding pharmacies. The most important piece of legislation about compounding is the Medicine Quality and Security Act 2013, which was introduced after a meningitis outbreak in 2012 was traced to a compounding pharmacy. This Act removed exemptions that were set out in the Federal Food, Medicine, and Cosmetic Act 1938, such as the Current Good Manufacturing Practices (CGMPs), labelling requirements and Food and Drug Administration (FDA) approval processes (USA FDA, 2016). CGMPs are set to ensure the safety of manufactured pharmaceutical products. These practices set out minimum requirements about the strength, quality and purity of the medicine products. All manufacturers must adhere to these standards (National Conference of State Legislature, 2016; USA FDA, 2015).

Biosimilar policy in the USA includes the introduction of two pathways for registration: a simpler pathway whereby the biosimilar will not be deemed interchangeable – therapeutically equivalent and safely switched with the originator – and a more complex pathway to determine that the biosimilar is interchangeable with its originator. To date, an interchangeable biosimilar has not yet been approved through the more complex pathway. A year of market exclusivity has been introduced as an incentive for drug developers to pursue this option. Substitution of biologic and biosimilar medicines at a pharmacy level is covered by state law in the USA. Most, but not all, US states have legislation that allows substitution for interchangeable biosimilars (Renwick et al, 2016).

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6 This is the price paid by the wholesaler to the manufacturer, less discounts.
3.1.3 Scope of services, settings and distribution

According to the NGA (2015), the scope of pharmacy practice in the USA entails four things: ensuring appropriate medicine therapy and outcomes, dispensing, engaging in health promotion and disease prevention and engaging in health system management. Specific examples of services provided by pharmacies in addition to dispensing are:

- **Medication Therapy Management (MTM).** Government funding for these services differs by state, with some states including performance-based funding models. For some Medicare programs, MTM is a compulsory service that must be provided (Centers for Medicare and Medicaid, 2016). MTM can include the following services:
  - **Medication therapy reviews:** this involves reviewing a patient’s medicine and coming up with a plan to resolve any medicine related issues.
  - **Pharmacotherapy consultation:** these consultations are normally provided to patients with complex needs. The pharmacist works to ensure prescribed medicine is appropriate.
  - **Disease management:** in addition to providing medicines, the pharmacist will provide advice about lifestyle changes to manage diseases.
  - **Anticoagulation management:** provide services to manage blood thinning medicines and offer support and advice to patients on these medicines.
  - **Immunisations:** pharmacists are authorised to provide vaccinations (American Pharmacists Association, 2016).

- **Comprehensive Medication Management (CMM) services.** CMM involves ensuring that each medicine prescribed to a patient is appropriate and safe to be taken, especially in cases of a patient taking multiple medicines. For a pharmacist to deliver CMM services, they must have a collaborative medicine therapy management agreement with a physician (Giberson, 2011).

A retrospective cohort study evaluated a community-based pharmacist-led face-to-face counselling program on medication adherence, for patients who were new to therapy for statin medications, that was implemented in 76 national community pharmacies located in mid-west USA. The study found that, compared to controls, patients who participated in brief face-to-face counselling sessions with a community pharmacist at the beginning of statin therapy demonstrated greater medication adherence and persistence (Taitel et al, 2012).

There are a variety of pharmacies within the USA. Community pharmacies in the USA include independent pharmacies, chain pharmacies, supermarket pharmacies, and mass merchandiser pharmacies (Todd et al, 2013). Chain pharmacies make up the majority (62%) of community pharmacies, followed by independent/private pharmacies (35%) and government pharmacies (2%). According to information from the National Community Pharmacists Association (2016), there are approximately 22,478 community pharmacies in the USA. There were approximately 1,759 independent rural pharmacies in 2011.

Approximately 90% of Americans live within 5 miles of a community pharmacy (Kelling, 2015). The number of pharmacies and pharmacists in the USA compared to the OECD average per 100,000 population is shown in Table 3.2.
### Table 3.2: Number of pharmacies and pharmacists, USA

<table>
<thead>
<tr>
<th></th>
<th>USA</th>
<th>OECD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of practising pharmacists</td>
<td>91.0</td>
<td>80.0</td>
</tr>
<tr>
<td>Number of pharmacies per 100,000 population</td>
<td>10.1</td>
<td>25.1</td>
</tr>
</tbody>
</table>

Source: OECD (2015)

Outside of pharmacies and hospitals, GPs are legally able to dispense medicines in 44 of the 50 states. In 38 of these states, nurses and GP assistants are allowed to dispense medicines. However, in six states non-pharmacist dispensing is prohibited. Rural regions in three of these states have an exemption allowing GPs to dispense medicines when they are geographically isolated from any pharmacies (Darekar et al, 2016).

In the USA, access to pharmacy services for those with limited English proficiency has been found to be inhibited due to language and cultural barriers. The population of the USA speak a variety of languages, with approximately 20% of the USA population speaking a language other than English at home. Studies have found that a lack of translation of prescription labels or other print materials presents a barrier to access. In some cases where a translation is provided, it is inaccurate or contains errors. Other studies have also argued that providing bilingual pharmacists aids in the care of patients (Bailey et al, 2012; Cipriano and Andrews, 2015).

#### 3.1.4 Wholesaler supply arrangements

For a pharmaceutical to be sold in the USA, it must first be approved by the FDA. The FDA is a regulatory agency that focuses on whether a medicine is safe, effective and of acceptable quality to be available for sale in the country. Once approved by the FDA, manufacturers will sell their pharmaceuticals to wholesalers. Wholesalers will then sell the medicines to pharmacies who in turn sell the medicines to consumers. The patient will either pay the full cost of the medicine, or a co-payment and their insurance package will cover the remaining cost. This money flows to the pharmacy, who pays the wholesaler who then pays the manufacturer. There are contracts between manufacturers and wholesalers and also pharmacies and wholesalers. In some cases, the manufacturer will also deal directly with a pharmacy if there are specialty medications that the pharmacy demands.

The USA supply chain also has a unique player within the supply chain. PBMs are hired by third parties, such as insurance companies, to negotiate prices with manufacturers and pharmacies. Once prices are agreed upon, there will be a contract between the PBM and the third party. The third party will also reimburse patient prescription costs through the PBM instead of paying pharmacies themselves. The PBM will receive rebates from manufacturers, which the PBM then passes on to the third party. This rebate represents the difference between the price paid by the consumer and the price agreed upon by the manufacturer and the PBM. The USA supply chain is shown in Figure 3.2 (Drug Channels, 2016).
Margins vary depending on arrangements with PBMs, wholesalers, insurance companies, pharmacies and manufacturers. In general, the payment made by insurance companies and employers who provide insurance to workers includes additional fees to pharmacies, PBMs and manufacturers (Medscape, 2016; Appleby, 2016).

3.1.5 Adoption of technology

A number of technologies have been adopted by pharmacies in the USA. Health information exchanges (HIEs) have been set up across the USA, which allow medical practitioners, including pharmacists, to access a patient’s information. Information such as lab tests, other medical tests and prescriptions can be transferred to other medical practitioners (Health Information Technology, 2014).

Between 2008 and 2014, two important policies were implemented to promote the use of e-prescribing in the USA. The “ePx incentive” began in 2008, offering financial incentives for providers to facilitate the use of e-prescribing (Gabriel and Swain, 2014). The Medicare and Medicaid EHR Incentive (“meaningful use”) Program commenced in 2011. Top demonstrate meaningful use, providers must use their EHRs to meet several program objectives, including e-prescribing (Gabriel and Swain, 2014).

The primary network used for e-prescribing is called Surescripts. This network services 240 million patients across the USA. From 2008 to 2012, the level of e-prescribing via an EHR had increased from 7% to 54%, with 94% of pharmacies accepting e-prescriptions in 2012 (Gabriel...
et al, 2013). A more recent analysis of the rates of physician e-prescribing, pharmacy capability to accept e-prescriptions and the volume of e-prescriptions identified that:

- by April 2014, 70% of physicians were e-prescribing using an EHR on the Surescripts network. All states had physicians e-prescribing using an EHR at a rate above 40% and 28 states had at least 70% of their physicians e-prescribing using an EHR;
- from December 2008 to April 2014, community pharmacies enabled to accept e-prescriptions increased from 76% to 96%;
- by April 2014, every state had at least nine in ten community pharmacies enabled to accept e-prescriptions; and
- in 2013, of the 1.8 billion new and renewal prescriptions, 1 billion were sent electronically, or 57% nationally.

A study of e-prescribing in the USA found that using EHRs to electronically communicate prescription data between GPs and pharmacies nearly halved the risk of dispensing errors when compared to printing the prescription and giving it to the patient (Moniz et al, 2011).

Hospitals are heavily involved in dispensing prescription medicine to inpatients. A trial of a computerised prescriber order entry system for improving efficiency and reducing errors in medicine orders in hospitals found that the system resulted in an 8.9% decrease in errors compared to paper-based medicine orders (Frost, 2011).

### 3.1.6 Reforms, innovations and trials

The most significant recent reform in the USA health care system is the ACA, commonly referred to as Obamacare. The ACA increased accessibility of health care for low-income earners through expansion of Medicaid and increased accessibility for middle and high income earners through subsidisation of private insurance. The ACA also has cost control and quality components (McDonough, 2013). Martin (2015) noted that the Act will be the source of future opportunities for pharmacists to provide comprehensive and higher quality services.

The impact of the ACA on the community pharmacy sector is summarised below:

- **increased reporting requirements for PBMs**: PBMs must disclose certain financial information to the government;
- **increased demand for pharmaceuticals**: due to the closure of the Medicare gap and the increase in uptake of insurance, pharmaceutical demand and subsequently expenditure will increase; and
- **Accountable Care Organizations (ACOs)**: an ACO is a team of interdisciplinary medical specialists who work together to coordinate patient care (Smock, 2013). ACOs were introduced to help improve the quality of health care. This has increased the use of the MTM services (Milenkovich 2010; Carrion and Martin 2015; Lamb 2016).

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7 The Medicare gap is a limit on what the medicine plan will cover for medicine. For more information see: Centers for Medicare and Medicaid (2016d)
3.2 Canada

3.2.1 Health system context and expenditure

The Canadian Federal Government funds universal health insurance called Medicare. Medicare provides free physician, diagnostic imaging services and medically necessary services to Canadians. The primary responsibility for delivering and organising health services falls to the province and territory (“jurisdictional”) governments. The jurisdictions provide their own universal insurance programs, however these plans have common elements such as the provision of Medicare services. The plans differ on coverage and eligibility requirements of other services such as prescription medicines and long term care services (Marchildon, 2013).

The Medicare program does not cover prescription medicines. Instead, jurisdictions determine their own prescription medicine coverage. For the general population no coverage is provided, but most jurisdictions cover the prescription medicine costs for retired persons, the unemployed, and indigent populations with only minor prescription filling fees for the user (Marchildon, 2013).

Private health insurance is also an option for Canadians. These policies tend to cover other services such as dental and vision, prescription medicines and private rooms in hospitals which are not covered in the public universal health insurance program. Private insurance is provided by employers and unions and makes up approximately 12% of total health expenditure (The Commonwealth Fund, 2016).

Funding for health services comes from tax revenue provided by the Federal Government in a combined social transfer program as well as jurisdictional tax revenue. It is estimated that expenditure on pharmaceuticals in 2013 constituted approximately 16.7% of total health care expenditure. Other statistics on the Canadian health sector are shown in Table 3.3 (The Commonwealth Fund, 2016; OECD, 2016b).

Table 3.3: Health care system indicators, Canada

<table>
<thead>
<tr>
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<th>Canada</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population, 2013</td>
<td></td>
</tr>
<tr>
<td>Total population (millions)</td>
<td>35.3</td>
</tr>
<tr>
<td>Percentage of population &gt;65 years</td>
<td>15.2%</td>
</tr>
<tr>
<td>Expenditure, 2013</td>
<td></td>
</tr>
<tr>
<td>Percentage of GDP spent on health care</td>
<td>10.7%</td>
</tr>
<tr>
<td>Health care expenditure per capita</td>
<td>$4,569</td>
</tr>
<tr>
<td>Average annual growth rate of real health care expenditure per capita, 2009-2013</td>
<td>0.2%</td>
</tr>
<tr>
<td>Out-of-pocket health care expenditure per capita</td>
<td>$623</td>
</tr>
<tr>
<td>Hospital expenditure per capita</td>
<td>$1,338</td>
</tr>
<tr>
<td>Expenditure on pharmaceuticals per capita</td>
<td>$761</td>
</tr>
</tbody>
</table>

Note: for consistency throughout the report, amounts in this table are expressed in USD.

In 2014, Canadians spent an estimated $28.8 billion on prescribed medicines (13.4% of total health expenditure) and $5.1 billion on non-prescribed medicines (2.4% of total health expenditure).
expenditure). The growth rate of prescribed medicine expenditure has slowed in both the public and private sectors since 2000. In 2014, 42.0% of prescription medicine expenditure was from government sources – mostly jurisdictional, with smaller contributions from Federal sources and social security funds. Saskatchewan had the largest percentage of government expenditure (51.0%), while New Brunswick had the smallest percentage (31.5%). Generic medicines accounted for 34.1% of public medicine expenditure, but 71.5% of claims (Canadian Institute for Health Information, 2015).

### 3.2.2 Remuneration and regulation

Each jurisdiction has a different agreement for community pharmacies operating within their jurisdiction. As a result, pharmacies receive different remuneration depending on which jurisdiction they are located in. For example, in Quebec a patient in the public medicine plan will pay a monthly set fee when they first purchase medicines for that month, this is called the deductible and is $18.85. The patient must also pay co-insurance which is 34.50% of the price of the prescription, minus the deductible. The co-insurance and deductible paid by the patient is called the patient’s contribution. The government will then pay the difference between the prescription price and the patient contribution. There is also a maximum monthly and annual amount – if a person reaches either then the government will pay for all remaining prescriptions (Regie de l’assurance maladie Quebec, 2016).

In most provinces, the medicine coverage is limited to populations in need, and a reduced co-payment fee for prescription filling is charged. Retail pharmacies offer very competitive rates on the co-payment fee for government sponsored medicine programs to secure market share. These are used as a competition lever to build their script/patient base. They are typically in the $7-$12 range, but can be as low as $2 and sometimes waived. Exemptions from co-payments for non-insured services such as prescription medicines vary among provinces and territories, and there are no caps on out-of-pocket spending. However, the federal Medical Expense Tax Credit supports individuals whose medical expenses, for themselves or their dependents, are significant (above 3% of income) (The Commonwealth Fund, 2016).

There are different price arrangements for patented and generic pharmaceuticals. For new patented medicines the Patented Medicine Prices Review Board (PMPRB) will set the maximum price. However, this price only impacts prices that manufacturers are able to charge bulk purchasers, wholesalers, hospitals and pharmacies. The price that wholesalers charge pharmacies and consumers is not subject to regulation. If the PMPRB has reason to believe that pricing of a pharmaceutical is excessively high, they may undertake negotiations to reduce the price. Jurisdictions are also able to negotiate the price of pharmaceuticals with manufacturers when deciding to give a pharmaceutical a government subsidy (Moore et al, 2015).

Regulation of pharmacies and pharmacists differs by jurisdiction. There is a national body in Canada called the National Association of Pharmacy Regulatory Authorities (NAPRA) which aims to address common issues facing the Canadian pharmacy industry. NAPRA is comprised of provincial and territorial pharmacy regulatory bodies, and sets regulation requirements for pharmacists and pharmacies in each jurisdiction. There is a National Model Licensing Program which is applicable to pharmacists. Within this program are core requirements about academic qualifications including degree and language proficiency information, pharmacy jurisprudence examinations and the national licensing examination. There are
several pharmacy associations, the largest of which is the Neighbourhood Pharmacies of Canada. Most chain and independent stores belong to this non-for-profit industry association (NAPRA, 2016a).

Each jurisdiction has their own “college” of pharmacy, the largest of which is the Ontario College of Pharmacists. Pharmacy accreditation fees and pharmacy licenses differ in each jurisdiction, as do the standards which must be met to obtain a licence. In some areas of Canada, such as the Northwest Territories and Yukon, there are no pharmacy accreditation or licensing programs in place. Other jurisdictions, such as Ontario, have annual fees of $700 (NAPRA, 2016b).

Other regulation that pharmacies must adhere to includes reporting of quality-related events (QREs). QREs includes events such as dispensing errors, or other errors that might be identified by pharmacy staff prior to the dispensing of medicines. The QRE requirements differ in each jurisdiction. At a minimum, community pharmacies are required to have a policy with steps outlined that must be taken when a QRE reaches the patient. Other jurisdictions require reporting of such incidents to a national database (Boyle et al, 2014).

Chemotherapy is predominantly hospital prepared and delivered. For infusions, there are dedicated clinics with associated regulation. The infusion clinics are independent of pharmaceutical manufacturers. In some communities, where infusion clinics do not exist, infusion medicines are often prepared and delivered in outpatient hospital clinics.

NAPRA also has information about standards for pharmacy compounding. There are two model standards released by NAPRA, these include The Model Standards for Pharmacy Compounding of Non-hazardous Sterile Preparations, and the Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations. These set out core requirements such as personnel, policies and procedures, facilities and equipment and general maintenance logs. Other requirements about products and preparations are also set out within these standards (NAPRA, 2016c).

In Canada, the medicines regulatory agency (Health Canada) does not make a determination on substitutability of a particular product with its originator but rather the decision is at the provincial level. However, evidence to support substitutability must be demonstrated, as Health Canada does not support automatic substitution of a biosimilar for its reference drug (University of South Australia, 2016).

3.2.3 Scope of services, settings and distribution

Other than dispensing services, pharmacies can provide a variety of other services; however, these vary in each jurisdiction. The scope of services provided by pharmacies is provided below (note that not all jurisdictions provide the full range of services):

- emergency prescription refills;
- renew/extend prescriptions;
- change medicine dosage/formulation;
- make therapeutic substitution;
- prescribe for minor ailments;
- initiate prescription medicine therapy;
• order and interpret lab tests; and
• administer a medicine by injection (Morrison, 2013).

Services that are publicly funded vary by jurisdiction. Some immunisation services are covered, and the span of government-funded immunisation is reviewed annually and adjusted. Advanced medicine review services receive public funding in only three jurisdictions. Some jurisdictions will pay for these services on a per service basis (Canadian Pharmacists Association, 2016). For example, for renewing or extending prescriptions or changing doses, the highest public remuneration for this service is $20 per assessment in Alberta, and the lowest is $6 in Saskatchewan. Another example is assessments of minor ailments; for this service Saskatchewan pays $18 per assessment while Quebec pays $16 per assessment (Canadian Pharmacists Association, 2016).

An example of a medicine review service provided by some jurisdictions is the MedsChecks service offered in Ontario, which is similar to the MedsCheck service offered in Australia. This is a government funded service which is offered to patients who are taking three or more prescription medicines. This service aims to ensure adherence to medicine and to provide information to the patient. It involves a discussion with the patient and pharmacist. Initially, a pharmacist was paid $50 for a 30 minute medicine review; however, in 2010 this was increased to $60. This service is also provided in the patient’s home and pharmacists are paid $150 for this service (Dolovich, 2016; Grindrod, 2013).

Twelve community pharmacies across Alberta participated in an investigation of the effect of a community pharmacist prescribing intervention on glycaemic control in patients with poorly controlled type 2 diabetes. Of the 100 patients recruited, 51% of the patients achieved the target blood sugar level at the end of the study. These results showed similar improvements in glycaemic control as previous physician-led studies (Hamarneh et al, 2013).

To explore the factors associated with achieving an effective relationship between patients and pharmacists, a Canadian study was conducted in five community pharmacies across Alberta. Results of 112 patient surveys indicated that there was a significant, positive correlation between patient-perceived pharmacist expertise and quality of the relationship. There were also significant, positive correlations between perceived expertise and patient satisfaction and relationship commitment (Alghurair et al, 2012).

According to data from the OECD (2015), Canada has approximately 26.7 community pharmacies per 100,000 population. When compared to the rest of the OECD, Canada has more pharmacists and pharmacies per 100,000 population than the average of the OECD. These figures are shown in Table 3.4.

<table>
<thead>
<tr>
<th>Table 3.4: Number of pharmacies and pharmacists, Canada</th>
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<tbody>
<tr>
<td>Canada</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>Number of practising pharmacists</td>
</tr>
<tr>
<td>Number of pharmacies per 100,000 population</td>
</tr>
</tbody>
</table>


The number of pharmacies varies by jurisdiction. Areas with high population density (such as Alberta, Quebec, Ontario and British Columbia) have a higher number of community
pharmacies. However, the number of pharmacies per 100,000 population is relatively consistent across the jurisdictions, with the exception of Nunavut (the most remote of the Canadian jurisdictions) which has the lowest number of pharmacies relative to population (13.5 pharmacies per 100,000 population). The highest number of pharmacies per 100,000 population is in Newfoundland and Labrador (36.2). The estimated number of pharmacies per 100,000 population across the jurisdictions is shown in Chart 3.1, for 2016 (NAPRA, 2016e; Statistics Canada, 2016).

![Chart 3.1: Pharmacies per 100,000 in each jurisdiction, Canada](image)

Source: Deloitte Access Economics calculations using NAPRA (2016e) and Statistics Canada (2016) data.
Note: the Northwest Territories, Nunavut and Quebec do not license community pharmacies, and so data for these jurisdictions are estimates only. The estimated number of community pharmacies in Yukon was not available.

### 3.2.4 Wholesaler supply arrangements

There are a number of stakeholders involved in the pharmaceutical supply chain in Canada. Health Canada is responsible for approving medicines for sale in Canada. To inform their decision, the Canadian Agency for Medicines and Technologies in Health will analyse the proposed medicine and provide recommendations about the sale of the medicine. It is then the decision of the jurisdiction whether to provide subsidies for the medicines and if so, the policy around the prices of the medicines. In some jurisdictions, the medicines must go through an additional review before it can be approved for subsidy on their medicine plan. The jurisdictions will negotiate with the wholesalers and distributors about pricing for the pharmaceutical. The wholesalers will then negotiate with the manufacturers (Moore et al, 2015).

Within the distribution of pharmaceuticals a pharmacy may also choose to be a self-distributing pharmacy. This approach is more common amongst chains of pharmacies. Other pharmacies may directly approach manufacturers and not go through a wholesaler. It
is estimated that wholesalers and self-distributing chains distribute 95% of pharmaceutical to community and hospital pharmacies (Moore et al, 2015). The supply chain is shown in Figure 3.3.

![Figure 3.3: Wholesaler supply arrangements, Canada](image)

Data on margins and rebates in Canada are difficult to find and in some cases are not available. However, one estimation of pharmacy mark-ups reports that mark-ups at the retail level are approximately 7-10% of the medicine’s retail price. At the wholesale level, the pre-tax profit margin for community pharmacy wholesales has been estimated to be 5% (Moore et al, 2015).

### 3.2.5 Adoption of technology

In Canada, EHRs contain patient history and health information such as test results and prescription medicine. One part of EHRs is the Drug Information System (DIS). DIS is the part of the EHR that stores information about the prescription medicines used by the patient. The DIS can also be used to send e-prescriptions. While the evolution of the EHR varies by province, DIS’ have been fully implemented in British Columbia, Alberta, Saskatchewan, Manitoba and Prince Edward Island as at early 2016. Other parts of Canada were also in the process of implementing the system. Many pharmacists who use DIS have reported productivity and quality-of-care benefits (Leung et al, 2016).

In 2014, it was estimated that 62% of all Canadians had medicine dispensing profiles in their EHRs. In 2010 a survey of pharmacists was conducted by the Canadian Government. Within this survey pharmacists reported that 40% of prescriptions they received were generated from e-prescriptions from EHRs (Phillips et al, 2015).

Other technological initiatives have been implemented throughout jurisdictions. One such initiative is a prescription dispensing machine which has been implemented in Ontario. These machines, called PharmaTrust MedCentres, are remote dispensing systems and allow users to communicate with a pharmacist who might be located elsewhere via videoconferencing. They have been installed in rural communities and allow access to
pharmacists in communities where pharmacies may be scarce (Canadian Pharmacists Journal, 2011).

3.2.6 Reforms, innovations and trials

There have been two recent policy debates in Canada of relevance to the community pharmacy sector. The first debate has focused on whether to provide a universal pharmaceutical care plan. A report was recently presented in the House of Commons that analysed the feasibility of a national prescription medicine program. One costing of the universal pharmaceutical program estimated savings to be approximately $11.4 billion per year, while another publication estimated savings to be $7.3 billion. Gagnon (2014) concluded that introducing a universal pharmaceutical care plan would result in a decrease in expenditure on dispensing fees, a reduction in administrative costs and a reduction in expenditure on tax incentives that are paid to employers to provide health insurance. However, there have been many debates regarding the increase in taxpayer’s costs as a result of the increased expenditure and the decrease in choice for consumers in a universal pharmaceutical plan (Gagnon, 2014; Morgan et al, 2015; Skinner, 2013).

The second debate has focused on expanding the pharmacists’ scope of practice. A number of jurisdictions have recently passed legislation that expanded the scope of pharmacists’ services. Some services, some of which were listed in section 3.2.3, were not originally provided by Canadian pharmacies ten years ago, and do receive funding from jurisdictional governments. Currently, there are a number of regulatory and/or legislative changes being implemented throughout the jurisdictions which will expand the scope of pharmacists’ services (Canadian Pharmacists Association, 2015).

Each jurisdiction has utilised a different approach to expanding the role of the pharmacist and the scope of pharmacy services. Some jurisdictions have taken a comprehensive approach, such as Alberta, which has implemented a broad scope of pharmacist practice as well as payment for these services. Other jurisdictions, such as Ontario, have implemented a selective scope and public payments for services, with funding aimed at individuals with chronic conditions and who consume multiple medications. In other cases, such as Manitoba, a broad scope of practice for pharmacists has been implemented but with limited remuneration from public sources (Canadian Pharmacists Association, 2016).
4 Continental Europe

This chapter presents information on six countries located in continental Europe: France, Spain, the Netherlands, Denmark, Norway and Sweden. The community pharmacy sector in these countries are compared with Australia in Chapter 6.

4.1 France

4.1.1 Health system context and expenditure

The French health care system features a single public payer (the French Government) and increasingly relies on tax-based revenue for financing health care. Universal and compulsory statutory health insurance (SHI) is provided to the resident population. There are various schemes available, use of which primarily depends on where people work; the schemes do not compete (Chevreul et al, 2015).

The majority of SHI is financed by employer and employee payroll taxes (64%); specific national income tax contributes 16% while taxes levied on tobacco and alcohol, the pharmaceutical industry, and VHI companies contribute 12%. State subsidies and transfers from other branches of social security contribute 2% and 6%, respectively (The Commonwealth Fund, 2016).

Lists of covered procedures, medicines, and medical devices are determined at the national level and apply to all regions of the country. Co-insurance rates are applied to all health services and medicines listed in the benefit package, and vary by:

- the type of care provided (inpatient, 20%; doctor visits, 30%; and dental, 30%);
- effectiveness of prescription medicines (highly effective medicines carry no co-insurance, while rates for all other medicines are 40%–100%, based on therapeutic value); and
- compliance with the recently implemented gatekeeping system (The Commonwealth Fund, 2016).

Most VHI complements SHI, covering mainly the co-payments for usual care, balance billing, and vision and dental care (minimally covered by SHI). VHI finances 13.8% of total health expenditure. People on low incomes are entitled to free or state-sponsored VHI, free vision care, and free dental care, with the total number of such beneficiaries estimated at around 10% of the population (The Commonwealth Fund, 2016).

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8 Balance billing is the practice of billing patients a fee above the one that is negotiated with, and reimbursed by the health authorities. This is the difference between what the patient’s health insurance chooses to reimburse and what the provider chooses to charge.
As shown in Table 4.1, total health expenditure constituted 11.1% of GDP in 2014, of which 78% was publicly financed (The Commonwealth Fund, 2016). Out-of-pocket payments from patients account for 7.5% of total health expenditure, well below the European Union (EU) average of 16.1% of total health expenditure (Chevreul et al, 2015).

Table 4.1: Health care system indicators, France

<table>
<thead>
<tr>
<th>Population, 2013</th>
<th>Total population (millions)</th>
<th>63.8</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Percentage of population &gt;65 years</td>
<td>17.7%</td>
</tr>
<tr>
<td>Expenditure, 2013</td>
<td>Percentage of GDP spent on health care</td>
<td>11.6%</td>
</tr>
<tr>
<td></td>
<td>Health care expenditure per capita</td>
<td>$4,361</td>
</tr>
<tr>
<td></td>
<td>Average annual growth rate of real health care expenditure per capita, 2009-2013</td>
<td>1.4%</td>
</tr>
<tr>
<td></td>
<td>Out-of-pocket health care expenditure per capita</td>
<td>$277</td>
</tr>
<tr>
<td></td>
<td>Hospital expenditure per capita</td>
<td>$1,600</td>
</tr>
<tr>
<td></td>
<td>Expenditure on pharmaceuticals per capita</td>
<td>$622</td>
</tr>
</tbody>
</table>

Note: for consistency throughout the report, amounts in this table are expressed in USD.

In 2015, sales of pharmacy medicines in France accounted for slightly more than €28 billion, of which almost €25.6 billion of which were reimbursable medicines. The support rate of reimbursable medicines by the state health insurance is estimated at 80.3% for 2015 at a cost of about €20.5 billion for the central government (Les Entreprises du Médicament en France (LEEM), 2016).

4.1.2 Remuneration and regulation

As of January 2015, pharmacists are paid a fixed sum per pack of medicine dispensed, in exchange for a reduction in the price-based margins. The fixed dispensing fees are €1.02 per item for reimbursed medicines, and €0.51 for prescriptions which have five or more medicines. The remuneration margins for pharmacies are calculated with reference to the manufacturer price of medicines (LEEM, 2016):

- Up to €22.90: 25.5% of the retail price.
- Between €22.91 and €150.00: 8.5% of the retail price.
- Over €150.00: 6.0% of the retail price.

The non-reimbursable co-payment for prescription medicines is €0.50. Exemptions apply to individuals with any of 32 specified chronic illnesses (13% of the population, with exemption limited to the treatments for those conditions); individuals who benefit from either complete state-sponsored medical coverage (3% of the population) or means-tested vouchers for complementary health insurance (6% of the population); and individuals receiving invalidity and work-injury benefits. Children and people with low incomes are exempt from paying non-reimbursable co-payments (The Commonwealth Fund, 2016).

The “Pharmaceutical Record” (“Dossier Pharmaceutique”) is a professional tool that allows community pharmacists to look after their patients’ health and the correct use of medicines. Information on medicines dispensed to a patient in any pharmacy connected to the system
is stored for a defined period of time. After receiving patient consent a pharmacist can consult the record during the consultation with a patient. This allows a pharmacist to identify potential medicine interactions and side-effects and advise best course of action to the patient. Almost all pharmacies (99.8%) in France are connected to this system (Pharmaceutical Group of the European Union, 2016).

France has strict regulations on pharmacy ownership and location. Ownership of pharmacies is restricted to pharmacists. Pharmacists can only own one pharmacy but can have direct or indirect participation (but not the majority stake) in a maximum of four other pharmacies, in addition to their own pharmacy. In terms of location, the establishment of new pharmacies must comply with certain distance and population criteria (Chave, 2014). As a result, there is little horizontal integration at the retail level.

The licensing of pharmacies is regulated by demographic criteria, with one pharmacy per 2,500 or 3,000 inhabitants according to the size of the locality (Perraudin et al, 2011). Until the 466 Decree was passed, pharmacists could be a partner in an unlimited number of community pharmacies. The number of pharmacies has been decreasing at a rate of approximately 0.3% per year since 2002 as a result of government attempts to reduce barriers to restructuring and mergers of pharmacies. However, the number of new pharmacies which can be opened is limited by the government (Chevreul et al, 2015; Le Moniteur des pharmacies, 2013).

In France, the preparation of infusions and injections for chemotherapy is only permitted in hospitals (Chevreul et al, 2015).

France encourages substitution of biosimilars for treatment-naïve patients. France’s 2014 Social Security and Finance Bill is the first example of legislation that explicitly permits automatic substitution of biosimilars at treatment initiation (Renwick et al, 2016). The ultimate prescribing decision is with the physician, and biosimilar prescriptions can be recorded to help to monitor safety and effectiveness. However, the interchanging of original drug and biosimilar, once treatment has been established, is not recommended. Biosimilars have an assigned improvement in medical benefit score of five (that is, no therapeutic improvement over existing treatments) and are subject to a compulsory minimum discounting of 10–20% of the reference medicine (Renwick et al, 2016).

4.1.3 Scope of services, settings and distribution

In response to increasing demand for health care, a health care reform law was adopted in 2009 (known as the “Hôpital, Patients, Santé, Territoires” law). Reforms include broadening the role of pharmacists in front-line health care, health care coordination, screening and therapeutic education (Bardet et al, 2015; Perraudin et al, 2011).

There are a number of services (in addition to dispensing) that are provided by community pharmacies in France. Pharmacists must provide counselling about appropriate use of medicines and can dispense emergency contraception to minors. This is covered by the health insurance system as a “prescription” by the pharmacist. Pharmacists also play an important role as educators for smoking cessation. Since 1999, pharmacists have been partners in efforts to increase the use of generic medicines: unless otherwise specified by the doctor, the pharmacist has the right to replace the original medicine with a generic. The profession has committed itself to attaining a substitution rate of 70% (Bourdon et al, 2008).
Since 2013, pharmacists have also been paid for consultations with patients with asthma, those treated with anticoagulants and renal insufficiency (€40/patient/year, which includes two consultations) (Chevreul et al, 2015).

An observational study of a random sample of French pharmacies was conducted to investigate the sociodemographic and clinical characteristics of patients who consulted a pharmacist directly rather than their GP for therapeutic advice about influenza-like illness and ear, nose and throat disorders. The study sample included 573 patients recruited across 133 pharmacies. Results showed that most symptoms improved significantly after three days and quality of life was enhanced. Over 85% of patients were satisfied with the advice they received (Danno et al, 2014).

Besides community pharmacies, other dispensaries are allowed to dispense prescription medicines to outpatients to guarantee medicines provision in remote areas. This is most commonly undertaken by dispensing doctors. Dispensing doctors can only dispense medicines if a community pharmacy does not exist in their vicinity, and must apply to their Regional Health Agency for permission. If they are approved, they can have a “home medicine depot” in order to dispense the medicines, and are also allowed to home-deliver the medicines if necessary. Doctors are also allowed to dispense non-authorised pharmaceuticals for those patients whose particular health state requires a treatment that has not been officially approved (after being approved for a temporary authorisation). The number of dispensing doctors has been declining and they do not play a major role in the retail sector (Kanavos et al, 2011). It has been recently estimated that there are about 150 dispensing doctors in France (Service-Public, 2013).

Table 4.2 shows the number of pharmacists and pharmacies per 100,000 population in France. Compared to the OECD average, France has higher number of both pharmacists and pharmacies.

<table>
<thead>
<tr>
<th>Per 100,000 population</th>
<th>France</th>
<th>OECD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of practising pharmacists (2013)</td>
<td>106.0</td>
<td>80.0</td>
</tr>
<tr>
<td>Number of pharmacies (2015)</td>
<td>34.0</td>
<td>25.1</td>
</tr>
</tbody>
</table>

Source: reproduced from OECD (2015)

The geographical distribution of pharmacies in France is relatively homogeneous because the licensing of pharmacies is regulated by demographic criteria, with one pharmacy per 2,500 or 3,000 inhabitants according to the size of the locality. In France, 35% of community pharmacies are located in regions of less than 5,000 inhabitants. In 2015, there were 21,591 registered community pharmacies in France, which is a decrease of 0.8% from 2014. There are approximately 2.47 pharmacists per pharmacy, which is an increase from the previous year of 0.35% (Perraudin et al, 2011; Conseil National de l’Ordre des Pharmaciens, 2016).

4.1.4 Wholesaler supply arrangements

The wholesaling sector in France is dominated by four firms (OCP, Alliance Healthcare, CERP network (Rouen, Bretagne-Atlantique, Rhin-Rhone Méditerranée) and Phoenix Pharma, which supply a network of nearly 200 sites across the country. In terms of turnover, 59% of
medicines are distributed by wholesalers, while 15% are sold directly to retail pharmacies and 26% to public and private hospitals by industry subsidiaries or contractors. Wholesalers are highly regulated (in a manner similar to CSOs in Australia) in terms of the range of medicines supplied, level of stock, delivery times as well as their profit margins. Wholesalers in France fill medicine orders for the 22,000 pharmacies within an average delivery time of 2.25 hours. Deliveries are made, on average, three times per day (Chevreul et al, 2015; Chambre Syndicale de la Répartition Pharmaceutique, 2016). There is very little vertical integration in the French supply chain.

Direct delivery to pharmacies from the pharmaceutical manufacturers (direct-to-pharmacy) distribution arrangements are increasingly being used. In France, the proportion of sales originating directly from the manufacturer is approximately 20%, with the rest being supplied by wholesalers. In France, direct delivery occurs particularly for high turnover products (Kanavos et al, 2011; Chambre Syndicale de la Répartition Pharmaceutique, 2016).

From January 2012, the regulated remuneration for wholesalers comprises two components: a 6.68% margin on the manufacturing price before taxes of between €0 and €450, plus a fixed fee of €0.30. Beyond €450, no additional remuneration is provided, and is capped at €30.06 plus the fixed fee.

4.1.5 Adoption of technology

France is currently implementing a high-level EHR project across the entire country, Le Dossier Médical Personnel. Approximately 0.8% of the population (551,000 patients) have an EHR, and an estimated 600 hospitals and 6,000 health professionals use them. Hospital-based and office-based professionals and patients have a unique electronic identifier. Patient authorisation is required for health professional access to and inclusion of information in the record. Patients are also able to access the information in their own records, either directly or through their GP (The Commonwealth Fund, 2016).

In 2012 a bill (Ordonnance n° 2012-1427) was passed which allows the sale of OTC medicines over the internet from January 2013 onwards. However, online sale of prescription medicines is not permitted. A website for the sale of medicines must be linked to a physical pharmacy, and a pharmacist must be responsible for it (Decaroli, 2016).

Ongoing national e-health programs relevant to community pharmacy in France include:

- pharmaceutical records: this allows health care professionals and patients to see their medicine history over the past 4 years and their vaccination history over the past 21 years, and also functions as a health monitoring app. In contrasts to the EHR which is opt-out based, this scheme is opt-in (Ordre National des Pharmaciens, 2015);
- e-prescriptions: in 2004 a law was introduced which allowed the electronic prescription of medicines (No. 2004-810 Article 34). Paperless e-prescriptions are possible through the prescribing doctor emailing the prescription to the patient. This can then be forwarded by the patient to a pharmacy, or printed out and taken to the pharmacy; and
- an online registry of Community Pharmacy establishments (Agence National de Securite du Medicament et des Produits de Sante, 2015).
Reforms, innovations and trials

Recent reforms, innovations and trials in France include increasing access to generic medicines, reducing package wastage and reducing low value care. Both patients and pharmacists have been given strong incentives to accept generic medicine substitution. Pharmacists receive financial incentives, and patients who refuse a generic substitute must pay the full price and claim reimbursement afterwards. This policy has allowed for rapid expansion of the generic medicine market, which in 2011 represented 24% of the reimbursable medicine market in value and 13% in volume. Furthermore, in 2013, a pay-for-performance scheme for pharmacists was initiated with an initial focus on generics. Pharmacists are eligible for an annual bonus of up to €3,000 depending on the share of generics delivered. In 2014, this premium got upgraded to up to €5,500, with a substitution objective of 85%. In 2015 the Government announced an additional €350m funding for the generics market (Chevreul et al, 2015).

Currently, almost all medicines are sold in fixed quantities in packs that are pre-packaged by the manufacturers. In an attempt to reduce wastage and thereby cost, from April 2014, a pilot initiative on unit dispensing started in 78 pharmacies. This involves pharmacists providing selected antibiotics and medicines by unit, rather than by pack (Chevreul et al, 2015). The pilot program will run for three years, and at its conclusion the pilot will be evaluated in terms of its effect on expenditure and the proper use of antibiotics.

A number of initiatives to reduce “low-value” care have been trialled, including:

- pay-for-performance to reduce use of benzodiazepines in elderly people;
- production of manuals of good practice in medicine consumption and most efficient therapeutic and diagnostic techniques;
- measures against supply disruptions of medicines with high therapeutic value. These are a set of rules to ensure the correct acquisition and availability of high impact medicines;
- elevating the importance of pharmacoeconomics in the price setting of medicines (Ministere des Affaires Sociales et de la Sante, 2016);
- clear advertising of the price of medicines which are on display to the public view in a community pharmacy (Le Service Public de la Diffusion du Droit, 2014);
- strengthening controls for the prescription of expensive statins and new anticoagulants; and
- encouraging the use of Avastin over Lucentis and other less costly biosimilar medicines (The Commonwealth Fund, 2016).

In 2015 the “Sunshine Act” was approved, which obligates pharmaceutical companies to publish all their remunerated deals with health care professionals in a specific transparency portal. The French government is also promoting the online sale of pharmaceuticals, mainly by lifting the ban on paid search engine listings. The Agence National de Securite du Medicament et des Produits de Sante (2016) has also released a set of publications on good practices in the manufacturing, distribution and dispensing of medicines.
## 4.2 Spain

### 4.2.1 Health system context and expenditure

The Spanish National Health System provides almost universal (99.5%) population coverage and guarantees a comprehensive benefits package to all citizens, which is stipulated by royal decree. Regions are free to supplement the common benefits package. Health care services are provided free of charge at the point of delivery with the exception of pharmaceuticals, which entail a basic 40% co-payment which can be increased on the basis of income (for people aged under 65, except those with chronic illnesses, who pay 10%). All hospital co-payment of medicines has been removed, and all medical care and surgery are free for citizens (García-Armesto et al, 2010; Gastelurrutia et al, 2005).

Private voluntary insurance schemes play a relatively minor, though increasingly relevant, role. Private voluntary insurance is independent from the public system and is complementary in nature. Schemes cover around 13% of the population, with wide regional variation (García-Armesto et al, 2010).

Health expenditure in Spain has followed the upwards international trend, reaching US$2,062 per capita and 9% of GDP in 2015; 71% of health expenditure is publicly financed, predominantly (94%) from taxation. Out-of-pocket expenditure, which covers mainly co-payments for prescriptions, adult dental care and optical products, has moved slightly downwards towards the current 24% (García-Armesto et al, 2010). Details on the health care system indicators for Spain are provided in Table 4.3.

<table>
<thead>
<tr>
<th>Table 4.3: Health care system indicators, Spain</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population</strong></td>
</tr>
<tr>
<td>Total population (millions) (2014)</td>
</tr>
<tr>
<td>Percentage of population 65+ years</td>
</tr>
<tr>
<td><strong>Expenditure</strong></td>
</tr>
<tr>
<td>Percentage of GDP spent on health care (2015)</td>
</tr>
<tr>
<td>Health care expenditure per capita (2015)</td>
</tr>
<tr>
<td>Average annual growth rate of real health care expenditure per capita, 2011-2015</td>
</tr>
<tr>
<td>Out-of-pocket health care expenditure per capita (2014)</td>
</tr>
<tr>
<td>Expenditure on pharmaceuticals per capita (2015)</td>
</tr>
</tbody>
</table>

Note: for consistency throughout the report, amounts in this table are expressed in USD.

The average growth rate of government expenditure on community pharmacy in the 2011-15 period has decreased by 4.7%. Government expenditure on prescriptions dispensed through pharmacies equates to 14% of total public health care expenditure (€9,534 million in 2015). The recent increase in community pharmacy public expenditure is mainly due to an increase in the number of prescriptions (an increase of 1.6%) and a small increase in the expenditure per prescription (0.3%) (Farmaindustria, 2015; Datosmacro, 2015).
4.2.2 Remuneration and regulation

The current system of payment for dispensing in Spanish community pharmacies is product-oriented through setting a margin that depends entirely on a percentage of the price of the medicine that is dispensed (Cobián Rodríguez et al, 2012). Spain has regressive margins both for wholesale and pharmacy remuneration. Prior to July 2010, two scales would apply to each of wholesale and pharmacy remuneration: for medicines with a manufacturer price of up to €91.63, there was a margin expressed as a percentage of the wholesale (7.6%) and pharmacy (27.9%) retail price respectively; and for higher priced medicines a fixed amount was added. In July 2010, the pharmacy margin scheme was changed, by adding two further scales (the first applying to medicines priced between €200 and €500, and the second applying to medicines priced more than €500) to which a fixed remuneration sum was added (€43.37 and €48.37 respectively). This measure was partly in reaction to the global financial crisis, in addition to price cuts for generics and discounts for higher-priced medicines (Kanavos et al, 2011).

To work as a community pharmacist, it is compulsory to register in a provincial pharmacists association, which are members of the National Pharmacists’ Association. All community pharmacies in Spain are privately owned, and only pharmacists can own a pharmacy. Moreover, a pharmacist can own only one pharmacy, although more than one pharmacist may jointly own one pharmacy. Pharmacy chain stores are therefore not allowed in Spain.

Preparation of infusions and injections for chemotherapy is only permitted in hospitals (Gastelurrutia et al, 2005).

The establishment of new pharmacies is controlled by state governments based on two criteria: population per pharmacy and distance from another existing pharmacy. The criteria for the opening of a new pharmacy include a minimum population of influence of 2,800-4,000 inhabitants and a distance between pharmacies of over 250 metres (García-Armesto et al, 2010). Access to new licences entails public tendering; once the pharmacist has won the licence for a specific location, however, it becomes a commodity and there is a market for them, though only another pharmacist can buy it (García-Armesto et al, 2010).

In 2013 the General Pharmaceutical Council of Spain formed a work group of best practices in community pharmacy. Their role was to elaborate specific best practices in the context of community pharmacy, such as pharmacotherapeutic monitoring services, pharmacovigilance, and indication services, as well as a general best practice guide (Mora; Ajado et al, 2016).

Additional regulation which promotes high standards of delivery and accountability is the Royal Decree 782/2013 on the distribution of human use medicines. This royal decree’s purpose is to regulate activities related to the distribution and brokering of medicinal products for human use. It sets the various requirements that distributors and storage companies of medicines (of human use) must comply with. This decree sets the minimum operation requirements and defines the best practices in the sector.

A specific law that requires high levels of quality, similar to the International Organization for Standardisation standards, regulates compounding. Different state governments have announced inspections to assess its implementation. The Good compounding practices and quality control in pharmaceutical compounding regulations were introduced in 2003, and restrict the types of medicines which can be compounded in a community pharmacy. This
list is updated regularly, most recently in 2015. Compounded medicines are generally regarded as the “last resource” and its use is almost exclusively authorised when all other therapeutic alternative have failed, even during a medicine shortage situation (Gastelurrutia et al, 2005; Ramon and Lachen, 2008).

4.2.3 Scope of services, settings and distribution

In addition to dispensing, community pharmacies provide the following range of services:

- medicine-oriented services such as pharmaceutical indications, medicine agreement, personal dosing systems, observational treatments, magistrates formulation, vaccinations, medicine therapy reviews, assessing adherence to treatments, pharmaceutical consultations, remote pharmacy reviews, pharmacovigilance and medicine review follow-up; and

- public health services such as anthropometric measurements, blood pressure and blood glucose testing (to test for “silent illnesses” such as diabetes and hypertension), health promotion, health education, health information, nutritional advice, and syringe exchange programs (Gastelurrutia et al, 2005).

The pharmacy margin includes remuneration for all these services, except compounding, which is paid on a fee-for-service basis. Most of these services are freely provided, except compounding (fee-for-service), administration of methadone, and directly observed treatments\(^9\). Community pharmacies providing methadone services to patients are paid €45 per month per patient (Gastelurrutia et al, 2005).

In Spain, community pharmacies are the only health establishments allowed to dispense prescription and OTC medicines. Hospitals are not allowed to dispense prescribed medicines. However there are other types of “prescriptions” called dispensing orders:

- **Hospital dispensing order for non-admitted patients**: these are medical prescriptions that doctors working in hospitals can prescribe to patients who do not require a bed. They require surveillance, supervision and control, and must be dispensed from the hospital pharmacy services. The patient collects the medicine from the hospital, and can take it home. In Spanish, these medicines are termed “medicación hospitalaria de dispensación ambulatoria”.

- **Dispensing order**: these are used by nurses, in other health centres and primary care centres, which allow the dispensing of medicines (with or without prescription) and other health products by pharmacies (Centro de Estudios para el Fomento de la Investigación, 2015).

A Spanish study investigated the efficacy of a smoking cessation campaign carried out at a Spanish pharmacy. The aim of the study was to evaluate the effects of pharmaceutical care on patients who decide to try to stop smoking. This investigation found that advertising of a smoking cessation program in a pharmacy increases the number of patients who use the pharmacy’s smoking cessation services and pharmaceutical care, and provides an effective means of achieving smoking cessation (Armero et al, 2015).

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\(^9\) Whereby the pharmacist directly observes the patient taking the medicine to ensure adherence and compliance.
In Spain, the numbers of health professionals per 100,000 people have increased over time. The numbers of pharmacists has increased at a faster rate than the average results for other health professionals. As at December 2015, there were 69,774 pharmacists in Spain, of which 69.4% worked in community pharmacies. There are an average of 2.2 pharmacists per pharmacy (Consejo General de Colegios Oficiales de Farmacéuticos, 2015).

Due to the geographic and population standards for the establishment of new pharmacies, there is an average of 1 pharmacy per 2,125 residents in Spain. This is one of the lowest ratios in the EU, but still well above the OECD average in 2015 (Gastelurrutia et al, 2005) – see Table 4.4.

<table>
<thead>
<tr>
<th>Per 100,000 population</th>
<th>Spain</th>
<th>OECD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of practising pharmacists (2015)</td>
<td>150.2</td>
<td>80.0</td>
</tr>
<tr>
<td>Number of pharmacies (2015)</td>
<td>47.2</td>
<td>25.1</td>
</tr>
</tbody>
</table>

Source: reproduced from OECD (2015)

At December 2015, there was 21,937 community pharmacies in Spain, with 35.8% located in a capital town, compared to 64.2% in municipalities outside of capital towns. This compares to the Spanish population distribution of 31.7% in capital cities, and 68.3% outside of capital cities. Approximately 99% of the population have access to a community pharmacy in their territory. The number of pharmacies is growing year-on-year, with most of this growth outside of capital cities. There was a net increase of 83 pharmacies in 2015, of which 92.5% were outside of capital cities. Of the pharmacies which closed in 2015, 69.6% were in capital cities (Consejo General de Colegios Oficiales de Farmacéuticos, 2015).

According to Lulch and Kanavos (2010), Spain has two general structures for pharmacy opening hours which vary by province. The first is for a pharmacy to be open 44.5 hours a week, Monday to Saturday. The second is where a pharmacy is open 24 hours a day, 365 days a year; this framework is mainly used in urban areas. In 2008, 15% of all pharmacies in Spain operated under the second structure.

4.2.4 Wholesaler supply arrangements

As mentioned in Section 4.2.2, Spain has regressive margins both for wholesale and pharmacy remuneration, whereby the percentage margin decreases as the price to which it refers increases. Wholesale margins are 7.6% for medicines with a manufacturer price of up to €91.63, and a flat rate of €7.54 for medicines priced above this. Only commercial discounts may be applied between wholesaler and pharmacy (Kanavos et al, 2011).

Community pharmacies receive most of their medicines from wholesalers (95%), although a small amount (5%) are sourced straight from the manufacturer. The five largest wholesalers in Spain are Cofares (the largest), followed by Bidafarma (a recent fusion of Cecofar, Cofarcir and Farmanova in 2016), Alliance Healthcare, Hefame, and Fedefarma. Regional wholesalers (55 companies) command the largest part of the market share at 58% (in comparison with other EU Member States where national wholesalers are the minority) yet occupy the position of key distributors. Most of these regional wholesalers are owned by pharmacist-owned co-operatives who control 75% of the market; only one wholesaler is
owned by a foreign entity (Kanavos et al, 2011; Federación de Distribuidores Farmacéuticos, 2013).

There are several restrictions in operation in the distribution channel, and as such there is no vertical or horizontal integration at the retail level – all pharmacies are owned by pharmacists and no pharmacies are part of a chain. However, there are buying groups (approximately 25 groups, each with 50 members) to help with purchase prices. At the wholesale level, concentration of ownership has increased in recent years, such as the merger of Cecofar and Farmanova which resulted in the company Bidafarma.

Further, the market is very fragmented (expressed by the dominance of regional wholesalers), which partly reflects the organisational structure of the country with emphasis on the autonomous provinces. The number of pharmacies per inhabitant has increased significantly over the past decade, which means existing pharmacies may be having issues with sufficient medicine stocks (Kanavos et al, 2011). However, as wholesalers enjoy markedly protective regulation that eliminates competition at the level of distribution the number of wholesalers has seen hardly any changes (despite the European single market integration process), while sales have increased annually (García-Armesto et al, 2010).

Historically, attempts were made by some Spanish pharmaceutical companies to create their own wholesaling company. This “shared” wholesaler would distribute some medicines from the pharmaceutical companies, and the remaining medicines would be distributed through other wholesalers. However, the initiative did not succeed, as the economies of scale of the shared wholesaler were not adequate. In addition, due to the strong relationships between wholesalers and pharmacies in Spain, it proved to be difficult to distribute medicines to a pharmacy without going through a pharmacy’s preferred wholesaler.

4.2.5 Adoption of technology

In Spain there have been various technological advances related to community pharmacies in recent years. Some key examples are detailed below:

- An app for the management of professional services of community pharmacists enables them to visualise and monitor the health problems of their patients (Farmacéuticos Comunitarios, 2016).
- In November 2013 the Ministry of Health, Social Services and Equality released Real Decreto 870/2013, which allowed pharmacies to sell OTC medicines through the internet. However, most pharmacies are not implementing this feature, as only 190 pharmacies in Spain sell products over the internet.
- The Ministry of Health, Social Services and Equality, in collaboration with red.es and the National Institute of Healthcare Management has developed a project which aims to compile all the relevant aspects of the Spanish Health records in one single database: Historia Clínica Digital del Sistema Nacional de Salud (Ministerio de Sanidad, Servicios Sociales e Igualdad, 2016).
- The Spanish Agency of Medicines and Medicinal Products (AEMPS) has created aempsCIMA. This is an application which aims to provide Spanish citizens and medical professionals with a complete list of information on medicines in order to guarantee their correct usage. There have been other similar initiatives in Spain before, most notably Bot PLUS 2.0 App, made by the General Counsel of Pharmaceutical Associations of Spain (AEMPS, 2014).
In recent years a number of community pharmacies have begun to experiment with remote dispensing robots. These machines are placed in a community pharmacy and dispense the required medicines directly to the pharmacist with the touch of a button, with no need for the pharmacist to search for the products (Automatizacion Farmaceutica, S.L, 2016). An analysis of these types of systems showed that, compared to a semi-automated system, the integrated robotics system appears to be a safer, more versatile and more efficient system (Ramos and Ferro, 2013).

- 24-hour vending machines for non-prescription products (Expofarm, 2016).
- e-prescriptions are widely used throughout Spain. The percentage of prescriptions dispensed electronically in the at the end of 2015 was over 80% (Ministerio de Sanidad, Servicios Sociales e Igualdad 2016b). This is a significant increase from 2010 levels (Gilabert-Perramon, 2010). E-prescriptions do not require a paper prescription, as the prescription information is stored in an individual’s healthcare card, which must be presented at the pharmacy in order to receive the prescription.

Progress in the implementation of e-health records, which allow for integrated care (primary care, specialised ambulatory care and tests), has been quick: by 2009 it was fully implemented in most of the territories, with only five regions finishing the roll-out (García-Armesto et al, 2010). Since 2009, the e-health record has been fully rolled out in all regions.

### 4.2.6 Reforms, innovations and trials

Recent policies have included measures for the rationalisation of pharmaceutical expenditure, such as the introduction of reference prices and aggressive generic use policies. These policies included public campaigns, professional incentives linked to generic prescriptions and pharmacists’ obligation to substitute publicly funded prescriptions with a generic equivalent. However, some incentives towards the use of generics have been abolished, namely the obligation of a pharmacist to dispense the generic version of a medicine where available (García-Armesto et al, 2010).

In 2015, the Collaboration Protocol between the General State Administration was signed between the Finance and Public Administration Ministry, the Health, Social Services and Equality Ministry and FARMAINDUSTRIA (National Spanish Association of Pharmaceutical Companies). This Protocol affects the evolution of public expenditure on “original non-generic medicines” between December 1, 2015 and November 30, 2016, but may be extended by up to three additional years. It is a collection of actions agreed between the three parties which are intended to improve the pharmaceutical environment in Spain. With this protocol there will be continuous monitoring of public pharmaceutical expenditure on non-generic original medicines, linking its growth in Spain to GDP growth, optimising patient access to innovative medicines, and addressing key challenges with the pharmaceutical industry.

In 2015, the law on guarantees and rational use of medicines and health products passed (Real Decreto Legislativo 1/2015). This law regulates most aspects of medicinal products in the Spanish market, including the regulation of all the agents involved in the market as well as their roles and responsibilities with one another. Some of the most important aspects cover supply guarantees and dispensing, guarantees on public health, traceability guarantees, authorisation of a laboratory, guarantees for the correct fabrication of medicines...
and raw materials, fabrication by third parties, guarantees for the accessibility and availability of medicines, administrative control of distribution, and operating requirements.

However, in the Law on State Budget for 2016, some important amendments to the law were introduced (Ley de Presupuestos Generales del Estado para 2016):

- Brand discrimination against prescriptions by active ingredient was eliminated.
- Pharmacists must now use information from the medicine verification system to check prices for patients who are not covered under the Spanish health system – these prices are typically higher.
- Removal of the 10% discount limit for early payment or volume of purchase, which are given by laboratories or distributors to community pharmacies for publicly-financed medicines.
- Hospital medicine co-payments were removed.

Spain has trialled a structured serviced medicine dispensing process described by Abaurre et al (2015). This review focused on the need to incorporate three measurements into prescribing services: personalised medicine information, problems associated with medicines and the negative results associated with medicine. Pharmacists noted that the tool was easy to apply, and focused on detecting deficiencies in the information provided to patients about their medicines, including problems associated with medicines and negative results associated with medicines. From a total 870 medicines dispensed, 49% of these cited a lack of personalised information, 10% reported problems associated with medicines and 8% suspected negative results associated with medicines. In a more recent study, Abaurre et al (2016) note that protocolised or structured dispensing services are significantly more effective than traditional dispensing with respect to improving medicine knowledge (odds ratio: 2.39; 95% confidence interval: [1.373-1.162]).

Recently, the Spanish Society of Community Pharmacy proposed a change in the current payment system (product-oriented) for dispensing in community pharmacies. The proposal was to change to a mixed payment system, based on a professional fee complemented by a variable logistics charge and a feasibility charge applicable to pharmacies with a reduced number of prescriptions (Cobain Rodriguez et al, 2012).

## 4.3 The Netherlands

### 4.3.1 Health system context and expenditure

In the Netherlands, SHI which is purchased from private insurers is mandatory for all Dutch residents (and non-residents who pay Dutch income tax), with the exception of active members of the armed forces and conscientious objectors. SHI is financed under the Health Insurance Act 2006, through a nationally defined, income-related contribution, a government grant (for people below age 18), and community-rated premiums set by each insurer. Health insurers are legally required to provide a standard benefits package defined by the government that includes, among other things, care provided by GPs, hospitals, and specialists; dental care and physiotherapy (up to age 18); prescription medicines; and basic ambulatory and mental health care. All applicants must be accepted by insurers and enrolees can change their insurer annually (The Commonwealth Fund, 2016).
Contributions are collected centrally and issued among insurers in accordance with a risk-adjusted capitation formula that considers age, gender, labour force status, region, and health risk (based mostly on past medicine and hospital utilisation). The insurance market is dominated by the four largest insurer conglomerates – VGZ-Groep, TRIAS-Groep, CZ/OZ and Achmea-Groep – which account for 90% of all enrollees. Currently, there is a ban on the distribution of profits to shareholders (The Commonwealth Fund, 2016).

In addition to statutory coverage, most of the population (84%) purchases a mixture of complementary voluntary insurance, on the most part, from the same provider as their SHI. Premiums for voluntary insurance are not regulated; insurers are allowed to screen applicants based on risk factors and offer both statutory and voluntary benefits. Benefits include dental care, alternative medicine, physiotherapy, spectacles and lenses, contraceptives, and the full cost of co-payments for medicines. People with voluntary coverage do not receive faster access to any type of care, nor do they have increased choice of specialist or hospital. In 2013, voluntary insurance accounted for 7.6% of total health expenditure. The government also provides subsidies, subject to asset testing and income ceilings, to cover community-rated premiums for low-income families. Approximately 5.4 million people receive allowances, set on a sliding scale, depending on income (The Commonwealth Fund, 2016).

As of 2015, every insured person over age 18 must pay an annual deductible of €375 for health care costs, including costs of hospital admission and prescription medicines but excluding some services, such as GP visits. The intention of excluding GP services is to incentivise the use of GPs in lieu of emergency departments and reduce the number of unnecessary emergency department presentations. Out-of-pocket expenses represented 13.8% (45% through deductible) of health care expenditure in 2013. In addition, the government provides subsidies to cover community-rated premiums for low-income families. Approximately 5.4 million people receive allowances set on a sliding scale (Sagan and Richardson, 2015; The Commonwealth Fund, 2016).

In 2015, the Netherlands spent 11.1% of its GDP on health care, principally (72%) financed through the compulsory health insurance contributions from citizens, with an additional 13% from general taxation (The Commonwealth Fund, 2016) – see Table 4.5.

Table 4.5: Health care system indicators, the Netherlands

<table>
<thead>
<tr>
<th></th>
<th>Netherlands</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population, 2013</td>
<td>16.8</td>
</tr>
<tr>
<td>Total population (millions)</td>
<td></td>
</tr>
<tr>
<td>Percentage of population &gt;65 years</td>
<td>16.8%</td>
</tr>
<tr>
<td>Expenditure, 2013</td>
<td></td>
</tr>
<tr>
<td>Percentage of GDP spent on health care</td>
<td>11.1%</td>
</tr>
<tr>
<td>Health care expenditure per capita</td>
<td>$5,131</td>
</tr>
<tr>
<td>Average annual growth rate of real health care expenditure per capita, 2009-2013</td>
<td>1.7%</td>
</tr>
<tr>
<td>Out-of-pocket health care expenditure per capita</td>
<td>$270</td>
</tr>
<tr>
<td>Hospital expenditure per capita</td>
<td>$1,849</td>
</tr>
<tr>
<td>Expenditure on pharmaceuticals per capita</td>
<td>$397</td>
</tr>
</tbody>
</table>


Note: for consistency throughout the report, amounts in this table are expressed in USD.
In 2013, the average community pharmacy received fee revenues of €627,000 for the dispensing of prescription and non-prescription medicines included in the statutorily insured medicine package. In 2013, there was a sharp decline in expenditure on medicines for the second year in a row. Community pharmacies in the Netherlands dispensed €4,088 million worth of medicines in the statutorily insured medicine package. This meant that the level of expenditure was €310 million lower than in 2012 and €912 million lower than in 2011. Prior to that from 2008 to 2011 medicine expenditure increased at an average annual rate of 2%, with even steeper increases of 6% to 8% before that period. There has been a constant fall in the share of total health care expenditure that is spent on pharmaceuticals since 2009 (10.0%) to 7.6% in 2014 (Foundation of Pharmaceutical Statistics, 2014; OECD, 2016b).

4.3.2 Remuneration and regulation

SFK bases expenditure on pharmaceutical care on invoices submitted to health care insurers by pharmacies. With the introduction of deregulated prices on 1 January 2012, health care insurers and pharmacists now have to agree the reimbursement for pharmaceutical care between them. The amounts paid to pharmacists by insurers in accordance with contractual agreements may differ from the cost of medicines specified in the invoices submitted to health care insurers by the pharmacies. SFK is not privy to these agreements (SFK 2014).

From January 2012, pharmacy remuneration arrangements experienced two important developments. Firstly, there was a distinction made between the costs of medicines and the professional service related activities provided by pharmacists, such as the provision of medicines information and checking the appropriateness of prescriptions. The Dutch Health Authority defined a number of care-related services provided by pharmacists that may be subject to reimbursement. The second important development was that the prices of all pharmacy professional services delivered are to be negotiated with health insurers (Kroneman et al, 2016).

There are two key remuneration models for the provision of medicines to patients. Most health insurers will nominate a specific brand of a medicine with the same active substance (‘preferred medicine policy’), which is generally the cheapest available. The preferred medicine of an insurer can change every six to twelve months. Pharmacists are obliged to provide only the nominated preferred brand to the insurance holders of a specific health insurer. The other option is a ‘preferred price policy’ whereby the insurer sets a maximum reimbursed price for a medicine. While the choice of the brand supplied is left to the pharmacist, the price difference cannot be recouped from patients. However, if the pharmacist can purchase the medicine at a cheaper price, they can keep the profits (Kroneman et al, 2016).

The pharmacy system in the Netherlands is deregulated. There are no regulations on the establishment of new pharmacies and all natural and legal bodies are allowed to own one or more pharmacies (multiple ownership). There have never been statutory or demographic restrictions on the establishment of pharmacies in the Netherlands however the Royal Dutch Pharmaceutical Society has previously attempted to apply its own policies. Since January 1998, restrictions on the establishment of pharmacies are forbidden by law. There are no state licenses required to own a pharmacy. However, private contracts with health insurers can be implemented to ensure the profitability of a pharmacy. Further, since 1996 there have been no regulations on the minimum amount and types of pharmaceuticals that a pharmacy must have in stock (Vogler et al, 2012).
The supply of prescription-only pharmaceuticals is exclusively reserved to pharmacists and dispensing GPs (in some rural areas). OTC pharmaceuticals are available both at pharmacies and chemists. Since 2007, this is regulated by a new law on medical supplies and medicine distribution, the *Medicines Act* (Geneesmiddelenwet). The Health Care Inspectorate enforces the proper distribution of pharmaceuticals according to this Act. Manufacturers, GPs and community pharmacists are jointly responsible to provide users with independent information on pharmaceuticals as published by the Farmacotherapeutisch Kompas (for pharmacotherapeutic guidelines) and Geneesmiddelenbulletin (for pharmaceuticals in general).

All pharmacists are obliged to undertake a minimum of 200 training points (one point for each hour of continuous training attended) every five years. In 2014, the National Health Care Institute was established to accelerate the process of quality improvement and evidence-based health care practice. The quality of care provided by individual health care workers, including pharmacists, is regulated through the *Individual Health Care Professions Act 1993* (BIG). Initial BIG registration and five-yearly re-registration is obligatory for individual providers. BIG stipulates that professionals should provide “responsible care”, and identifies “reserved operations” which can only be performed by a recognised professional (Vogler et al, 2012; The Commonwealth Fund, 2016; Kroneman et al, 2016).

4.3.3 Scope of services, settings and distribution

In 2015, 13 different professional pharmacy care services were defined, of which seven are covered by the *Health Insurance Act 2006*:

- care related to the delivery of a first-time prescription including a review of the appropriateness of the prescription, side effects, dosage and administration instructions and potential to interact with other medicines used by the patient;
- care related to the delivery of a prescribed medicine (repeat prescription), including a check on appropriateness, correct use and side effects experienced by the patient;
- instructions for the use of a device needed to take a medicine (such as an inhaler);
- a periodic evaluation of the medicines used by patients with a chronic disease;
- pharmaceutical counselling (including a medicine review) in case of a hospital admission;
- pharmaceutical counselling in case of a hospital discharge; and
- pharmaceutical counselling in the case of day care or outpatient hospital visits (Kroneman et al, 2016).

Insurers and pharmacists negotiate on volume and price for the provision of these primary services to ensure sufficient pharmaceutical care can be delivered to a given area. Other (non-insured) professional services include advice for travellers, advice on the use of self-care medicines, group counselling of patients with a specific disease or using a specific medicine, and services between pharmacists. The availability and price of these non-insured secondary services is negotiated with health insurers but this is not obligatory (Kroneman et al, 2016).

An examination of the effect of medicine reviews on blood pressure and cholesterol of elderly patients was conducted in ten Dutch community pharmacies. Community pharmacists visited the patient at home, interviewed the patient about their medicine use...
and proposed a pharmaceutical care plan based on information from both the patient medication and clinical records, and the data from the patient interview. Blood pressure was measured at home for both intervention and control patients. In addition, patients were offered additional laboratory measurements of cholesterol. This study showed that home medication review for elderly home dwelling patients has effects on clinical outcomes (Kwint et al, 2012).

At the end of 2013 there were 1,974 community pharmacies in the Netherlands: seven fewer than the year before. The opening of 29 new pharmacies was outweighed by the closure of 36 pharmacies. It is notable that more than the half of the pharmacies that closed had opened since 2000 (Foundation of Pharmaceutical Statistics, 2014). Most public pharmacies are owned by independent operators, with around 45% being part of a chain of pharmacies. Many of these chains are owned by pharmaceutical wholesalers (Kroneman et al, 2016).

Community pharmacists are evenly spread across the Netherlands, given the relatively small size of the country. Of the 418 Dutch municipalities 44 did not have a pharmacy in 2011, compared to 55 in 2008. In the absence of pharmacists in some rural areas, dispensing GPs can provide medicines directly to patients. Dispensing doctors are available in areas where the distance to the closest pharmacy is more than 4.5 kilometres. In 2014, there were 394 GP dispensing practices (Kroneman et al, 2016; Vogler et al, 2012).

The increase in the pharmacy workforce in the Netherlands has kept pace with the increase of the population. Currently, the majority of pharmacists are male, however this is likely to change over time, as a growing number of pharmacy students are female (Kroneman et al, 2016). The supply of pharmacists per 100,000 population in the Netherlands is significantly below the number in the surrounding countries, as well as the average in the OECD (Kroneman et al, 2016) – see Table 4.6.

**Table 4.6: Number of pharmacies and pharmacists, the Netherlands**

<table>
<thead>
<tr>
<th>Per 100,000 population</th>
<th>The Netherlands</th>
<th>OECD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of practising pharmacists (2013)</td>
<td>21.0</td>
<td>80.0</td>
</tr>
<tr>
<td>Number of pharmacies (2015)</td>
<td>11.7</td>
<td>25.1</td>
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</table>


There are three types of pharmacy in the Netherlands: public pharmacies, hospital pharmacies and dispensing general practices. Most pharmacies are owned by independent entrepreneurs. Around 45% are part of a chain of pharmacies. Many of these chains are owned by the pharmaceutical wholesalers (European Observatory on health Systems and Policies, 2016; Kroneman et al, 2016).

In 2014, there were nearly 1,980 public pharmacies, of which 79 were located in a hospital but served outpatients. These hospital-based outpatient pharmacies are a new development in the past decade. Most public pharmacies are owned by independent entrepreneurs. Hospital pharmacists may be allowed, under specific conditions, for specific patients and/or specific products, to dispense to out-patients (Kreonman et al, 2016; Kanavos et al, 2011).

Recently, internet pharmacies have been increasing in presence. These are defined as “the long distance purchase of Prescription-Only-Medicines from Internet sources outside of the network of actual pharmacies”. There are currently 10 of these companies. These are
pharmacies without physical locations that deliver nationally, via couriers, directly to the homes of their clients. However, these internet pharmacies must be attached to an actual pharmacy (Kanavos et al, 2011; Kroneman et al, 2016).

4.3.4 Wholesaler supply arrangements

Wholesale margins are not set by law in the Netherlands. Since manufacturers pay the distributors, in practice their margin is already included in the ex-factory price. According to the Royal Dutch Pharmaceutical Association of Distributors in 2004, the discount on wholesale selling prices was an average of 12%, which was equally shared by pharmacies and wholesalers (Garattini et al, 2008).

There are five full line wholesalers (which are also members of the wholesale association BgPharma) which have a combined market share of more than 90%. Three of the full line wholesalers are owned by foreign companies. On average wholesalers have one or two distribution centres in the Netherlands (Vogler et al, 2012).

Direct delivery to pharmacy from the pharmaceutical manufacturers (direct-to-pharmacy) distribution arrangements are increasingly being used. In the Netherlands, the proportion of sales originating directly from the manufacturer is over 10% (Kanavos et al, 2011).

4.3.5 Adoption of technology

All Dutch patients have a unique identification number (the “burgerservicenummer”). However, electronic records for the most part are not nationally standardised or interoperable between domains of care. Authorities are working to establish a central health information technology network to enable providers to exchange information. At present, all hospitals have an EHR (The Commonwealth Fund, 2016).

Most GPs in the Netherlands register their prescriptions electronically, and can receive lab results electronically (The Commonwealth Fund, 2016). However, some still print it out and provide a paper version to the patient, or fax it to the pharmacy (Tan, 2009). In 2008, Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie (the Dutch professional and trade association for pharmacists) estimated that 50-80% of all prescriptions are e-prescriptions Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie, (2008).

A study by Kooy et al (2013) evaluated the effectiveness of counselling alongside an electronic reminder device in community pharmacies in the Netherlands to improve adherence to statin treatment in typically non-adherent patients. Use of the electronic reminder device was found to be not significantly higher than the control group.

4.3.6 Reforms, innovations and trials

The Netherlands operates under a deregulated community pharmacy market. Vogler et al (2014) reported that this deregulation has resulted in rapid development of new pharmacies and dispensaries of over the counter medicines, with a select few wholesalers gaining market dominance. The authors noted that in some deregulated countries, pharmacists can experience an increased workload, with little change (if any) to the price of medicines.
Rising cost of medicines and the need for cost containment has been a focus of public debate in the Netherlands. Measures used to control costs have relied primarily on market forces while regulating competition and improving efficiency of care. In addition, implementation of reforms to provider payments have shifted from budget-oriented reimbursement to a performance-and outcome-driven system (The Commonwealth Fund, 2016).

Expenditure growth on pharmaceuticals in the Netherlands has fallen significantly, to 1.8% in 2014. Between 2000 and 2009, average annual growth in real per capita pharmaceutical expenditure was 3.4%. Average prices of pharmaceuticals have fallen as a result of a range of measures including caps on reimbursement of generics, and negotiation of reimbursement for expensive medicines being left to the hospital and insurer. Other measures include the more than doubling of the annual deductible for pharmaceuticals, which contributes to the majority of out-of-pocket patient expenses, from €170 to €375. This has led to concern that more people will abstain from or postpone needed medical care (The Commonwealth Fund, 2016; OECD, 2014b).

Since 1 July 2005 a number of health care insurers have been making use of the so-called ‘preferential pricing policy’. This allows health care insurers to designate specific medicines within a group of medicines with the same active ingredient and mode of administration that are eligible for reimbursement. The preferred medicine is usually the lowest priced generic within the same therapeutic class. Patients who choose a non-preferred medicine are only reimbursed up to the price of the preferred medicine. In parallel with this reform, health care insurers started to issue tenders for contracts to supply several high-volume drugs. The result of these reforms were that list prices of the ten highest-volume generics fell by between 76% and 93%, which generated savings of €348 million per year (Schut et al, 2013).

Over 2007 to 2009, expenditure on multisource medicines decreased by more than 30%, despite an increase in volume of about 12%. In 2009, the preferred medicines policy was extended to include more generic drugs, and was also adopted by more health care insurers. Combined with an additional reform to reduce the scope of the basic benefits package, total expenditure on outpatient prescription medicines covered by basic health insurance declined by 5% (Schut et al, 2013).

Within the Netherlands, the Dutch Medicines Evaluation Board recently supported substitution of biosimilars at the pharmacy level for treatment-naïve patients (Renwick et al, 2016). Under this framework, prescribing physicians retain the right to request no substitution and must be notified if a substitution is made (University of South Australia, 2016). Close monitoring of patients substituted on biosimilars is required. However, interchanging an original biologic medicine and biosimilar during treatment is not recommended if the patient is responding well to treatment. Biosimilar pricing is dictated by a fixed reference price system: the price is set at or below the average price of biological products in the same cluster (Renwick et al, 2016).

### 4.4 Denmark

#### 4.4.1 Health system context and expenditure

Universal access to health care is the underlying principle of Denmark’s Health Law, as set out in the *Danish Health Care Act (Sundhedsloven)* 2007. Other core principles include: high
quality health care; easy and equal access to care; service integration; choice; transparency; access to information; and short waiting times for care. Publicly financed health care covers all primary, specialist, hospital, and preventive care, as well as mental health and long-term care services. Dental services are fully covered for children under age 18. A national health tax, set at 8% of taxable income, finances the majority of health care (The Commonwealth Fund, 2016).

While the national government sets the regulatory framework for health services, delivery is the responsibility of regions and municipalities. The regions own, manage, and finance hospitals and the majority of services delivered by GPs, office-based specialists, physiotherapists, dentists, and pharmacists. There is no defined benefits package, however there are very few restrictions for treatments that are evidence-based and clinically proven (The Commonwealth Fund, 2016).

There are two types of public insurance coverage. Under the “Group 1” coverage option, which covers 98% of the population, there is no out-of-pocket payment for medical services, however people are required to register with an available local GP. “Group 2” coverage allows for free choice of GP and access to specialists without referral, however, a co-payment is required. Under both groups, access to hospitals requires referral (The Commonwealth Fund, 2016).

Voluntary insurance, purchased on an individual basis, covers statutory co-payments—mainly for pharmaceuticals and dental care—and services not fully covered by the state (for example, physiotherapy). Some 2.2 million Danes have such coverage, which is provided almost exclusively by the not-for-profit organisation Danmark (The Commonwealth Fund, 2016). Patients with outpatient medicine expenses of more than 3,045 DKR – about $394 USD – per year are reimbursed at the highest rate of 85%. Chronically ill people with high medicine usage and costs can apply for full reimbursement above an annual out-of-pocket ceiling of 3,775 DKR ($498 USD) (The Commonwealth Fund, 2016).

Health expenditure represented 11.1% of GDP in 2013 (see Table 4.7). More than 80% of health care expenditure is financed by the state through a combination of block grants and activity-based financing. Out-of-pocket payments represented 12.4% of total health expenditures in 2013, covering mostly outpatient medicines, corrective lenses, hearing aids, and doctor and dental care. The importance of out-of-pocket payments differs markedly by service, playing a major role in financing medicines, dental services and glasses, while playing only a minor role for other services (The Commonwealth Fund, 2016; Olejaz et al, 2012).
Table 4.7: Health care system indicators, Denmark

<table>
<thead>
<tr>
<th></th>
<th>Denmark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population, 2013</td>
<td></td>
</tr>
<tr>
<td>Total population (millions)</td>
<td>5.6</td>
</tr>
<tr>
<td>Percentage of population &gt;65 years</td>
<td>17.8%</td>
</tr>
<tr>
<td>Expenditure, 2013</td>
<td></td>
</tr>
<tr>
<td>Percentage of GDP spent on health care</td>
<td>11.1%</td>
</tr>
<tr>
<td>Health care expenditure per capita</td>
<td>$4,847</td>
</tr>
<tr>
<td>Average annual growth rate of real health care expenditure per capita, 2009-2013</td>
<td>-0.2%</td>
</tr>
<tr>
<td>Out-of-pocket health care expenditure per capita</td>
<td>$625</td>
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<tr>
<td>Hospital expenditure per capita</td>
<td>$2,070</td>
</tr>
<tr>
<td>Expenditure on pharmaceuticals per capita</td>
<td>$288</td>
</tr>
</tbody>
</table>

Note: for consistency throughout the report, amounts in this table are expressed in USD.

Government expenditure on prescription medicines sold through pharmacies in Denmark was 5.6 billion DKR in 2014 (4% of total health expenditure), which is a decrease from 7.3 billion DKR in 2007. Total expenditure on community pharmacy (including patient contributions) was 9.9 billion DKR in 2014. In addition to prescription-only medicine, over 2 billion DKR is spent on OTC products (Sundheds-Aeldreministeriet, 2016).

4.4.2 Remuneration and regulation

Most health service providers, including pharmacists, are financed through fee-for-service mechanisms in order to promote activity. Most fee-for-service mechanisms, however, involve upper limits to turnover to enable the regions to keep their expenditures within their budgets. In Denmark, a significant proportion of pharmacy income comes from fixed dispensing fees, which are an additional source of pharmacy income added to the pharmacy retail margin. In 2012, pharmacist remuneration for reimbursed medicines included a flat mark-up of 8.8% on the pharmacy purchase price (PPP) plus €1.80 (Olejaz et al, 2012; Kanavos et al, 2011; Dylst et al, 2012). In 2016, this had been changed to a flat mark-up of 8.4%, plus €1.07 (Retsinformation, 2016a).

The income of the proprietor pharmacist is determined by the pharmacy’s turnover, the pharmacy’s costs and the regulation by the state, which redistributes income from pharmacies with a relatively high turnover to pharmacies with a relatively low turnover. This ‘solidarity contribution’ is re-distributed nationally to level out pharmacy earnings based solely on pharmacy sales (regardless of its population base) in order to ensure rural access to pharmacies (Kanavos et al, 2011).

The total gross profits of community pharmacies are fixed by the Ministry of Health and the Danish Association of Pharmacists every two years on the basis of current figures and forecasts. In 2010, the total gross profit of the pharmacies was 12.4 billion DKR (excluding value-added tax (VAT)). The average total gross profit per pharmacy was 49.2 million DKR. Prescription pharmaceuticals made up 77.5% of the turnover of pharmacies in 2009. Pharmacies sold a total of 98.5 million packs of medicine in 2009, of which 56.7 million (58%) were prescription pharmaceuticals (Olejaz et al, 2012).
Pharmacies are privately run but under strict government regulation. Community pharmacies are private entities but subject to comprehensive state regulation to ensure that everybody has reasonable access to a pharmacy, even in rural areas where pharmacies may not be profitable. A collective financial equalisation system is in place, under which pharmacies with above-average turnovers contribute to pharmacies with below-average turnovers (Olejaz et al, 2012).

To run a pharmacy, a person must hold a master’s degree in pharmacy. However, non-pharmacists may own pharmacies, under specific conditions which include having a pharmacist being the (majority) owner of the pharmacy. Changes to legislation on June 1, 2015 allow pharmacists to establish up to 6 separate outlets within 75 kilometres from their main pharmacy (Olejaz et al, 2012; Herborg et al, 2007; Kanavos et al, 2011; Retsinformation, 2016b).

The Danish Institute for Quality and Accreditation in Healthcare develops, plans and runs the Danish accreditation program for health care providers, called the Danish Healthcare Quality Program. While participation by pharmacies is voluntary, 83% are enrolled. The pharmacies report adverse events at the pharmacies and adverse events that originates from other parts of the health care system to the national patient safety database (Danmarks Apotekerforening, 2016).

The extemporaneous preparation of infusions and injections for chemotherapy are solely conducted by hospital pharmacies. The medicines are only available through the hospitals.

4.4.3 Scope of services, settings and distribution

Most services provided by pharmacies are obligatory, and are performed by every community pharmacy. These services are funded through the agreed retail gross profits for prescription medicines. The first obligation is to provide all pharmacy-restricted medicines, regardless of whether they are prescription-only or OTC. In practice, this means that the pharmacy must have any medicine requested in stock or be able to deliver it within 24 hours. Apart from pricing, labelling, and checking prescriptions, there are a number of obligations related to handling prescription-only medicine (Herborg et al, 2007):

- handling of extemporaneous preparations;
- choosing the cheapest possible medicine;
- checking dosage, indication, interactions, and contraindications;
- providing basic information to customers on the use of the medicine;
- reporting data to authorities for statistical and reimbursement purposes;
- providing documentation for the use of narcotics (a so-called “medicine passport”);
- receiving unused medicine from customers for destruction; and
- providing information leaflets and access to an information site for the public.

Pharmacies are also obliged to provide automated dose dispensing of medicine – the medicine for the individual user is packed in unit doses with indications on when to take the content of the bags. This service is remunerated by the state, via the agreed retail gross

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10 Personal communication, Danish Institute for Quality and Accreditation in Healthcare.
profits for prescription medicines. A limited number of pharmacies handle dose dispensing, and provide this service to other pharmacies. Except for very simple processes, compounding of pharmaceutical materials is centralised at three pharmacies (Herborg et al, 2007).

Many pharmacies offer body mass index, blood sugar, blood pressure and cholesterol measurements, quit-smoking counselling and inhalation counselling for patients who use inhalators; however, only inhalation services are reimbursed, plus quit-smoking counselling in some instances. Smoking cessation courses are partially reimbursed by most regional authorities in Denmark. Medicine review services are provided by some pharmacies, and are paid for by individuals (Olejaz et al, 2012; Herborg et al, 2007).

A Danish study investigated differences in the provision of counselling services by community pharmacies and the factors associated with patient uptake of these services. Pharmacists reported difficulties in engaging consumers in discussions about their medicine use due to lack of interest. This study sought to identify differences in how pharmacists attempt to encourage consumers to engage in conversations about their medicine use. The results showed that pharmacies serving the most customers per day were the most successful. An association between consumers that were presenting to the pharmacy for a refill (rather than an original) prescription and reduced likelihood of taking up counselling offered by pharmacists was also identified. The study concluded that there is considerable variability in how pharmacists engage consumers in dialogue about their medicines use, and their success in doing so (Kaae et al, 2014).

In 2010, there were 3,646 pharmacists in Denmark. The number of pharmacists per 100,000 population is lower in Denmark than in the other Nordic countries and the UK, as well as the OECD average (see Table 4.8). However, because of the relatively high population density in Denmark, as well as short travelling distances, on average, a Danish citizen has 3.8 km to the nearest pharmacy. The number of pharmacists per population has increased since 2000, but not significantly (Olejaz et al, 2012).

Table 4.8: Number of pharmacies and pharmacists, Denmark

<table>
<thead>
<tr>
<th></th>
<th>Denmark</th>
<th>OECD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of practising pharmacists (2013)</td>
<td>50.0 (2012)</td>
<td>80.0</td>
</tr>
<tr>
<td>Number of pharmacies (2015)</td>
<td>3.9</td>
<td>25.1</td>
</tr>
</tbody>
</table>

Source: reproduced from OECD (2015)

In addition to pharmacies, medicines may also be sold in other types of pharmacy-operated outlets without pharmacists (“branch pharmacies”), which are staffed by pharmacy assistants (Herborg et al, 2007). Since October 2001, other outlets, such as supermarkets and kiosks, have been permitted to sell a selection of non-prescription medicines. The total consumption of OTC medicines has not changed despite this increased number of outlets. In Denmark, prescription medicines may be ordered and paid for over the internet and can be sent to an address of a patient’s choosing or picked up at the pharmacy (Olejaz et al, 2012; Kanavos et al, 2011). A paper prescription is not required for purchasing pharmaceuticals off internet pharmacies, as internet pharmacies are able to access national infrastructure for e-prescriptions (see Section 4.4.5).
4.4.4 Wholesale supply arrangements

Denmark has two wholesalers – Nomeco, owned by Phoenix Group; and TMJ, owned by Celesio AG – distributing medicines to private pharmacies, in addition to some wholesalers that only distribute medicines for veterinary use. Both wholesalers supply medicines to all pharmacies, with each of the wholesalers being the dominant supplier for different pharmacies. Wholesale profits are fixed through individual negotiations between the manufacturers or importers and the wholesalers; the profit level is generally determined through competition, and is comparable for the two wholesalers (Olejaz et al, 2012; Kanavos et al, 2011; Konkurrencen om Distribution af Medicin, 2016).

While direct delivery to pharmacy from the pharmaceutical manufacturers (direct-to-pharmacy) distribution arrangements are used in Denmark, these arrangements are not common and approximately 95% of medicines are purchased through the two wholesalers (Olejaz et al, 2012; Kanavos et al, 2011; Konkurrencen om Distribution af Medicin, 2016).

4.4.5 Adoption of technology

Denmark is generally recognised as being at the forefront of e-health initiatives and has a history of being at the forefront of using information technology within the health care setting. Technology is used at all levels of the health system as part of a national strategy supported by the Danish Health Data Authority. Each region uses its own electronic patient record system for hospitals, with adherence to national standards for compatibility. Danish GPs were ranked first in an assessment of overall implementation of EHRs in 2014 (Department of Health (Ireland), 2013; The Commonwealth Fund, 2016).

All citizens in Denmark have a unique electronic personal identifier, which is used in all public registries, including health databases. A shared medical card—accessible by all relevant health professionals—has been implemented. It contains encoded information about each patient’s prescriptions and medicine use. E-prescriptions are widely used in Denmark, with more than 90% of the country’s total prescriptions sent electronically (Kirkegaard, 2013). E-prescriptions do not require paper prescriptions, and are routed through a national dedicated secure infrastructure and stored on a national server, which makes them available for all pharmacies.

4.4.6 Reforms, innovations and trials

As the pricing of medicinal products is not directly controlled but is governed by negotiations, Denmark has implemented policies to control pharmaceutical expenditure. Since 2005, the basis for reimbursement was changed to the lowest price paid in the EU. These policies have included generic substitution, prescribing guidelines, and assessment by the regions of deviations in prescribing behaviour. Pharmaceutical companies report a monthly price list to the Danish Health Authority, and pharmacies are obliged to choose the cheapest alternative with the same active ingredient, unless a specific medicine is prescribed. Patients can choose the more expensive medicine, but they have to pay the difference. Another approach to controlling pharmaceutical expenditure is through parallel imports of pharmaceuticals, which has been undertaken since the beginning of the 1990s (The Commonwealth Fund, 2016; Olejaz et al, 2011).
Since 2004, a number of initiatives have been carried out centrally to help optimise medicine treatment (Herborg et al, 2007):

- personal electronic medicine profile;
- electronic patient journal;
- national interaction database;
- independent medicine information for health professionals;
- reporting system for errors and adverse medicine events;
- patient reporting of adverse effects; and
- prescription statistics at a national and regional level.

From 1 July 2015, new regulations which removed the restrictions on the creation of branch pharmacies resulted in an increase in the number of branch pharmacies. Between July and December 2015, 56 new branch pharmacies were created, and between January and September 2016 an additional 407 pharmacies and branch pharmacies were opened. This means that since 1 July 2015 there has been a 30% increase in the number of outlets in Denmark where patients can present their prescriptions.

4.5 Norway

4.5.1 Health system context and expenditure

The Norwegian Government is responsible for providing health care to the Norwegian population. Responsibility for specialist care lies with the state while municipalities have responsibility and flexibility for primary health and social care delivery. The nationally managed and financed health system, providing more than 95% of all health care, is built on universal coverage and on the principle of equal access for all regardless of socioeconomic status, ethnicity, and area of residence. While the Norwegian Parliament determines what is covered, only new and costly treatments are specifically defined in the benefits package. In practice, what is covered by national health care includes planned and acute primary, hospital, and ambulatory care, rehabilitation, and outpatient prescription medicines that are included on the formulary (the list of reimbursed medicines, or the “blue list”) (The Commonwealth Fund, 2016; Ringard et al, 2013).

Primary care is financed from municipal taxes, block grants from the central government, and earmarked grants for specific purposes. Public sources account for over 85% of total health expenditure, mostly comprising financing from the central and local governments and from the National Insurance Scheme (around 12% of total health expenditure). The vast majority of the 15% of health expenditure that is privately financed comes from households’ out-of-pocket payments; mainly for pharmaceuticals and dental care, though there is a co-payment for GP visits. Out-of-pocket payments finance about 14% of total expenditure. The role of VHI in health care financing is negligible despite an increase in the number of Norwegians holding private health insurance to over 5% of the population. About 92% of policies are paid for by an employer (Ringard et al, 2013; The Commonwealth Fund, 2016).

Cost-sharing has been a long-standing feature of the Norwegian health care system. GP and specialist visits, including outpatient hospital care and same-day surgery, require co-payments (141 NOK and 320 NOK per visit in 2015, respectively), as do covered
prescription medicines (up to 520 NOK per prescription). Public providers cannot charge patients more than these amounts. Consultations for antenatal and postnatal follow-up, and for prevention and treatment of transmittable diseases are exempt from co-payments. Hospital admissions and inpatient treatment are free. Home-based and institutional care for older or disabled people require high cost-sharing (up to 85% of personal income), but are means-tested (Ringard et al, 2013; The Commonwealth Fund, 2016).

The major safety net mechanisms are annual caps for out-of-pocket expenditure set by Parliament, above which fees are waived. For 2015, the cost-sharing ceiling for most services is 2,105 NOK. A second ceiling is set at 2,675 NOK for services such as physiotherapy and certain dental services. Long-term care and prescription medicines outside the “blue list” do not apply toward these ceilings (The Commonwealth Fund, 2016).

Total health expenditure represented 9.4% of GDP in 2013, which is in line with the average for countries in the OECD. However, Norway ranks among the highest in the OECD in terms of absolute expenditure per capita (56,400 NOK) in 2014 (The Commonwealth Fund, 2016).

<table>
<thead>
<tr>
<th>Table 4.9: Health care system indicators, Norway</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Norway</strong></td>
</tr>
<tr>
<td>Population, 2013</td>
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<tr>
<td>Total population (millions)</td>
</tr>
<tr>
<td>Percentage of population &gt;65 years</td>
</tr>
<tr>
<td>Expenditure, 2013</td>
</tr>
<tr>
<td>Percentage of GDP spent on health care</td>
</tr>
<tr>
<td>Health care expenditure per capita</td>
</tr>
<tr>
<td>Average annual growth rate of real health care expenditure per capita, 2009-2013</td>
</tr>
<tr>
<td>Out-of-pocket health care expenditure per capita</td>
</tr>
<tr>
<td>Hospital expenditure per capita</td>
</tr>
<tr>
<td>Expenditure on pharmaceuticals per capita</td>
</tr>
</tbody>
</table>

Note: for consistency throughout the report, amounts in this table are expressed in USD.

In Norway, 7.6% of total health expenditure is on pharmacies. According to statistics provided by the Norwegian Health Economics Administration, the Norwegian government paid approximately €3,267 million in reimbursements and benefits in 2012. About a third of this is reimbursement of pharmaceuticals. In total, the Norwegian state finances about two thirds of the pharmaceutical expenses in Norway (OECD, 2014b).

### 4.5.2 Remuneration and regulation

The Norwegian Medicine Agency (NoMA) regulates the prices of all prescription-only medicines under patent by determining the pharmacy purchase price (PPP). The PPP is set through external reference pricing based on the average of the three lowest PPP in Sweden, Finland, Denmark, Germany, UK, the Netherlands, Austria, Belgium and Ireland. The pharmacy retail price is thereafter determined by adding the regulated maximum pharmacy mark-up. This is also set by NoMA (OECD, 2014b).

If the pharmacy manages to obtain a purchase price (PPP) lower than the maximum purchase price, the rewards of this has to be split with the final consumer. The pharmacy has to set
the retail price lower than the maximum retail price, in a way that the reward is split in two (OECD, 2014b).

As of 2015, the pharmacy mark-up scheme includes the following items:

- a maximum mark-up of 7%, where the PPP is between 0-200 NOK (€0-€24);
- a maximum mark-up of 3%, where the PPP is greater than 200 NOK (€24); and
- fixed mark-up per package:
  - all prescription-only medicine packages: 25 NOK (€3); and
  - additional fees for addictive medicines and narcotics: 10 NOK (€1) (Gesundheit Österreich GmbH, 2015).

Co-payments for prescription medicines covered by public insurance on the “blue list” in Norway are up to 520 NOK ($55 USD) per prescription. Out-of-pocket payments finance about 14 percent of total expenditure.

The activities of pharmacies were deregulated by the Pharmacy Act 2000 and its associated amendments and regulations. The Act liberalised the pharmaceutical market: limitations on the ownership of pharmacies were removed (anyone, not just pharmacists, can own a pharmacy), as were the limitations on establishing new pharmacies (previously, regulations on the number of pharmacies owned). Deregulation had a rapid impact on the number of pharmacies, which increased from 392 in 2000 to 524 by June 2004. The number of pharmacies has increased by 50% in the first ten years since the 2000 liberal Pharmacy Act came into force (Rudholm, 2008; Mandt et al, 2010).

In terms of ownership, each pharmacy must have two separate licences: one licence to own the pharmacy (the proprietor’s licence) and the other to run the pharmacy (the operating licence). Only pharmacies or medicinal outlets (controlled by pharmacies) may carry out the retail sale of pharmaceutical products (although there may be exceptions, for example for pharmaceuticals which are intended for scientific use). Pharmacy chains are allowed. This has allowed for new ownership structures that has led to the establishment of three multi-pharmacy chains with international owners comprising over 90% of the community pharmacies in Norway – Apotek 1, Vitusapotek/ Ditt Apotek, and Boots Apotekene, which had approximately 40%, 30% and 20% market share, respectively, in 2012. (Ringard et al, 2013; Mandt et al, 2010). The maximum number of pharmacies allowed in a chain is 40% of all pharmacies (OECD, 2014b). This was the result of an intervention of the Competition Authority after one group organised more than 80% of the pharmacies following liberalisation of the market.

Ownership and operations of pharmacies must be approved by NoMA. Doctors and pharmaceutical manufacturers are not allowed to own a pharmacy in Norway. The minimum requirements for pharmacy operations are laid down in laws and regulations. The pharmacies are obligated to deliver all pharmaceuticals with a marketing permit, and to carry the pharmaceuticals most in demand (OECD, 2014b).

To ensure sufficient supply of medicines in the rural areas, NoMA has the ability to impose the creation and operation of pharmacies or medicine outlets (“branch pharmacies”). In addition, they can give operational support to pharmacies which operate in areas where it is not profitable to operate (OECD, 2014b). Doctors in rural areas are allowed to dispense
medicines when normal availability is restricted due to weather or geographical complications (PHIS, 2011).

4.5.3 Scope of services, settings and distribution

In general, only community and hospital pharmacists are allowed to dispense medicines, along with small outlets belonging to the pharmacies. Other dispensaries (medicine stores, supermarkets, kiosks and petrol stations), are allowed to distribute a small selection of OTC products (Gesundheit Österreich GmbH, 2015).

Prescription interventions, including checking for prescription errors and counselling on appropriate medicine use, are established activities within the dispensing process in Norwegian pharmacies. Provision of information on appropriate medicine use legislated in Norway. Specifically, pharmacists are obliged to aid the customer in obtaining sufficient information to enable the proper use of the medicine. This provision of information is not linked to any economic incentive further specifying the content, amount, or outcomes of the communication: it is included in the general pharmacy-mark up (Mandt et al, 2010; Svensberg et al, 2015).

Besides medicine dispensing, all pharmacies in Norway offer their customers repeat dispensing and disposal of unwanted medicines. In 2006, an investigation of pharmaceutical care and services provided in other countries was carried out and services and needs which would be useful to provide in Norwegian pharmacies were identified. Medicine reviews and smoking cessation programs were identified as service offerings that should be established. Norwegian pharmacies are increasingly offering additional services, such as blood pressure measurement or specific disease (for example, asthma and diabetes) management programs (Vogler et al, 2012).

In a study investigating the medicine-related problems identified through medication reviews by community pharmacists, patients with type 2 diabetes were recruited by 24 Norwegian community pharmacists who performed structured medication reviews based on the patients’ medication profiles and patient interviews. The pharmacists identified 88 medicine-related problems in 43 of the 73 patients. The most common problems were adverse drug reactions and wrong medicine or dose. The evaluation demonstrated that community pharmacists were able to identify problems of high to medium clinical relevance, and to perform follow-ups of these problems with the patients and the physicians of a good or satisfactory quality (Granás et al, 2010).

Since the liberalising Pharmacy Act 2000, the number of pharmacies has grown significantly. Consumption of medicines has grown in recent years, though it is still substantially lower than in neighbouring Sweden and Finland. Before 2001, the Norwegian pharmacy sector was subject to strict regulations. Restrictions on the establishment (number and location) of new pharmacies were stipulated by means of a five year “pharmacy plan”, and Norway had a relatively low number of pharmacies per inhabitants compared to other European countries (Ringard et al, 2013; Vogler et al, 2012).

As of 2014, there are 738 community pharmacies in Norway. Most new pharmacies are established in the urban areas. Norway still has a low pharmacy coverage compared to other European countries (Savlind, 2015) – see Table 4.10.
Table 4.10: Number of pharmacies and pharmacists, Norway

<table>
<thead>
<tr>
<th>Per 100,000 population</th>
<th>Norway</th>
<th>OECD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of practising pharmacists (2013)</td>
<td>69.0</td>
<td>80.0</td>
</tr>
<tr>
<td>Number of pharmacies (2015)</td>
<td>15.0</td>
<td>25.1</td>
</tr>
</tbody>
</table>

Source: reproduced from OECD (2015)

A 2014 study found a significant decrease in the population serviced by each pharmacy, as a result of the opening of numerous new pharmacies. However, it was noted that new pharmacies tended to be established in urban areas with few in rural locations (Vogler et al, 2014).

Accessibility of pharmacy services has improved since the deregulation of pharmacies. As mentioned in section 4.5.2, the activities of pharmacies were deregulated by the Pharmacy Act 2000. This deregulation improved the accessibility of pharmacies as it resulted in an increase in the number of pharmacies and led to an increase in the opening hours of pharmacies. Under these changes, pharmacy opening hours increased on average from 42 hours per week to 53 hours per week (Rudholm, 2008; Chemist Warehouse, 2014).

4.5.4 Wholesaler supply arrangements

To carry out a wholesaling business, the person or the company must obtain approval from the Norwegian Medicines Agency (NoMA). Wholesalers have an obligation to be able to deliver pharmaceuticals to all pharmacies all over the country in 24 hours (in some peripheral areas the time requirement is 48 hours). Previously, wholesalers were also obliged to carry the full assortment of pharmaceuticals in demand in the Norwegian market (“the full assortment requirement”). However, this requirement was removed by the Ministry of Health and Care Services effective from 1 January 2015 (OECD, 2014b).

Wholesale remuneration is negotiated between manufacturers and wholesalers; the wholesale mark-up is not regulated. There are three wholesalers in the market, all three belonging to leading European pharmaceutical distribution companies: Norsk Medisinaldepot (with a market share of 47.6%), Apokjeden AS (28.9%) and Boots Norge AS (23.7%). Each of the wholesalers is vertically integrated with their own pharmacy chain (Gesundheit Österreich GmbH, 2015; Ringard et al, 2013).

Since March 2001, the pharmacy market in Norway has become very much integrated, both horizontally and vertically: horizontally because many pharmacies are now organised in chains, and vertically in that retailers and wholesalers now have the same owners. Vertically integrated pharmacy chains have bought most of the existing pharmacies in Norway and established a lot of new ones. On 1 January 2011, 81% of the Norwegian pharmacies were in ownership of one of the three large international pharmacy chains, each vertically integrated with a pharmaceutical wholesaler. In addition, there is a chain of 55 semi-independent pharmacies (Ditt Apotek) and some independent pharmacies (Vogler et al, 2012).

The Norwegian Competition Authority has expressed concern with the oligopolistic structure which has developed. The vertical integration has impacted on the accessibility of medicines, as vertically integrated pharmacies are more likely to align their product range with the
product range of their in-chain manufacturer, and less-frequently requested medicines were not as available in pharmacies (Vogler, 2014).

Direct distribution from the manufacturer to the end-user is in general not allowed. As a result all distribution, with some minor exceptions, is done by a wholesaler. The main bulk of pharmaceuticals are then further distributed by pharmacies. An important exception is a limited selection of OTC medicines that can be sold to the end user by other channels as well (Gesundheit Österreich GmbH, 2015). Prescription pharmaceuticals are permitted to be sold via the internet in Norway (Dudley, 2012).

4.5.5 Adoption of technology

The National Health Network provides efficient and secure electronic exchange of patient information between all relevant parties within the health and social services sector including pharmacists. While the system is fragmented, almost all GPs use electronic patient records and transmit prescription electronically to pharmacies.

In Norway, the e-prescription program was introduced on 18 October 2011 and has since been gradually rolled out throughout the country. By 2013, almost 90% of municipalities had implemented e-prescription systems. Approximately 80% of the total reimbursed prescription claims were electronic in 2013. A personalised web service named ‘Mine resepter’ provides citizens with an overview of their valid e-prescriptions. Since the system was introduced, co-payments for patients obtaining a prescription without a consultation (for example, subsequent prescription for treatment of an ongoing condition) were removed. Research suggests that this change led to an increase in the number of prescriptions of 6.1-8.0% (Kierkegaard, 2013; Eriksen and Melberg, 2015).

The Directorate for Health has responsibility for the national strategy for health information technology. Every resident is assigned a unique personal identification number, which is used in primary care and for hospital medical records. All patients have the right to see or get a copy of their complete record, including doctors’ notes, but there is not yet an electronic solution for doing so. An ongoing project on patient access currently gives 2.3 million inhabitants access to their core medical record, also allowing for correction of personal information (The Commonwealth Fund, 2016).

4.5.6 Reforms, innovations and trials

Generic substitution has been allowed in Norway since 2001. The generics share of the pharmaceutical market increased strongly between 2000 and 2008 (though this is likely the result of the Pharmacy Act 2000), but has been stable in recent years. In 2011, sales of generic medicinal products accounted for 41.5% of total sales, measured in terms of volume, compared to 23.6% in 2001 (Norwegian Ministry of Health and Care Services, 2015; The Commonwealth Fund, 2016).

Access to medicines has improved in Norway in recent years, and medicines have become substantially less expensive in recent years. In the period from 2000 to 2011, medicine prices fell by an average of 2.4% annually in nominal terms. One of the changes introduced since July 2002 is the use of an international price referencing system to set maximum prices for both new and existing medicines (see Section 4.5.2). A pricing survey conducted in
2010-2011 showed that prices of non-generics in Norway were among the lowest in Western Europe.

In addition to price, while Norway used to have the lowest density of pharmacies in Europe, the number of pharmacies has grown significantly since the Pharmacy Act 2000 liberalised the pharmaceuticals market. This removed limitations on the ownership of pharmacies, as well as removing the limitations on establishing new pharmacies (Ringard et al, 2013). Over 2001 to 2004 128 new pharmacies opened in Norway (a 32% increase), which compares to an increase of only 71 pharmacies between 1991 and 2000 (Vogler, 2014).

In Norway, the interchangeability of a biologic medicine and its biosimilar(s) is at the discretion of the prescribing physician. Substitution at the pharmacy level is currently prohibited. However, NoMA is currently sponsoring an interchangeability trial, known as NOR-SWITCH, to establish whether rheumatoid arthritis patients treated with infliximab can safely be switched to a biosimilar. The results of this trial are pending (Renwick et al, 2016).

### 4.6 Sweden

#### 4.6.1 Health system context and expenditure

Health care coverage in Sweden is universal and automatic. The system covers all legal residents and emergency coverage is provided to all patients from EU/ European Economic Area countries. Approximately 10% of all employed individuals aged 15 to 74 years have supplementary private health insurance, however private health insurance accounts for less than 1% of expenditure (The Commonwealth Fund, 2016).

Three basic principles apply to all health care in Sweden:

- Human dignity: all human beings have an equal entitlement to dignity and have the same rights regardless of their status in the community.
- Need and solidarity: those in greatest need take precedence in being treated.
- Cost-effectiveness: when a choice has to be made, there should be a reasonable balance between the costs and the benefits of health care, measuring cost in relationship to improved health and quality of life (The Commonwealth Fund, 2016).

In Sweden, county councils and municipalities are responsible for organising and financing health care, and so services vary throughout the country. The county councils set co-payment rates per health care visit and providers cannot charge above the scheduled fee. In 2013, about 16% of all health expenditure was privately financed, 93% of which was out-of-pocket expenditure (predominantly on medicines). People are required to pay the full out-of-pocket payments for health care (including prescription pharmaceuticals) up to 1,100 SEK (US$123) per individual. After this point, the subsidy gradually increases to 100%, with the maximum annual amount of co-payments capped at 2,200 SEK ($246 USD). The annual maximum of 2,200 SEK applies collectively to all children of the same family. Co-payments for prescribed medicine are consistent throughout the country and fully regulated by the government (The Commonwealth Fund, 2016; Anell et al, 2012).

Health expenditure represented 12% of GDP in 2013 (see Table 4.11). About 84% of this expenditure was publicly financed, with county councils’ expenditures amounting to 57%,
municipalities’ to 25%, and the central government’s to almost 2%. The county councils and the municipalities levy proportional income taxes on their populations to help cover health care services (The Commonwealth Fund, 2016).

Table 4.11: Health care system indicators, Sweden

<table>
<thead>
<tr>
<th></th>
<th>Sweden</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population, 2013</td>
<td>9.6</td>
</tr>
<tr>
<td>Total population (millions)</td>
<td></td>
</tr>
<tr>
<td>Percentage of population &gt;65 years</td>
<td>19.0%</td>
</tr>
<tr>
<td>Expenditure, 2013</td>
<td></td>
</tr>
<tr>
<td>Percentage of GDP spent on health care</td>
<td>11.5%</td>
</tr>
<tr>
<td>Health care expenditure per capita</td>
<td>$5,153</td>
</tr>
<tr>
<td>Average annual growth rate of real health care expenditure per capita, 2009-2013</td>
<td>7.0%</td>
</tr>
<tr>
<td>Out-of-pocket health care expenditure per capita (2012)</td>
<td>$726</td>
</tr>
<tr>
<td>Hospital expenditure per capita (2012)</td>
<td>$1,907</td>
</tr>
<tr>
<td>Expenditure on pharmaceuticals per capita</td>
<td>$496</td>
</tr>
</tbody>
</table>

Note: for consistency throughout the report, amounts in this table are expressed in USD.

Government expenditure on prescribed medications was 20.6 billion SEK in 2014, which was 5% of total health expenditure. This is lower than levels in 2012 (20.7), 2011 (21.8) and 2010 (21.6), but higher than the level in 2005 (19.7). In addition to government expenditure, households paid 7.8 billion SEK in out-of-pocket costs for prescribed medications (Statistics Sweden, 2016).

4.6.2 Remuneration and regulation

Pharmacy margins in Sweden are regressive, and are composed of a fixed percentage which decreases as the price to which it refers increases. There are four categories ranging from less than €8.08 to greater than €646.40 of the PPP, with an average margin of 21.3%. No pharmacy dispensing fees exist and value added tax (VAT) on prescription medicines is zero. However, non-prescription medicines follow normal VAT rules (Kanavos et al, 2011).

There were 1,303 pharmacies (up from 1,282 in 2013) throughout the country as at January 2014 distributing prescription and non-prescription medicines to the population and to hospitals and other health services. Until 2009, all pharmaceuticals in Sweden were distributed and sold to the general public by the state-owned National Corporation of Swedish Pharmacies. Deregulation (sometimes referred to as re-regulation) of the pharmacy market in 2009 allowed new owners to operate pharmacies and the sale of OTC medicines outside pharmacies. After the pharmacy reforms, regulations on the location and ownership of pharmacies (with the exception of prescribers and pharmaceutical manufacturers) were removed. These reforms increased the number of pharmacies by 40% (mostly in large cities) and improved access for most people. Prior to the reforms, only one pharmacy chain existed, the state owned Apoteket.

The recent changes have opened up the market with 11 companies covering most of the market, with the three largest being Cura Apoteket/Apotek Hjartat, Apoteket AB, and Kronans Apotek. As of June 2010, about 50% of the state pharmacies have been sold to other owners and the remaining 50% continue to be under public control (Anell et al, 2012;

A State Treasury evaluation of deregulation in Sweden concluded that the policy aims of increased accessibility and lower expenditure had largely been realised. However, the aims of delivering better service quality and a broader range of services as well as maintaining competence and safety in pharmaceutical supply had only been met to some extent (Vogler et al, 2014).

There are several government bodies involved with regulation of pharmacies in Sweden to ensure high standards of delivery and accountability in the pharmacy sector. For prescription medicines, the central government and the county councils negotiate agreements of defined periods, on the levels of subsidy paid by the government to the councils. Tendering contracts may also be used as cost-control measures by count councils and municipalities. The financing of health services through global budgets, volume caps, capitation formulas, and contracts, as well as salary-based pay for staff, also contributes to cost control. In addition, the Dental and Pharmaceutical Benefits Agency uses value-based pricing for prescription medicines, whereby the level of reimbursement is based on an assessment of health needs and cost-effectiveness (The Commonwealth Fund, 2016).

Mandatory generic substitution by pharmacists has applied to prescriptions since 2002. Prior to 2002, pharmaceutical costs increased by about 10% per annum in Sweden. Between 2002 and 2003 the increase in costs were only 2%, partly because of the introduction of generic substitution and the expiry of patents. The increase in costs has remained at a low level although the introduction of new biological medicines led to a higher level of costs during 2006–2008. The increase in costs fell back to less than 2% again between 2008 and 2009. Five years after the generic substitution policy in Sweden, there has been an average price reduction for prescription medicines of about 22%, and 50% for off-patent medicines (Anell et al, 2012; Frisk et al, 2011).

The extemporaneous preparation of infusions and injections for chemotherapy is conducted by hospital pharmacies. These are either fully or partly covered by the counties themselves, or by private pharmacies who submit tenders for providing the services.

4.6.3 Scope of services, settings and distribution

In Swedish pharmacies, repeat dispensing is allowed, medicine waste disposal is offered, medicines review services are provided, and some pharmacies offer minor diagnostics including blood pressure testing and weight, cholesterol checking and blood glucose testing. Medical interventions include emergency contraception, smoking cessation, vaccinations and home care services. Most of these additional services are paid for by individuals, however, medicine reviews are provided for free (Kanavos et al, 2011).

In recent years, a small number of pharmacies have increased their breadth of service to include diagnostic and counselling services. Professional counselling responsibilities of pharmacists include identifying and solving medicine-related problems, giving appropriate advice, and supporting patients in different ways depending on their needs. Counselling is remunerated as part of the pharmacy margin (Kanavos et al, 2011; Montgomery et al, 2010; Olsson et al, 2014; Tully et al, 2011; Vogler et al, 2012).
Pharmacists in Sweden take their responsibility for detecting, preventing and solving prescription errors seriously and consider it necessary to contact prescribers for clarification before dispensing. Several studies have investigated the role of community pharmacists in helping to prevent and correct dispensing errors to improve patient safety and quality use of medicines. In 2010, pharmacists contacted prescribers for clarification in approximately 1% of new prescriptions (around 330,000 prescriptions) per year. Of these, around 60% were considered to be issues that may compromise patient safety, such as dosage schedules (Ekedahl, 2010, Norden-Hagg et al, 2012).

A prospective randomised controlled trial in Stockholm was conducted to investigate whether a pharmacist-led medication review reduces the number of medicines and the number of medicine-related problems. A significant decrease in medicine-related problems was observed in the intervention group as well as a significant difference in change in self-rated health between the groups. The study concluded that the addition of a skilled pharmacist to the primary care team may contribute to reductions in numbers of medicine and maintenance of self-rated health in elderly patients with polypharmacy (Lenander et al, 2014).

The number of pharmacists per inhabitant is higher in Sweden than in the other Nordic countries, but is slightly lower compared to the OECD average in 2013 (Anell et al, 2012), as shown in Table 4.12.

Table 4.12: Number of pharmacies and pharmacists, Sweden

<table>
<thead>
<tr>
<th>Per 100,000 population</th>
<th>Sweden</th>
<th>OECD</th>
</tr>
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<tbody>
<tr>
<td>Number of practising pharmacists (2013)</td>
<td>77.0 (2012)</td>
<td>80.0</td>
</tr>
<tr>
<td>Number of pharmacies (2015)</td>
<td>13.3</td>
<td>25.1</td>
</tr>
</tbody>
</table>


Of the 1,280 pharmacies in Sweden in September 2012, 1,066 were located in city areas with at least 3,000 inhabitant, 145 were located in smaller cities which were less than 45 minutes’ drive to larger cities, and 34 were located in rural areas which were more than 45 minutes’ drive to larger cities. From 2013, a special financial support is provided for pharmacies in remote areas (Statskontoret, 2013).

Currently, the average distance to the nearest pharmacy in Sweden in total is 3.9 kilometres. In 2011, 29% of the Swedish population had a distance less than one kilometre to the nearest pharmacy while more than 50% have a distance less than three kilometres to the nearest pharmacy. The distance to pharmacy was reported to have been reduced by an average of 150 meters since deregulation was implemented (Vogler et al, 2012).

While there are currently no specific regulations for the establishment of pharmacies in rural areas, safeguard washout regulations exist whereby those community pharmacies sold from the state to private companies have to be kept running at least three years after purchase. This rule is especially important for rural pharmacies to ensure adequate mechanisms are in place for accessing medicines (Vogler et al, 2012).

In Sweden, there are no dispensing doctors or hospitals dispensing to out-patients in place of community pharmacists. In practice, a number of community pharmacies (both private and state owned Apoteket) are also located at hospital premises. There are no branch
pharmacies in Sweden. The sale of OTC medicines outside pharmacies has been allowed in supermarkets and petrol stations since November 2009 (Vogler et al, 2012).

Alternative arrangements for distribution of pharmacy services include internet pharmacies, which are defined as “the long distance purchase of Prescription-Only-Medicines from internet sources outside of the network of actual pharmacies”. In Sweden, patients have an electronic ID to access their e-prescriptions, which allows them to choose which medicines to order as well as examine previously prescribed medicines. Paper prescriptions are not required. Medicines are delivered to patients’ homes, post office or local pharmacy within 3-5 days. Counselling on the safe and quality use of medicines can take place at a local pharmacy or over the telephone via a call centre (Kanavos et al, 2011).

4.6.4 Wholesaler supply arrangements

The Swedish wholesale market consists of two companies, Kronans Droghandel (Oriola KD) and Tamro (Phoenix group), which are allowed to deliver to pharmacies, primary care centres and hospitals, but not directly to patients. These two main wholesalers have 95% of the market share. Neither Kronans Droghandel nor Tamro are full-line wholesalers, therefore pharmacies have to order the products from both wholesalers. Sweden has a single channel distribution systems whereby a wholesaler has the exclusive right to distribute medicines for a manufacturer. In a single-channel system the market power of wholesalers is higher than in other European countries with a distribution system with more channels. This single-channel system is only found in one other EU member state (Finland) (Vogler et al, 2012; Kanavos et al, 2011).

Sweden has an unregulated, privately negotiated wholesale market; wholesale margins are not statutory, but negotiated directly with pharmaceutical companies. The margins of the two wholesalers are relatively low compared to other countries, whereas ex-factory prices used to be comparably high in Sweden. No mandatory discounts exist but commercial discounts do exist from wholesalers to pharmacies. It is estimated that wholesaler margins are on average 2-3% of the ex-manufacturer price. There are no regional wholesalers in Sweden (Vogler et al, 2012; Kanavos et al, 2011).

4.6.5 Adoption of technology

The Swedish e-health agency (eHälsomyndigheten) was formed in 2014 to strengthen the national e-health infrastructure. Its activities focus on promoting public involvement and providing support for professionals and decision makers. Generally, both the quality of information technology systems and their level of use are high in hospitals and in primary care; more than 90% of primary care providers used electronic patient records for diagnostic data in 2009 (The Commonwealth Fund, 2016).

Patients increasingly have access to their electronic medical record, via a national portal which enables scheduling appointments, and provides contact details of providers and interactive services. Recent figures show that about a fifth of the Swedish population have set up accounts in the portal (The Commonwealth Fund, 2016; BMJ, 2015).

Electronic prescribing in Sweden is well advanced; it has both a long history of use and a national system with a common infrastructure for transmission and storage. The world’s first e-prescription from prescriber to pharmacist was transmitted in Sweden in 1983. Nearly all
Swedish prescriptions are e-prescriptions; more than 90% of prescriptions are dispensed from e-prescriptions (Hammar et al, 2015; Makinen et al, 2011; Ax et al, 2010; BMJ, 2015). E-prescriptions are stored in a national database, and are accessible by all pharmacies.

4.6.6 Reforms, innovations and trials

A number of recent reforms have been used to contain pharmaceutical expenditure in Sweden. The low mark-ups in the distribution chain and no VAT for prescription medicines secure very low public prices of medicines in contrast to the ex-factory prices, which are among the highest in Europe. Generic substitution is mandatory, and pharmacists are required to dispense the least expensive medicine on the Swedish market. This triggers competition in generics (Vogler et al, 2012).
5 United Kingdom and Ireland

Information on community pharmacy in England, Wales, Scotland and Ireland is presented in the following sections. Given the similarities in the community pharmacy sector between England, Wales, Scotland, they are referred to collectively as the UK (noting the Northern Ireland was not included as a country of interest in this report). However, where there are differences between the countries this is noted.

5.1 United Kingdom

5.1.1 Health system context and expenditure

The UK health care system is primarily funded through taxation and each country in turn decide their own policy for health care through each country’s National Health Service (NHS). Coverage by publicly financed health care is universal for all those “ordinarily resident” in the UK. Non-residents who hold a valid EU insurance card are also covered (The Commonwealth Fund, 2016).

Table 5.1 below outlines key health care system indicators within the UK. In 2013, the UK spent 8.8% of GDP on health care, with services predominately financed from general taxation, generating 83.5% of the total health expenditure. The remainder was sourced from private medical insurance and out-of-pocket payments. In 2012, 10.9% of the UK population was covered by private VHI. With the bulk provided by employers (3.97 million policies) versus individual policies (0.97 million policies). Private health insurance often provides those covered with faster and more convenient access to care, particularly for elective hospital procedures. However, most UK private health insurance policies do not cover emergency care, mental health services, maternity services and general practice (Cylus et al, 2015; King’s Fund, 2014; The Commonwealth Fund, 2016).

Table 5.1: Health care system indicators, UK

<table>
<thead>
<tr>
<th></th>
<th>UK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population, 2013</td>
<td></td>
</tr>
<tr>
<td>Total population (millions)</td>
<td>64.1</td>
</tr>
<tr>
<td>Percentage of population &gt;65 years</td>
<td>17.1%</td>
</tr>
<tr>
<td>Expenditure, 2013</td>
<td></td>
</tr>
<tr>
<td>Percentage of GDP spent on health care</td>
<td>8.8%</td>
</tr>
<tr>
<td>Health care expenditure per capita</td>
<td>$3,364</td>
</tr>
<tr>
<td>Average annual growth rate of real health care expenditure per capita, 2009-2013</td>
<td>-0.9%</td>
</tr>
<tr>
<td>Out-of-pocket health care expenditure per capita</td>
<td>$321</td>
</tr>
<tr>
<td>Expenditure on pharmaceuticals per capita</td>
<td>$471</td>
</tr>
</tbody>
</table>

Note: for consistency throughout the report, amounts in this table are expressed in USD.

In 2016-17, the UK has seen overarching declines in health expenditure on community pharmacies, with Scotland as an exception. The NHS has committed £2.63 billion in 2016-17 to community pharmacies in both England and Wales for dispensing and for providing both
essential and advanced services to the public. This funding is delivered under the Community Pharmacy Contractual Framework. This expenditure is a reduction from the 2015-16 budget of £2.8 billion, representing a reduction of 6% sector (Pharmaceutical Services Negotiating Committee (PSNC), 2016).

The 2014-15 remuneration scheme for Scotland included a global sum from the previous year and additional new money totalling to £174.85 million. Unlike other countries in the UK, core service funding for community pharmacies in 2015-16 increased for Scotland to £177.36 million due to a higher previous year global sum, additional new money and an uplift offered to account for increased overhead and salary costs being experienced in Scotland (Community Pharmacy Scotland, 2016).

5.1.2 Remuneration and regulation

The community pharmacy funding model in the UK is made up of one cover fee for essential services, and funding for advanced services including a pool of retained margins. Figure 7.1 details the funding model in England, which is similar to Wales and Scotland.

![Figure 5.1: Funding model for community pharmacy, England](source: Adapted from Moore et al (2015)).

Under this structure, the NHS funding framework contributes to remuneration of essential and advanced services, and retained margins which are determined using the margins survey. Overall, this funding contributes to the overall operation and function of community pharmacies.

All pharmacists receive a professional fee for each item dispensed (90 pence per item). Additional fees are specified in Part IIIA of the Medicine Tariff and include prescription fees equivalent to 2% of the net ingredient cost of items priced over £100. Pharmacists may also be entitled to ‘top up’ payments if a given pharmacist’s monthly establishment payments over a six month period are less than the amount had the payments been calculated on a six month basis. For repeat dispensing, an annual payment of £1,500 is paid monthly (PSNC, 2016b).

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11 An annual survey of 120 community pharmacies is undertaken to verify the purchase prices and quantities of medicines.
Outpatient prescription medicines are subject to a co-payment, set nationally by the Department of Health (currently £8.20 per prescription item in England); drugs prescribed in NHS hospitals are free. Exemptions from co-payments apply to children under age 16 and those 16 to 18 in school full time; people age 60 or older; people with low income; pregnant women and those who have had a baby in the past 12 months; and people with cancer, certain other long-term conditions, or certain disabilities. Patients with high prescription medicine needs can also buy prepayment certificates, which cost £104 for 12 months. Users incur no further charges for the duration of the certificate, regardless of how many prescriptions they need (The Commonwealth Fund, 2016).

The NHS regulates pharmacies and pharmacists in the UK, under the Pharmacy Act 1954 and the NHS Regulations 2013. Regulation of community pharmacies in the UK has undertaken significant change since the implementation of tough regulatory restrictions on the market in the 1980s. These restrictions led to a significant decline in the number of pharmacies in the UK, with higher costs to both taxpayers and individuals. As more and more people turned to supermarkets to obtain over the counter medicines (which were up to 30% cheaper), the UK implemented reforms in 2005 to deregulate the sector. Consequently, there has been a continual increase in the number of pharmacies, a reduction in waiting time, less travel times, and cheaper prices in the UK. Whilst access to pharmacies has been found generally to improve after deregulation, studies have suggested that access is likely to favour urban populations with already good accessibility (Vogler et al, 2014; Chemist Warehouse, 2014).

With respect to location, community pharmacies cannot be on the same site as another health provider (such as a GP) unless the National Health Service Commissioning Board confirms that the pharmacy will secure the uninterrupted provision of essential services during opening hours and the effective provision of face to face contact (NHS, 2013). There are no regulations on how close pharmacies can be to one another, with many pharmacies being clustered in groups of two or three.

The Medicines and Healthcare Products Regulatory Agency is responsible for regulation and governance of the manufacturing, licensing and the control of pharmaceutical prices. They are an executive agency of the UK Department of Health and also authorise the clinical trials of medicines, assesses the results of trials, monitors the safety and quality as well as the subsequent removal of a medicine from the market if required (Cylus et al, 2015).

Within the UK, all pharmacists, pharmacy technicians and pharmacy premises must be registered with the General Pharmaceutical Council. This organisation is responsible for workforce regulation in England, Scotland and Wales. The Pharmaceutical Society of Northern Ireland is the regulatory and professional body for pharmacists in Northern Ireland (Cylus et al, 2015).

The guidelines for extemporaneous preparation of infusions and injections for chemotherapy include:

- treatment must be administered by professionally qualified practitioners who have demonstrated clinical competence in the administration of cytotoxic chemotherapy;
- staff involved in the transportation or disposal of cytotoxic agents or their by-products should be given additional training;
- all required safety equipment (fridges, biologic safety cabinets, benchtop hoods with filters) should be present at the community pharmacy dispensing the cytotoxic agent;
intravenous chemotherapy agents are not to be stored for long periods of time in community environments; and

intrathecal, intravesical, intracavity and intraocular treatments are prohibited as methods of administering chemotherapy in a community setting (NHS, 2012).

Chemotherapy expenditure accounts for an estimated £1.4 billion a year and is the single biggest expense within NHS England’s Specialised Commissioning. It alone makes up almost a tenth of the entire central budget and the cost of medicines represents some 80% of this expenditure. This figure is also growing rapidly, with annual increases of around 8% due to rising demand and higher charges from medicine companies.

In the UK, decisions on the interchangeability of the original biologic medicine and biosimilar remain at the discretion of the prescribing physician. Substitution at the pharmacy level is currently prohibited. To increase awareness and uptake, hospitals in the UK publicise success stories about biosimilar effect. Biosimilars are included in the Pharmaceutical Price Regulation Scheme in which medicine prices are based on negotiations and manufacturer profit levels (Renwick et al, 2016).

5.1.3 Scope of services, settings and distribution

Community pharmacies provide a number of essential and advanced services to the public. Primarily, they are involved in dispensing medicines and facilitating repeat dispensing. In addition, they also provide the following essential services: anticoagulation monitoring, emergency hormonal contraception, head lice management and treatment, medical administration services, minor ailment scheme, prescriber support services, aged care visits, gluten free advice and assistance, home delivery services, medicines assessment and compliance support, out of hours services, pregnancy testing, palliative care, prescriber support services, return of sharps boxes, seasonal flu vaccination services, supervised administration of prescribed medicines, screening services, smoking cessation services, and syringe and needle exchange. These services are typically paid for under the funding arrangements described in Section 5.1.2 (PSNC, 2016c; Community Pharmacy Wales, 2016).

Advanced services include:

- **Appliance Use Review (AUR):** specialised services to assist patients with prescribed appliances such as catheters, stoma and incontinence appliances. Information services on these appliances is also provided. A pharmacist may receive £28 for conducting a review within the pharmacy itself, or £54 for a review that is performed in the patient’s home.

- **Discharge Medicines Review:** provided to patients recently discharged from hospital to ensure that patients know about changes to their medicines and when to take them.

- **MUR:** this involves a pharmacist explaining to a patient how to properly and safely use their medicines and to facilitate any questions the patient may have. Pharmacists are reimbursed £28 for the provision of a MUR.

- **Stoma Customisation Service:** Stoma appliances are modified and tailored based on patient preference. A fee of £4.32 is provided per qualifying item dispensed.

- **New Medicine Service** is a service that assists patients with adjusting to taking a new medicine, and to receive advice. Pharmacists receive £20–£28 for each completed service (Community Pharmacy Wales, 2016; PSNC, 2016c).
To evaluate the impact of a pharmacist-led patient education and diabetes monitoring program on blood glucose and other cardiovascular risk factors in the community setting, 46 patients with type 2 diabetes attending two community pharmacies in Hertfordshire were randomised to either an intervention or control group. These patients were seen for monitoring and counselling by a community pharmacist on 6 occasions over a 12-month period. Significant reductions in blood glucose, blood pressure, body mass index and blood glucose were observed in the control versus intervention groups. The study concluded that education and counselling by community pharmacists can result in favourable improvements to the cardiovascular risk profile of patients with type 2 diabetes (Ali et al, 2012).

Another study conducted in community pharmacies across four Primary Care Trusts in England evaluated the effectiveness of a community pharmacy weight management clinic in assisting obese patients to reduce their weight. After six months, weight and waist circumference were reduced and there was a reduction in blood pressure. The study concluded that a community pharmacy weight management program can assist participants to reduce weight and waist circumference (Boardman and Avery, 2014).

Besides community pharmacies, other dispensaries may be allowed to dispense prescription medicines to outpatients. One reason for this is to guarantee medicines provision in remote areas. This is most commonly undertaken by dispensing doctors (Kanavos, 2011). While restricted, the selling of prescription medicines over the internet is allowed also in the UK (Kanavos, 2011). Prescriptions can either be electronic (sent from the GP), or a paper-based prescription can be posted to the internet pharmacy provider. Some internet sites offer online consultations, and following the consultation a prescription is sent to a community pharmacy (NHS, 2015).

As can be seen in Table 5.2, in 2015 there were 22.1 community pharmacies per 100,000 population in the UK (FIP, 2015). In the UK, more than 80% of pharmacies belong to a chain (European Union, 2014). For each country, the breakdown of the number of pharmacies is:

- **England**: there were 11,674 pharmacies in 2015, or 5,577 people per pharmacy. (Department of Health England, 2015). Pharmacies in England are often clustered in groups of three or more (ATKearney, 2012).
- In **Wales** in 2013-14 there was a total 714 community pharmacies. This equates to 4,291 people per pharmacy (Welsh Government, 2015).
- In **Scotland**, there are approximately 1,200 community pharmacies in 2016. This is approximately 4,518 people per pharmacy in 2016 (Scotland Government, 2016a).

<table>
<thead>
<tr>
<th></th>
<th>UK</th>
<th>OECD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of practising pharmacists per 100,000 population (2013)</td>
<td>80.0</td>
<td>80.0</td>
</tr>
<tr>
<td>Number of pharmacies per 100,000 population (2015)</td>
<td>22.1</td>
<td>25.1</td>
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</tbody>
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As recent statistics for England show that 89% of the population has access to a community pharmacy within a 20 minute walk. The results are better for urban areas (98%), and worse in town and fringe areas (80%) and rural areas (19%) (Todd et al, 2014).
In England, pharmacy opening hours must be approved by local health board authorities. A pharmacy must be open for 40 hours a week (the “core contractual hours”), which cannot be amended without consent from NHS England. To be open for more than the core contractual hours a pharmacy needs to apply to NHS England (Pharmacy Services Negotiating Committee 2013). Prior to 2012, a pharmacy was allowed to open in large shopping centres and one-stop primary care centres if they agreed to be open 100 hours a week. However, this exemption was removed in 2012. The pharmacies that received the exemption prior to 2012 are still required to be open 100 hours a week (Pharmacy Services Negotiating Committee 2013; McKee, 2012).

5.1.4 Wholesaler supply arrangements

Within the pharmacy sector, manufacturers produce and distribute pharmaceuticals to wholesalers who subsequently on-sell these to pharmacies. Wholesalers supply approximately 85% of pharmacy dispensed medicines, with the remainder supplied by manufacturers or importers (OECD, 2014c).

Medicines are supplied to the market via two paths illustrated in Figure 5.2 and Figure 5.3. In pathway one, manufacturers sell medicines to wholesalers who then on-sell the medicines to pharmacies and hospitals.

**Figure 5.2: Pathway one for wholesale supply arrangements, UK**

![Pathway one for wholesale supply arrangements, UK](source: Deloitte Access Economics)

However, under pathway two, manufacturers sell directly to pharmacies and hospitals, while paying wholesalers a fixed fee for delivery.

**Figure 5.3: Pathway two for wholesale supply arrangements, UK**

![Pathway two for wholesale supply arrangements, UK](source: Deloitte Access Economics)
Margins captured at each level of the supply chain are critical in an environment where driving costs down is priority for the consumer. Manufacturers are therefore opting to distribute goods based on pathway two, otherwise known as direct to pharmacy supply, to protect their margins. This arrangement is detrimental to wholesalers’ profits, and adds a degree of complexity to the supply chain that previously did not exist (Moore et al, 2015).

Margins in Scotland have been documented in Moore et al (2015): in October 2014, the generic rate was 1.3% and the proprietary rate 5.7%. Margins between the government and manufacturer are accounted for under a voluntary agreement between the government and generic manufacturers to determine the price the government will reimburse pharmacists for dispensing generic medicines. Under the medicine tariff, the price paid by the government for these generic medicines is determined using the weighted average price charged by manufacturers. However, Scotland is exempt from this, as it has its own medicine tariff scheme (Moore et al, 2015).

Between the wholesaler and pharmacy, a standard discount deduction of 8.6% is applied against medicines being dispensed by pharmacies. The purchase price and quantity of medicines is determined with a number of community pharmacy representatives, with Scotland again having its own system and margin system (Moore et al, 2015).

### 5.1.5 Adoption of technology

The England NHS has implemented an EHR, which is used by community pharmacies along with many other organisations in the wider health system. The 2014 NHS Five Year Forward View (NHS England et al, 2014) outlined the ‘paperless strategy’ for clinicians in primary care, urgent and emergency care services be paperless and utilising electronic health (e-health) records by 2018. All other parts of the NHS are to be paperless by 2020 (NHS England, 2014). It is estimated that 49% of prescriptions were electronic, as at October 2016 (NHS Digital, 2016).

The National Programme for Information Technology (NPFIT), which ran from 2002 to 2011 made significant steps in implementing technology in UK health delivery. As of 2009, the Department of Health had confirmed that over 500,000 prescriptions had been transmitted electronically in England. The NPFIT also introduced the Summary Care Record Programme which provided all England patients a NHS number which served as a unique identifier. Subsequent basic GP records included patient information, such as allergies and ongoing medicine that are now used by more than 90% of GPs (King’s Fund, 2016).

Robotic dispensing in hospitals is now commonplace in the UK, and allows clinical staff more time to deliver more direct patient care and allowing for medicines optimisation. This is also occurring in community pharmacy. Recent studies of incorporating robotics into pharmaceutical dispensing have yielded positive results in the UK. A qualitative survey at Sunderland Royal Hospital pharmacy in 2012 suggested that a robotic dispensing machine linked to an electronic prescribing system not only increased efficiency but also offered enhancement of professional aspects of clinical pharmacy (Beard, 2012).

The NHS has also begun trialling remote dispensing machines (similar to those in Canada, see Section 3.2.5), which aim to reduce dispensary queues and improve access in remote locations. Results from these trials have shown that these machines are a viable alternative
to conventional pharmacies and can reduce costs, noting that the machines will never fully replace conventional pharmacies (ATKearney, 2012).

5.1.6 Reforms, innovations and trials

Examples of recent reforms in the UK are provided for each of the three countries of interest. **Scotland** recently implemented the Quality and Efficiency Payment which involves registered pharmacists receiving a monthly payment of £150 to boost quality and efficiency in pharmacies across Scotland (Community Pharmacy Scotland, 2016b).

In **England**, incentive schemes such as the New Medicine Service remuneration scheme encourage pharmacists to provide key help and assistance to patients along their medical journey (PSNC, 2016c). It has been noted that the current funding system needs to undergo reform so pharmacists receive the correct incentives for delivering professional services (Pharmacy Voice, 2011).

NHS England hopes to reduce variation and wastage in chemotherapy by implementing a national system of ‘dose banding’. The new banding system means that doses will be grouped into discrete bands that lie within 5–10% of a patient’s calculated dose (NHS England, 2016a). Dose banding will help speed up plans currently being developed as part of the Chemotherapy Services Review to deliver chemotherapy in a range of community and health settings other than hospitals. By implementing a national approach, NHS England expect that more than 90% of chemotherapy doses will be prescribed and administered in accordance with bandings by March 2018. A financial incentive scheme, has been developed and implemented, to encourage rapid adoption of the new approach (NHS England, 2016a).

A three year pilot which is deploying clinical pharmacists into GP practices may also be a key development for collaborative, cross sector pharmacy practice (Ridge, 2015). Within this pilot, clinical pharmacists are working as part of the general practice teams to resolve day-to-day medicine issues and consult with and treat patients directly. This includes providing extra help to manage long-term conditions, advice for those on multiple medicines and better access to health checks (NHS England, 2016b). A trial in 37 community pharmacies in Bradford City freed an estimated 900 hours of GP time across 27 practices by promoting self-care and pharmacist consultation before contacting the GP surgery (Urban, 2015).

In March 2016, the **Welsh** government announced that they would provide a £750,000 injection into the Efficiency Through Technology Fund aimed at fully integrating GPs and hospitals with community pharmacies. Additionally, the scope of community pharmacy services is to be increased under the Choose Pharmacy Scheme where individuals can access advice and treatment for minor ailments on demand from their local community pharmacy (Welsh Government, 2016).

5.2 Ireland

5.2.1 Health system context and expenditure

The Irish public health care system is primarily managed by the Government and the Department of Health and Children. The Health Service Executive (HSE) is responsible for the budget and management of health services, and is directly accountable to the Minister of
Health. The system is primarily funded through taxation. In 2006, 78.3% of total health expenditure (both public and private) was raised through from taxes incorporating pay-related social insurance as well as other income sources including excise duties. The remainder of health care expenditure are from private sources including VHI payments, out-of-pocket expenditure, pharmaceuticals and hospital stays (McDaid et al, 2009).

A majority of the Irish population have VHI, with the largest provider being the VHI Board, who accounted for approximately 75% of the market in 2006. The VHI operates as a not-for-profit, semi-state private insurance body, with the board appointed by the Minister of Health and Children (McDaid, et al, 2009).

The pharmaceutical sector is one of the largest economic output contributors in Ireland. In 2004 Ireland had net pharmaceutical exports of €15 billion, making it the largest net exporter globally. The Irish Pharmaceutical Healthcare Association (IPHA) noted that in 2007, 120 overseas companies had plants in Ireland, including 14 of the largest 15 pharmaceutical companies in the world (IPHA, 2007).

In 2013, Ireland’s pharmaceutical expenditure was €703 ($765) per capita (see Table 5.3), which was significantly higher than the EU average of €350 per capita. In 2011, the total cost of medicines under the General Medicines Scheme and Community Medicine Scheme was €1.51 billion, including the ex-factory cost of medicines and non-medicines (€1.34 billion), costs of distribution (estimated to be €129 million) and the retail mark-up to pharmacy contractors (€39 million) (OECD, 2016b).

### Table 5.3: Health care system indicators, Ireland

<table>
<thead>
<tr>
<th></th>
<th>Ireland</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population, 2014</td>
<td>4.6</td>
</tr>
<tr>
<td></td>
<td>Total population (millions)</td>
</tr>
<tr>
<td>Percentage of population &gt;65 years</td>
<td>12.7%</td>
</tr>
<tr>
<td>Expenditure, 2013</td>
<td>8.0%</td>
</tr>
<tr>
<td>Percentage of GDP spent on health care</td>
<td></td>
</tr>
<tr>
<td>Health care expenditure ($US) per capita</td>
<td>$4,157</td>
</tr>
<tr>
<td>Average annual growth rate of real health care expenditure per capita, 2009-2013</td>
<td>2.5%</td>
</tr>
<tr>
<td>Expenditure on pharmaceuticals per capita</td>
<td>$765</td>
</tr>
</tbody>
</table>

Note: for consistency throughout the report, amounts in this table are expressed in USD.

#### 5.2.2 Remuneration and regulation

The HSE’s Primary Care Reimbursement Service is responsible for making payments to Pharmacists in return for services and prescription medicines and items that they provide to the public under community drug schemes. The reimbursement price is the drug price paid by the HSE to Community Pharmacists when they dispense medicines:

- For medicines dispensed under the General Medical Services Scheme, community pharmacists are paid a dispensing fee which is based on volume of items dispensed (between €3.50 - €5).
For medicines dispensed under the Long Term Illness or Drugs Payment Schemes, the HSE pays community pharmacists a dispensing fee which is based on volume of items dispensed (between €3.50 - €5) plus 20% mark-up.

The National Corporate Pharmaceuticals Unit was established by the HSE to negotiate with industry regarding pharmaceutical pricing. Prices for pharmaceuticals are governed by agreements between the HSE, the Association of Pharmaceutical Manufacturers of Ireland and IPHA. The Irish Pharmacy Union is the community pharmacy representative and professional body in Ireland (McDaid et al, 2009).

The Pharmaceutical Society of Ireland (PSI) is responsible for registering pharmacists and pharmacies in Ireland. The scope of the PSI’s responsibilities also includes assessing and accrediting degree courses, inspecting pharmacies, maintaining codes of conduct and quality assurance, and processing complaints. The PSI is also the competency authority of recognising qualifications gained outside of Ireland (McDaid et al, 2009).

Ireland is subject to the same community pharmacy rules and regulations specified for the UK (see Section 5.1.2) as per the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013. Additionally, the PSI (2008) details criteria for pharmacy premises which include ensuring that the premises are easily accessible, secure, are identifiable as a health facility and have access to health information and promotional material. Criteria for the dispensary include that the physical environment must be clean, robust and hygienic, must be of sufficient size to accommodate operations of the pharmacy, must have adequate means of storage and appropriate and adequate equipment.

Chemotherapy guidelines for community pharmacies are the same as for the UK (see Section 5.1.2). For medicines self-administered by patients at home, anti-cancer medicines are funded by the community medicine schemes under the Primary Care Reimbursement Service (including the General Medical Services Scheme and Medicine Payment Scheme). Hospitals are able to recover the full cost of the specified systemic anti-cancer medicine treatment (Health Service Executive, 2014). Pharmacists are reimbursed the ingredient cost of the extemporaneously prepared infusions and injections of chemotherapy however there is an extemporaneous fee that they must cover (Health Service Executive, 2006).

5.2.3 Scope of services, settings and distribution

Community pharmacies in Ireland provide the following services (Pharmaceutical Society of Ireland, 2016): dispensing and repeat dispensing services, supply of emergency medicines, delivery services, vaccination services, testing services, extemporaneous dispensing, and aged care services. Other services include specialised offerings for smoking cessation, managing medicines services for patients on four or more medicines, the minor ailments scheme (a system where patients can go to the pharmacist first before needing to make a GP appointment), and MURs (Community Pharmacy North Ireland, 2013).

An investigation of the contribution of MURs to counselling practice in Irish community pharmacies found that pharmacists failed to realise the full potential offered by MURs. The findings revealed that MUR consultations were brief encounters dominated by closed questions, enabling quick and easy completion of the MUR form. Patients rarely asked questions and indeterminate issues were often circumvented by the pharmacist when they did. MURs did little to increase patients’ knowledge and rarely affected medicine use.
Barriers reported by pharmacists included workload and pharmacy organisation, which undermined pharmacists’ capacity to implement the MUR service effectively (Latif et al, 2011).

In September 2011 there was a total 1,659 community pharmacies registered with the PSI (Grant Thornton, 2012). Approximately half of these pharmacies are concentrated in Dublin, Cork, Galway, Waterford and Limerick. Location of these pharmacies is either on a main street (49% of pharmacies) or within local shopping centres (34%) that are situated nearby other health care services such as GP surgeries or primary care services (Grant Thornton, 2012). In recent years, an increased number of pharmacies have been organised into chains, particularly in the cities. However, Ireland still has a high number of individual pharmacies (Vogler et al, 2012). As shown in Table 5.4 the number of pharmacists and pharmacies per 100,000 people is higher in Ireland than for the rest of the OECD.

| Table 5.4: Number of pharmacies and pharmacists, Ireland |
|----------------|---------------|---------------|
|                | Ireland       | OECD          |
| Number of practising pharmacists per 100,000 population (2013) | 114.0 | 80.0 |
| Number of pharmacies per 100,000 population (2015) | 37.5 | 25.1 |

Source: OECD (2015)

Currently, GPs may provide medicines and medicines directly to patients if the GP has only one practice centre and it is three miles or more from the nearest retail pharmacist. Hospitals and other specialist institutions may also provide medicines, medicines and aids and appliances directly. The rules regarding whether medicines are free or subsidised are the same regardless of who provides them. Currently, 108 rural GPs are prescribing simple medicines in Ireland (Citizens Information 2016; The Journal, 2016).

5.2.4 Wholesaler supply arrangements

In Ireland, the distribution arrangements follow two pathways, as per the UK (see Section 5.1.4). Similar to the UK, Irish manufacturers are choosing to bypass the wholesaler to sell directly to pharmacists (pathway two). Bypassing the wholesaler in this manner removes the cost of fulfilling the services provided by the wholesaler (ISPOR, 2009). Since the mid-2000s, the Irish Government has introduced a series of reforms with the aim of reducing pharmaceutical prices and expenditure. This included a halving of the wholesale mark-up from 17.66% in 2008 to the current mark-up of 8% (Economic and Social Research Institute, 2013).

5.2.5 Adoption of technology

In 2015 the Irish HSE leadership presented seven strategic programs in conjunction with the Office of the Chief Information Officer. The seven programs would be areas of focus and priority, acting as the catalyst for better integrating and incorporating technology in the delivery of health in Ireland (eHealth Ireland, 2015).

One of the seven programs identified is the ePharmacy Program which will assist the delivery of an ePharmacy Strategy for Ireland. The program will identify centres of ePharmacy excellence, for sharing lessons and current best practices. The eHealth Program will support a series of initiatives including (eHealth Ireland, 2015): a national medicinal product
catalogue, e-prescriptions in primary care, hospital group closed loop pharmacy, a patient portal, paediatrics digital pharmacy record, tools for better pharmacy management, prescribing records as part of discharge processes, prescribing analytics, and better care through improved pharmacy. E-prescriptions in Ireland are still at an early stage (Mudiwa, 2015).

5.2.6 Reforms, innovations and trials

Reforms implemented from 2007 onwards in Ireland have significantly altered the environment that community pharmacies operate and function in. Established by the Pharmaceutical Society of Ireland, the outcome of these reforms has included having a senior pharmacist in charge of the clinical governance of all community pharmacies, the establishment of private consulting rooms in all community pharmacies and the development of the role of the pharmacist to include administering vaccinations for seasonal influenza (Leading Edge Group, 2012). Reforms are now looking to develop the role of pharmacists in Ireland in line with best practice methods internationally.

The Pharmacy Act 2007 defined the role of the superintendent pharmacist and supervising pharmacist, also stipulating that a pharmacy owner cannot lawfully operate a pharmacy without both a superintendent and supervising pharmacist. The management and administration of the sale and supply of medicines is under the personal control of the superintendent pharmacist. The superintendent pharmacist is the person who is in overall control of professional and clinical management. They are able to act in respect to multiple pharmacies and must have a minimum of three years post-registration experience. The supervising pharmacist is the pharmacist who is responsible for day-to-day management of the pharmacy. A supervising pharmacist can only act in respect of one pharmacy premises and must have at least three years of post-registration experience (Pharmacy Act, 2007).

The superintendent pharmacist model was introduced as a measure to ensure that the management and administration of the sale and supply of medicines in retail pharmacies in Ireland is firmly under the control of a senior pharmacist with a defined minimum level of experience. Prior to the introduction of the Pharmacy Act 2007 which established the superintendent pharmacist role, pharmacy in Ireland was largely unregulated in terms of openings and practice. As such, it was possible for non-healthcare professionals to own and operate a pharmacy without having a defined relationship between the owner and the responsible pharmacist(s). The responsibilities and accountabilities for that pharmacy practice and most importantly, for the patient, were not clearly defined. With the introduction of the superintendent pharmacist as a legal prerequisite for a company to open or operate a registered pharmacy, the role of the pharmacist and owner are inextricably linked (O’Brien, 2010).

The 2012 reforms implemented by the Irish Government included an agreement with the Irish Pharmaceutical Healthcare Association which involved savings of up to €400 million due to a new pricing and supply model. Part of these reforms involved increasing the penetration of generic medicines as a proportion of the off-patent market. In 2016, generics count for over 53% of the total off patent market by value and 73% by volume. As of March 2016, ongoing negotiations for a new supply agreement were being discussed with the Department of Health, the Health Service Executive, the Department of Public Expenditure and Reform and the Office of Government Procurement (European Commission, 2016).
Previously the Irish government implemented two interrelated policies that (a) restricted the opening of new pharmacies and (b) increased the quality of pharmacy services through contract specification. The outcomes of these policies resulted in increased returns to existing pharmacies, however both policies were found to have little effect on incentivising community pharmacies to improve quality services (Gorecki, 2011).
6 Analysis

This chapter presents a comparative analysis of community pharmacy models in the other countries with the Australian model under the 6CPA.

6.1 Health system context and expenditure

Of the 13 countries that our research and analysis covers (including Australia), each have differing structures, policies and responsibilities within their health care systems. It is clear that for all countries, government plays an integral role in managing, delivering services and funding health care.

Of the 13 countries, 12 countries (excluding the USA) provide universal public health care to their citizens, primarily funded by government. Some countries, including Australia offer one national health insurance system which provides reimbursement of defined health care services. Similarly, Canada, Denmark, Ireland, New Zealand, Norway, Spain, Sweden, and the UK provide universal health coverage through a national scheme, with some regional oversight. In contrast, there are a range of insurance providers offering public health coverage in France and Japan. In France, insurance schemes are selected primarily on the basis of where people work; the schemes do not compete. In the Netherlands, SHI is purchased from private insurers, which can be changed annually. In Japan, there are more than 3,400 insurance providers, and insurance plans are based on employment status and/or place of residence. The USA does not have a universal public health care system; health services are mainly provided privately.

Private health insurance also plays a role, to varying degrees, in the different countries’ health systems. In general, private health insurance plays a supplementary role to public health insurance in all systems, excluding the USA and the Netherlands. In Australia, Canada, Denmark, Ireland and Japan, uptake of private health insurance is higher. However, it still primarily supplements public health care, offering greater choice of providers, faster access and rebates for selected services. Around half of the Australian population has private hospital and/or general treatment coverage. Around two-thirds of Canadians, one-third of Danes, and the majority of Japanese hold private health insurance for services not covered by public reimbursement. In contrast, uptake of supplementary private health insurance covers 10.9%, 8%, 13%, and 10% of the populations of the UK, Norway, Spain and Sweden, respectively in 2015.

Two commonly used measures to compare national expenditure on health are on a per capita basis and as a percentage of GDP. GDP represents the total value of goods and services produced in a given time period, in this case one year. The information used for our analysis and in the figures below have been compiled from the OECD World Data Bank and The Commonwealth Fund.

Note: this treats the UK as a single country.
Chart 6.1: Health expenditure, by country


Chart 6.1 shows that total health expenditure per capita varies significantly between the countries identified for comparison to Australia. Average per capita expenditure on health care ranged from $2,204 in Spain, up to $9,086 in the USA. In Australia, per capita health expenditure is $4,121.5. Australia’s per capita health expenditure is comparable to 7 of the 12 other countries reviewed. This includes Canada ($4,569), Denmark ($4,847), France ($4,361), Ireland ($4,157), Japan ($3,713), New Zealand ($3,855), and the UK ($3,364). The Netherlands ($5,131), Norway ($6,170), Sweden ($5,153) and the USA ($9,086) had per capita health expenditure substantially higher than Australia, and in the case of the USA, higher than all other countries reviewed. Australia’s health expenditure is below the 12 country average of $4,718, but is likely skewed by the wide range of values.

Average health expenditure as a proportion of GDP of the 13 countries reviewed ranged between 8% in Ireland, up to 17.1% in the USA, based on latest figures. The other 11 countries ranged between 8.8% (the UK) to 11.5% (Sweden). In Australia, health expenditure as a proportion of GDP was 9.4% in 2013. The 12-country average health expenditure as a percentage of GDP was 10.8%.

Whilst the majority of the countries examined have similar per capita expenditures and similar expenditure as a percentage of GDP, the sources of funding differ. Australia’s health care system is primarily funded by general government taxation, including the Medicare Levy. This is similar to Canada, Denmark, Ireland, New Zealand, Norway, Spain, Sweden and the UK, whilst the French and Japanese health care systems are predominantly privately funded.
Pharmaceuticals and medicines are an important component of any health system. In comparing countries, pharmaceutical expenditure per capita is a useful measure. Chart 6.2 illustrates that pharmaceutical expenditure per capita ($USD) varies greatly between countries, ranging from $288 in Denmark, to $1,034 in the USA. This compares to $590 in Australia, which was higher than the majority of countries studied, excluding Canada ($761), France ($622), Japan ($756), and the USA ($1,034). Australia’s pharmaceutical expenditure per capita is higher than the comparison average of $578. There are a number of factors which influence this, including the uptake of generic medicines, differing pricing regulation and differing policies on medicines which may be supplied over the counter in certain countries, yet require prescription in others.

**Chart 6.2: Per capita pharmaceutical expenditure, by country**


The terms of reference for this report included identifying the government expenditure on community pharmacy in each of the 13 countries (see Section 1.1). In the Australian context, this includes the government expenditure for community pharmacy, as specified in the 6CPA. This includes: pharmacy remuneration for dispensing, the Premium Fee Dispensing Incentive Funding, Community Pharmacy Programs, remuneration for wholesalers that is covered by CSOs, the CSO funding pool, and fees for CSO distributors and pharmacies to distribute National Diabetes Services Scheme products. On an annual basis, this is equivalent to $2.1 billion USD per year.

However, data which covers a similar scope of expenditure was only available for two of the other countries: the UK, and New Zealand. Government expenditure on community pharmacy in the UK includes funding for essential services (such as dispensing fees, special dispensing fees, out of hours fees, and Practice Payments) and advanced services (these are outlined in Section 5.1.3). As the wholesale sector in the UK is not regulated in the same way
as the Australian system, there is no CSO-style spending in the wholesale sector. Government expenditure on community pharmacy in New Zealand is provided through the CPSAs, which are negotiated with each DHB. Services which are funded by the New Zealand government under the CPSAs include core pharmacy services, Long Term Condition pharmacy services, and specific pharmacy services (further detail is provided in Section 2.2.3). As per the UK, the wholesale sector in New Zealand does not include CSO-style payments, and so these are not specified in the CPSAs. The UK Government is estimated to spend $3.3 billion USD annually on the community pharmacy sector, which is equivalent to $50 per capita. For New Zealand, the annual expenditure is $0.3 billion USD, which is equivalent to $60 per capita. In Australia, the estimated per capita expenditure is $86.

While no other country outlines its government expenditure on community pharmacy as transparently as Australia does through the 6CPA, most other countries included in this report provide detail on the amount of government expenditure on prescribed medications. On an annual basis, this ranges from $0.8 billion USD in Denmark, through to $123.6 billion USD in the USA. On a per capita basis, government expenditure in these countries was the highest in the USA ($380), followed by Ireland ($351), France ($348), the Netherlands ($264), Canada ($252), Sweden ($237), Spain ($228), Norway ($226) and Denmark ($146).

### 6.2 Remuneration and regulation

This section compares international approaches with the Australian approach in regards to remuneration, regulation, regulatory and other arrangements or incentives to promote high standards of delivery, chemotherapy arrangements and biosimilar policy.

#### 6.2.1 Remuneration

Changes to pharmacy remuneration in Australia were recently implemented with the commencement of the 6CPA on 1 July 2015. An AHI fee was introduced to replace the former six-tier pharmacy mark-up. The intention of this revision was to delink remuneration from the price of a medicine to allow changes to pricing policy that will not have a significant flow-on impact on pharmacy remuneration.

Similar to Australia, pharmacy remuneration arrangements in five of the other countries reviewed consisted of both a regulated dispensing fee and regulated pharmacy margin (now AHI fee in Australia) that are paid to pharmacists by the government on a per service basis. This includes Denmark, France, New Zealand, Norway and Ireland. In contrast, pharmacy margins are unregulated at a national level in Canada, Japan, the Netherlands, the UK and the USA and are either negotiated privately between pharmacies and wholesalers (Japan, the USA and the Netherlands), or negotiated at the jurisdictional level (Canada). In the UK, the funding model for pharmacists includes a pool of retained margins.

There are generally four different types of regulated pharmacy margins (or mark-ups): regressive (a fixed percentage which decreases as the price to which it refers increases), progressive (a fixed percentage which increases as the price to which it refers increases), linear (an equation is applied to all price ranges) or flat fee (a flat percentage is applied to all price ranges), or a combination of these. The most common type of pharmacy margin was regressive; this was the case in France and Sweden, and a combination of regressive and fixed is used in both Norway and Spain. Australia previously had a regressive pharmacy margin.
that was replaced in 2015 with the AHI fee – of a predominantly fixed type. In New Zealand, the pharmacy margin is progressive and increases from 4% to 5% as the price of the medicine increases. In Denmark, pharmacy margins are linear, in which an equation is applied to all medicines regardless of price. In Ireland, a flat margin of 20% is applied to medicines dispensed under the Long Term Illness and Drug Payment Scheme. Table 6.1 shows the pharmacy margins and dispensing fees for each of the countries.

Table 6.1: Pharmacy margins and dispensing fees, by country

<table>
<thead>
<tr>
<th>Country</th>
<th>Margin Type</th>
<th>Margin Amount</th>
<th>Dispensing Fees Amount (AUD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Fixed (predominantly)</td>
<td>$3.54 (&lt;$180)</td>
<td>$7.02</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$3.54 + 3.5% ($180-$2,089.71)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>$70.92 (&gt; $2,089.71)</td>
<td></td>
</tr>
<tr>
<td>Canada</td>
<td>Varies by jurisdiction</td>
<td>Varies by jurisdiction</td>
<td>Varies by jurisdiction</td>
</tr>
<tr>
<td>Denmark</td>
<td>Linear (fixed)</td>
<td>8.4% + $1.53</td>
<td>$1.91</td>
</tr>
<tr>
<td>France</td>
<td>Regressive</td>
<td>25.5% - 6%</td>
<td>$0.73-$1.45</td>
</tr>
<tr>
<td>Ireland</td>
<td>Flat fee</td>
<td>20% (in some situations)</td>
<td>$4.98 - $7.12</td>
</tr>
<tr>
<td>Japan</td>
<td>Privately negotiated</td>
<td>N/A</td>
<td>$1.89 - $5.17 + $4.79 - $6.30 (guidance)</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Unregulated</td>
<td>N/A</td>
<td>Deregulated</td>
</tr>
<tr>
<td>New Zealand</td>
<td>Progressive</td>
<td>4% - 5%</td>
<td>$4.10 + $0.94 (handling)</td>
</tr>
<tr>
<td>Norway</td>
<td>Combination of regressive and fixed</td>
<td>7% - 3%</td>
<td>Nil.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>+ $4.27</td>
<td></td>
</tr>
<tr>
<td>Spain</td>
<td>Combination of regressive and fixed</td>
<td>27.9% (&lt;$130.51); $54.65 ($130.51-$284.86); $61.77 ($284.86-$712.16); $68.89 (&gt; $712.16)</td>
<td>Nil</td>
</tr>
<tr>
<td>Sweden</td>
<td>Regressive</td>
<td>Average of 21.3%</td>
<td>Nil</td>
</tr>
<tr>
<td>UK</td>
<td>Unregulated</td>
<td>Retained margins</td>
<td>$1.43</td>
</tr>
<tr>
<td>USA</td>
<td>Unregulated</td>
<td>N/A</td>
<td>Nil</td>
</tr>
</tbody>
</table>

Source: Deloitte Access Economics analysis.
Note: N/A = not available.

As shown in Table 6.1, pharmacy margins range from 3% in Norway (for higher priced medicines as the margins are regressive), up to 27.9% in Spain, 25.5% in France and, on average, 21.3% in Sweden. Noting that in both Spain and Sweden, dispensing fees are not available and in France, dispensing fees are the lowest of the countries reviewed.

Dispensing fees are not provided to pharmacists in Spain, Sweden or the USA. Dispensing fees ranged from $0.73 per pack dispensed in France (for prescriptions with five or more medicines), up to $7.12 in Ireland. Australia was only slightly lower than the highest dispensing fees at $7.02. In Japan, dispensing fees for pharmacists include both the technical fee (up to $5.17) and a fee for the provision of medication guidance to patients (up to $6.30). Therefore, pharmacy dispensing fees in Japan can range up to $11.47 per pack dispensed. In
general, where dispensing fees were higher (or absent), pharmacy margins were comparably lower. In both Spain and Sweden, dispensing fees are foregone while pharmacy margins are generally higher.

Interestingly, dispensing fees in Ireland, and to some extent, Japan and France, operate on a volume basis. In Ireland, the fee reduces from €5.00 (lower volume) to €3.50 (higher volume) depending on the volume of medicines dispensed. In Japan, dispensing fees are subject to a premium which considers the number of prescriptions dispensed per month. In France, the fixed dispensing fees vary from €1.02 per item to €0.51 for prescriptions which have five or more medicines. In all other countries reviewed, dispensing fees were fixed per item dispensed.

As some of the margins in Table 6.1 are expressed in percentage terms and are thus difficult to compare with margins expressed in dollar terms, a simple analysis was undertaken to calculate the total pharmacy remuneration (margins plus dispensing fees) for each country, based on the Australian price of the top three medicines (by government expenditure) on the PBS. It is important to note that the price of a particular medicine can vary significantly between countries. For example, Medicine A may be more expensive in Australia than in Canada, but Medicine B may be more expensive in Canada than in Australia. However, obtaining local prices for each medicine in each of the countries and conducting a detailed benchmarking exercise is beyond the scope of this analysis, and so Australian prices have been used for this analysis.

Table 6.2 compares the pharmacy remuneration (in AUD) by country for atorvastatin, esomeprazole and adalimumab, based on the Australian PBS price. This assumes that one prescription for one quantity of the medicine is dispensed. The price of the medicine is not included in the remuneration. The stated remuneration does not include any difference between the approved price paid to pharmacy by the government or insurer, and the actual negotiated price paid by the pharmacy to the wholesaler or manufacturer, which can provide a significant source of revenue in some cases.
Table 6.2: Comparison of pharmacy remuneration for three commonly used medicines, by country

<table>
<thead>
<tr>
<th></th>
<th>Atorvastatin 80mg</th>
<th>Esomeprazole 40mg</th>
<th>Adalimumab 20mg/0.4mL injection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Australia</strong></td>
<td>$10.56</td>
<td>$10.56</td>
<td>$60.91</td>
</tr>
<tr>
<td><strong>Canada</strong></td>
<td>Varies by jurisdiction</td>
<td>Varies by jurisdiction</td>
<td>Varies by jurisdiction</td>
</tr>
<tr>
<td><strong>Denmark</strong></td>
<td>$3.88</td>
<td>$5.37</td>
<td>$139.39</td>
</tr>
<tr>
<td><strong>France</strong></td>
<td>$2.80</td>
<td>$7.30</td>
<td>$98.56</td>
</tr>
<tr>
<td><strong>Ireland</strong></td>
<td>$7.12</td>
<td>$7.12</td>
<td>$7.12</td>
</tr>
<tr>
<td><strong>Japan</strong></td>
<td>Unregulated</td>
<td>Unregulated</td>
<td>Unregulated</td>
</tr>
<tr>
<td><strong>Netherlands</strong></td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>New Zealand</strong></td>
<td>$5.25</td>
<td>$5.96</td>
<td>$85.96</td>
</tr>
<tr>
<td><strong>Norway</strong></td>
<td>$4.64</td>
<td>$5.88</td>
<td>$52.82</td>
</tr>
<tr>
<td><strong>Spain</strong></td>
<td>$1.47</td>
<td>$6.40</td>
<td>$68.89</td>
</tr>
<tr>
<td><strong>Sweden</strong></td>
<td>$1.12</td>
<td>$4.88</td>
<td>Unclear</td>
</tr>
<tr>
<td><strong>UK</strong></td>
<td>Unregulated</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>USA</strong></td>
<td>Unregulated</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Source: Deloitte Access Economics analysis.

As shown in Table 6.2, pharmacy remuneration was highest in Australia for both atorvastatin and esomeprazole (both $10.56). Remuneration was lowest in Sweden (noting that only an average margin was available for this calculation) for both atorvastatin ($1.12) and esomeprazole ($4.88). In Sweden, dispensing fees are not included in the pharmacy remuneration arrangement. For the higher cost medicine (adalimumab), pharmacy remuneration was highest in Denmark ($139.39), which uses a fixed mark-up scheme and lowest in Ireland ($7.12), which only provides a flat dispensing fee for medicines dispensing under the General Medical Services Scheme. Remuneration in Australia for adalimumab was in the middle of the range ($60.91) and comparable to Norway ($52.82) and Spain ($68.89). It is important to note that these results do not take into consideration how pricing arrangements are affected by volume, and the operating costs, purchasing power and the price to pharmacy in each country.

Evidence of co-payments and safety nets was found for most of the countries in this analysis. In Australia, once the threshold for out of pocket expenses is reached, concessional patients no longer have to make a co-payment towards their medicines, and regular patients pay only the concessional co-payment ($6.20 instead of $38.30). Countries such as France, Japan, Norway and the UK have different co-payment rates or different safety net levels for some members of society, such as children, the elderly, concessional patients and those with certain medical conditions; or have different co-payments for essential and highly effective medicines. Norway provides free access to essential medicines for some people.

Sweden has two tiers, whereby out-of-pocket payments are reduced from a certain tier, until the second tier is reached at which point no more out-of-pocket expenses are levied on a patient. Under the ACA, the USA caps out-of-pocket expenses for most individuals and
families at $6,600 USD and $13,200 USD, respectively. Denmark reimburses 85% of expenses once a safety net of $394 USD is reached, however chronically ill people with high medicine usage can apply for 100% reimbursement once they reach $498 USD in a year. Japan has a co-payment ceiling for low income people, and sets ceilings for other people based on income and age.

The UK allows people with high prescription medicine needs to prepay an amount of $147 USD for 12 months, which caps their expenditure at this level for the entire year regardless of the amount of medicines they use. New Zealand families are only required to pay co-payments for the first 20 prescriptions in a year, after which all subsequent prescriptions are free. In Canada, out-of-pocket spending is capped when it reaches 3% of an individual’s income.

6.2.2 Regulation

Consistent with the restrictions in Australia, ownership of pharmacies is limited to pharmacists in Spain and France. However, there are no restrictions on ownership in Ireland, Canada, Japan, the Netherlands, the UK and the USA. In Norway and Sweden, only doctors and the pharmaceutical industry are excluded from ownership. While in New Zealand and Denmark, non-pharmacists can have part ownership in a pharmacy if a pharmacist is the majority owner.

Restrictions on the number of pharmacies per owner exist in Australia, Denmark, France, New Zealand, and Norway. In New Zealand, a pharmacy owner can have a majority share in up to five pharmacies, while in Norway, no pharmacy or pharmacy chain can have a national market share (in terms of number of pharmacies) greater than 40%. The number of pharmacies a pharmacist can own or co-own varies among the jurisdictions in Australia. No restrictions exist in the two Territories, while Western Australia and Tasmania allow four, Queensland, NSW and Victoria allow five; and South Australia allows six per pharmacist.

In terms of pharmacy location, Australia, Denmark, France and Spain restrict the location of pharmacies on the basis of population serviced, and proximity to other pharmacies. The UK and Ireland also place restrictions on the location of pharmacies and approval is needed prior to opening a new pharmacy; however this does not consider proximity to other pharmacies. There are no restrictions on location of pharmacies in Canada, Japan (although approval is needed), the Netherlands, Norway, New Zealand, Sweden and the USA.

There was no obvious relationship observed between countries which restrict ownership to pharmacists (Australia, France and Spain) and the degree of horizontal integration among retail pharmacies. For example, in Australia 65.3% of the retail market is controlled by five companies, while in Spain and France there is limited horizontal integration.

Other countries which do not restrict ownership to pharmacists also display horizontal integration. In the Netherlands, approximately 45% of community pharmacies are part of a chain, and many of these are owned by wholesalers. In Sweden, recent reforms have opened up the retail market, with 11 companies covering most of the market, of which three are dominant providers. In the UK, 80% of community pharmacies belong to a chain, while in Ireland the number of pharmacies in a chain has increased in recent years, particularly in cities (however, there are still a large number of individual pharmacies).
6.2.3 Regulatory and other arrangements or incentives to promote high standards of delivery

Evidence was found that many of the countries promote high standards of delivery and accountability by requiring that pharmacists be registered, possess appropriate academic qualifications, and undertake ongoing learning. To be recognised as a qualified pharmacist in Australia, pharmacists must be registered with the Pharmacy Board of Australia having met the ongoing standards of professional registration including relevant qualifications (minimum four-year Bachelor of Pharmacy degree) and supervised practice arrangements. In New Zealand, pharmacists are required to hold Pharmacy Council of New Zealand registration and an Annual Practising Certificate, which requires a minimum of 450 hours practice over the preceding three years.

In Japan, the Council of Pharmacists’ Credentials was established in 2004 to encourage continuing professional knowledge and skill development of pharmacists. Pharmacist qualifications in Japan have recently been revised from a four-year to a six-year degree. In the Netherlands, the quality of care provided by pharmacists is regulated through the BIG. Initial BIG registration and five-yearly re-registration is obligatory for individual providers. All pharmacists are obliged to undertake a minimum of 200 training points (one point for each hour of continuous training attended) every five years. To work as a community pharmacist in Spain, it is compulsory to register in a Province Pharmacists’ Association. To run a pharmacy in Denmark, a person must hold a master’s degree in pharmacy.

In the USA, pharmacists must pass the North American Pharmacies Licensure Examination, and the Council on Credentialing in Pharmacy has developed guiding principles for post-licensure credentialing of pharmacists. In Canada, there is a National Model Licensing Program which specifies core requirements for academic qualifications of pharmacists including degree and language proficiency information, pharmacy jurisprudence examinations and the national licensing examination. Within the UK, all pharmacists, pharmacy technicians and pharmacy premises must be registered with the General Pharmaceutical Council. In Scotland, to encourage quality and efficiency in pharmacies, a monthly Quality and Efficiency Payment for registered pharmacists of £150 was recently introduced. In Ireland, the PSI is responsible for registering pharmacists, and their role includes accrediting degree courses, and deciding whether qualifications gained outside of Ireland will be recognised.

In addition to regulating pharmacists, several countries also prescribe quality standards for pharmacies. A pharmacy that engages in model community pharmacy practices in Japan is certified as an accredited pharmacy by the pharmaceutical society of the relevant prefecture. Such pharmacies are allowed to display a sign indicating their accreditation at the front of the establishment. Also, some premiums are available for community pharmacies that meet the criteria, including level of generic substitution and service offerings such as operating hours, product line-up and collaboration with other dispensing pharmacies in the region. Pharmacy accreditation fees and pharmacy licenses differ in each jurisdiction in Canada, as do the standards which must be met to obtain a licence. In some areas of Canada there are no pharmacy accreditation or licensing programs in place, while other jurisdictions have annual fees for accreditation.
In Ireland, the PSI details criteria for pharmacy premises which include ensuring that the premises are easily accessible, secure, are identifiable as a health facility and have access to health information and promotional material. Criteria for the dispensary include that the physical environment must be clean, robust and hygienic, must be of sufficient size to accommodate operations of the pharmacy, must have adequate means of storage and appropriate and adequate equipment. In the USA, all states have some form of regulation around secure storage, recordkeeping, the forms or pads used for patient prescriptions and purity.

Some countries also require that pharmacies report adverse events, in order to promote high standards of delivery and accountability. In Denmark, under the Danish Healthcare Quality Program, pharmacies report adverse events at the pharmacies and adverse events that originate from other parts of the health care system to the national patient safety database. In Canada, pharmacies are required to report QREs, which include events such as dispensing errors, or other errors that might be identified by pharmacy staff prior to the dispensing of medicines. While standards differ in each jurisdiction, at a minimum community pharmacies are required to have a policy with steps outlined that must be taken when a QRE reaches the patient. Other jurisdictions require reporting of such incidents to a national database.

Limited evidence was found of regulatory arrangements to promote high standards at the wholesale and manufacturing level. At the manufacturing level, Australia regulates the manufacturing of medicines through the Therapeutic Goods Act 1989 and the Therapeutic Goods Regulation 1990. These requirements ensure that products which are manufactured by licence holders are safe and of a high degree of quality. The USA regulates pharmaceuticals through the FDA, which is a regulatory agency that focuses on whether a medicine is safe, effective and of acceptable quality to be available for sale in the country. In Canada, Health Canada is responsible for approving medicines for sale in Canada, and works with the Canadian Agency for Medicines and Technologies in Health to analyse the proposed medicine and provide recommendations about the sale of the medicine. In Spain, Royal Decree 782/2013 regulates activities related to the distribution and brokering of medicinal products for human use. It sets the various requirements that distributors and storage companies of medicines (of human use) must comply with, sets the minimum operating requirements and defines the best practices in the sector.

6.2.4 Chemotherapy arrangements and biosimilar policy

In Australia, due to its complexity and limited availability (less than 50 pharmacies provide more than 70% of services) chemotherapy preparation attracts additional remuneration arrangements. Evidence of chemotherapy compounding pharmacies was also found for Japan, the USA (remuneration for which is negotiated privately), and the UK and Ireland, remuneration for which is prescribed by the NHS. Pharmacists are reimbursed the ingredient cost of the extemporaneously prepared infusions and injections of chemotherapy however there is an extemporaneous fee that they must cover. In Canada, chemotherapy is predominantly hospital prepared and delivered, which is similar to France and Spain.

Similarly to Australia, biosimilar policy in the countries evaluated has focused on interchangeability at the prescriber level and substitutability at the pharmacist level. For a biosimilar to be considered interchangeable, therapeutic equivalence must be demonstrated to ensure a biosimilar can be safely switched with the originator. In Australia, in order for a biosimilar to be approved as such, comparability to the reference product must be
demonstrated through clinical study. In the USA, registration of biosimilars has been distinguished with two separate pathways – one for non-interchangeable biosimilars, and one for interchangeable biosimilars, a process that is significantly more complex.

In France and the Netherlands, interchanging between an original biologic medicine and a biosimilar once treatment has been initiated is not recommended, particularly where a patient is responding to treatment. However, substitution at a pharmacy level – whereby pharmacists have the authority to switch patients from a branded biological to a biosimilar – is encouraged for patients who are naïve (newly initiating) to treatment. In the USA, substitution is covered by state law however it is only allowed for those medicines that have been registered through the more complex pathway that determines a biosimilar is interchangeable. To date, an interchangeable biosimilar has not yet been approved through this pathway. Similarly, in Canada, decisions on substitutability are made at the provincial level however Health Canada has explicitly stated that it does not support automatic substitution. Currently, in Australia, the PBAC has the authority to determine whether a biosimilar can be substituted at a pharmacy level; this determination is made on a case-by-case basis. This is contrast to Norway and the UK, where substitution of biologic medicines with biosimilars by a pharmacist is prohibited.

6.3 Scope of services, settings and distribution

In addition to dispensing medicines, community pharmacists in Australia undertake professional services, such as reviewing medicines to improve adherence and management, and counselling about appropriate medicine use. These additional services are remunerated by the Australian government on a fee-for-service basis. Other countries that remunerate pharmacists on a per service basis for additional patient services include Canada (varies by province but includes immunisation and advanced medicine review); Denmark (dose dispensing and counselling); France (counselling for asthma and anticoagulant use); Japan (medicine guidance and provision of patient information); Netherlands (device instruction medicine guidance, review and counselling); New Zealand (reviews of medicine management, use, therapy and long term condition, anticoagulation management); Spain (compounding); and the UK (advanced services such as appliance use, discharge review and new medicine review).

A number of countries as well as Australia offer unused medicine disposal services. This includes Denmark, Norway, Spain and Sweden. Counselling on quitting smoking is offered in Denmark (partially reimbursed), Ireland, Spain and the UK. Measurement services including blood pressure and blood glucose are offered in Denmark, Ireland, Norway, Spain, Sweden, the UK and the USA. These services do not generally attract additional remuneration. Anticoagulant management services provided by pharmacists are remunerated in France (€40 per patient) and New Zealand ($540 per user per year). Australia, Sweden, Ireland and the UK provide emergency contraception assistance.

Specific remuneration arrangements and incentives for pharmacists exist for generic switching Japan (additional dispensing and guidance fee) and France (increased rebate and annual bonus of up to €3,000 depending on the share of generics delivered). In France, it is mandatory for pharmacists to dispense generic medicines unless under specific instruction of the prescriber. Similarly, generic substitution is mandatory in Sweden.
In direct contrast to Australia, pharmacists in Canada have a wide range of professional offerings which would be considered beyond the scope of normal pharmacy practice in Australia. This includes the ability to prescribe medicines to patients for minor ailments, initiate prescription medicine therapy, offer therapeutic substitution, order laboratory tests and administer medicines by injection. Pharmacist Prescribers in New Zealand are also able to modify, initiate or discontinue medicines for patients under a team care arrangement with prescribers.

Besides community pharmacies, and hospital pharmacies for inpatients on discharge, emergency departments and outpatient clinics, the only other setting in which prescription medicines may be dispensed to the community in Australia, is by medical practitioners where there is no pharmacy located nearby. Dispensing doctors in rural areas are also able to dispense medicines in France, Ireland, Netherlands, Norway and the UK. In Spain and Sweden, only community pharmacies can dispense prescription medicines to the community.

In contrast to Australia, branch pharmacies – small outlets under the supervision of a pharmacy – can dispense medicines to the community in Denmark and Norway. Furthermore, in stark contrast to Australia, prescribers can dispense medicines directly to patients in Japan (although this is declining) and in the majority of USA states.

Similar to Australia, Denmark, the Netherlands, Norway, Sweden and the UK allow the purchase of prescription medicines from internet sources (‘internet pharmacies’). In the Netherlands, internet pharmacies must be attached to an actual pharmacy. In Sweden, patients can access and order e-prescriptions that are attached to their electronic ID. Counselling on appropriate medicine use can take place at a local pharmacy or over the telephone via a call centre. In the UK, internet pharmacies must be legally constituted with a supervising pharmacist and a storehouse. Prescriptions can either be sent electronically direct from GPs, or the patient can post their paper-based prescription. Pharmacists that sell over the internet in New Zealand need to have an Internet Pharmacy Accreditation. In Denmark, all prescriptions that are dispensed from online pharmacies are electronic, as the pharmacy can access the national infrastructure for e-prescriptions.

Chart 6.3 below compares the number of pharmacists and pharmacies per 100,000 population. These measures are useful in considering how many physical pharmacies and qualified pharmacists are serving a given population. It is important to note that a limitation of these measures is that they just reflect the geographic spread and location of pharmacists and pharmacies, and do not consider the consequent ease of access. For example, Denmark and the Netherlands do not have populations which would be considered rural or remote in the Australian context – so their relatively low rates likely reflect the permission of online sourcing in these countries, and hence are unlikely to indicate an access constraint.
The data collected highlight that Australia is just below the 12 country average of 87 pharmacists per 100,000 population, and 24 for the number of pharmacies per 100,000 population. In comparison to the Netherlands, which had the lowest number of pharmacists per 100,000 population, Australia has around four times the number of pharmacists per 100,000 population and nearly twice as many pharmacies per 100,000 population. When compared to Japan, which had the highest density of pharmacists and pharmacies, Australia has approximately half as many pharmacists and pharmacies per 100,000 population.

In terms of the average number of pharmacists per pharmacy, Table 6.3 shows that most pharmacies are grouped between 1.8 (the Netherlands) and 5.8 (Sweden), with the USA (9.0) and Denmark (12.8) being outliers. In comparing the average number of pharmacists per pharmacy, it is important to note that the underlying data on the number of pharmacists also includes pharmacists who work outside of community pharmacies, such as in hospital pharmacies. For this reason, care should be taken in interpreting these figures. For example, in 2012 75% of pharmacists in Canada worked in a community pharmacy, while in Japan 55% of pharmacists worked in a community pharmacy (OECD, 2015).
Table 6.3: Average number of pharmacists per pharmacy, by country

<table>
<thead>
<tr>
<th>Country</th>
<th>Pharmacists per pharmacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Netherlands</td>
<td>1.8</td>
</tr>
<tr>
<td>Ireland</td>
<td>3.0</td>
</tr>
<tr>
<td>France</td>
<td>3.1</td>
</tr>
<tr>
<td>Spain</td>
<td>3.2</td>
</tr>
<tr>
<td>Canada</td>
<td>3.4</td>
</tr>
<tr>
<td>Japan</td>
<td>3.6</td>
</tr>
<tr>
<td>Australia</td>
<td>3.6</td>
</tr>
<tr>
<td>New Zealand</td>
<td>3.6</td>
</tr>
<tr>
<td>UK</td>
<td>3.6</td>
</tr>
<tr>
<td>Norway</td>
<td>4.6</td>
</tr>
<tr>
<td>Sweden</td>
<td>5.8</td>
</tr>
<tr>
<td>USA</td>
<td>9.0</td>
</tr>
<tr>
<td>Denmark</td>
<td>12.8</td>
</tr>
</tbody>
</table>

Source: Deloitte Access Economics analysis.

The number of pharmacists and pharmacies in each country, on a per capita basis and also in terms of the number of pharmacists per pharmacy, is impacted by a number of factors. The OECD (2015) notes that the number of community pharmacies is impacted by the scale of involvement by government in sectoral planning, the remuneration model in each country, and the different dispensing channels for medicines in each country. For example, the number of pharmacists and pharmacies in Japan has increased significantly in recent years due to government efforts to separate prescribing and dispensing functions. As a result of this, the percentage of all prescriptions dispensed by pharmacists has increased from less than 40% in 2000 to 67% in 2013, with the number of pharmacies increasing by 18% over this period.

The USA has the highest per capita expenditure on pharmaceuticals of all the countries in this report, which may explain its relatively high number of pharmacists per pharmacy. In the Netherlands, the relatively low number of pharmacists per pharmacy can be partly explained by the fact that prescription pharmaceuticals can be purchased directly from doctors in some areas of the country. In Denmark, there are relatively few, but large, pharmacies which include branch pharmacies that are attached to the main pharmacy (OECD, 2015).

In Australia, by remoteness, the number of pharmacies per 100,000 population in urban areas in 2011-12 was 29.1 while in rural areas it was 12.6. It has been estimated that only 16% of pharmacists work in rural and remote regions. In New Zealand, only 1-2% of the population live more than 25 kilometres away from a pharmacy. Similarly in Spain, approximately 99% of the population have access to a community pharmacy in their territory. In England, 89% of the population has access to a community pharmacy within a 20 minute walk. On the other hand, the geographic distribution of pharmacies in France is relatively homogeneous because the licensing of pharmacies is regulated by demographic criteria.
6.4 Wholesaler supply arrangements

In Australia, medicines can be delivered from manufacturers to pharmacies using wholesalers (the ‘traditional method’), or via direct-to-pharmacy methods, an example of which is the Pfizer Direct exclusive distribution model which utilises DHL as sole logistics service provider (bypassing the wholesaler from the distribution equation).

As shown in Table 6.4, a number of countries allow direct delivery arrangements from the pharmaceutical manufacturers to pharmacies. These include employing a restricted number of wholesalers as sole agents to distribute products directly to pharmacy, or, indeed, using wholesalers as logistics providers for the same purpose. While the majority of pharmacy sales continue to originate from (full-line) wholesalers, in a number of countries the proportion of pharmacy sales originating directly from the manufacturer is over 10 percent (Denmark, Ireland, Netherlands, UK) and can be over 20 percent (France). In Canada, self-distributing pharmacy models exist whereby pharmacies do not use wholesalers but rather buy medicines from manufacturers directly. Sweden has a single channel distribution system whereby a wholesaler has the exclusive right to distribute medicines for a manufacturer.

Direct to pharmacy distribution is not currently used in Japan, New Zealand, or Sweden. In these countries, the traditional model is used for the distribution of medicines throughout the supply chain.
Table 6.4: Direct-to-pharmacy availability and uptake, by country

<table>
<thead>
<tr>
<th>Country</th>
<th>Direct-to-pharmacy Availability</th>
<th>Direct-to-pharmacy Estimated uptake</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Yes</td>
<td>Unclear</td>
</tr>
<tr>
<td>Canada</td>
<td>Yes</td>
<td>Unclear</td>
</tr>
<tr>
<td>Denmark</td>
<td>Yes</td>
<td>&gt;10%</td>
</tr>
<tr>
<td>France</td>
<td>Yes</td>
<td>&gt;20%</td>
</tr>
<tr>
<td>Ireland</td>
<td>Yes</td>
<td>&gt;10%</td>
</tr>
<tr>
<td>Japan</td>
<td>No*</td>
<td>N/A</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Yes</td>
<td>&gt;10%</td>
</tr>
<tr>
<td>New Zealand</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>Norway</td>
<td>Unclear</td>
<td>Unclear</td>
</tr>
<tr>
<td>Spain</td>
<td>Yes</td>
<td>~5%</td>
</tr>
<tr>
<td>Sweden</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>UK</td>
<td>Yes</td>
<td>&gt;10%</td>
</tr>
<tr>
<td>United States</td>
<td>Unclear</td>
<td>Unclear</td>
</tr>
</tbody>
</table>

Source: Deloitte Access Economics research and analysis.
Note: * In Japan, 3% of medicines are provided directly from manufacturers to medical institutions.

As shown in Table 6.5, wholesalers in Australia are remunerated on the basis of a regressive margin that decreases as the price of the medicine increases. For medicines that cost up to and including $930.60, the mark-up for wholesalers is 7.52%. For medicines that cost over $930.06, there is a flat mark-up price of $69.94.
Table 6.5: Wholesaler remuneration, by country

<table>
<thead>
<tr>
<th>Country</th>
<th>Margin Type</th>
<th>Margin Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Combination of regressive, fixed</td>
<td>7.52% (≤$930.06)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$69.94 (&gt; $930.06)</td>
</tr>
<tr>
<td>Canada</td>
<td>Unregulated</td>
<td>5%</td>
</tr>
<tr>
<td>Denmark</td>
<td>Unregulated</td>
<td>N/A</td>
</tr>
<tr>
<td>France</td>
<td>Combination of regressive, fixed</td>
<td>6.68% (&lt; €450)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>€0.30 (fixed fee)</td>
</tr>
<tr>
<td>Ireland</td>
<td>Regulated</td>
<td>8%</td>
</tr>
<tr>
<td>Japan</td>
<td>Unregulated</td>
<td>N/A</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Unregulated</td>
<td>N/A</td>
</tr>
<tr>
<td>New Zealand</td>
<td>Unregulated</td>
<td>3.5%</td>
</tr>
<tr>
<td>Norway</td>
<td>Unregulated</td>
<td>N/A</td>
</tr>
<tr>
<td>Spain</td>
<td>Combination of regressive, fixed</td>
<td>7.6% (≤ €91.63)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>€7.54 (&gt; €91.63)</td>
</tr>
<tr>
<td>Sweden</td>
<td>Unregulated</td>
<td>Average of 2-3%</td>
</tr>
<tr>
<td>UK</td>
<td>Unregulated</td>
<td>N/A</td>
</tr>
<tr>
<td>United States</td>
<td>Unregulated</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Source: Deloitte Access Economics research and analysis.
Note: N/A = information could not be located.

Of the countries included in the analysis, most do not regulate wholesale margins. Australia, France and Spain have regulated wholesale margins, while the other countries do not. The regulated countries all use a combination of regressive and fixed margins for wholesale remuneration. In France, the regulated remuneration for wholesalers comprises two components: a 6.68% margin on the manufacturing price before taxes of between €0 and €450, plus a fixed fee of €0.30. Spain similarly has a regulated margin that consists of both a fixed and regressive component.

For the unregulated countries, an official margin is not stipulated by the government and typically depends on private negotiations between the wholesaler and the pharmacy. As a result, the wholesale prices of medicines vary with individual pharmacies and hospitals. In the USA, PBMs influence the agreed wholesale margins. Of the unregulated countries for which market information was available, the average wholesale margin ranged from a low of 2% in Sweden to a high of 17.7% in Ireland.

The degree of horizontal and vertical integration differs between the countries. For example, Norway does not regulate its wholesale market, however there are three primary wholesalers in the market in Norway, with all three vertically integrated with their own pharmacy chain. The Norwegian Competition Authority has noted that this has led to reduced medicines accessibility. In Spain, there are several restrictions in operation in the distribution channel, and as such there is no vertical or horizontal integration at the retail level – all pharmacies are owned by pharmacists and no pharmacies are part of a chain. However, at the wholesale level the market is becoming more concentrated, and this is
expected to continue. In France, there is little horizontal integration at the wholesale level, and no vertical integration in the supply chain. In New Zealand the regulations which prohibit a pharmaceutical company from owning an equity stake in a pharmacy effectively negate any vertical integration.

Interestingly, compared to other developed markets, wholesalers in Japan take greater roles. The roles of wholesalers in Japan include price negotiation with medical institutions, collection of receivables from medical institutions, and medicines information provision on behalf of representatives from pharmaceutical companies.

6.5 Adoption of technology

Globally, there has been increased uptake of electronic technology within the health and pharmacy sectors. Main outcomes have included the development of:

- **EHRs**, which store patient information that can be shared between various health professionals that come into contact with a patient over their health care journey; and
- **E-prescriptions**, which includes systems which replace the traditional handwritten or printed methods of generating a prescription for a patient to take to their dispensing pharmacist, and also systems which store prescription information electronically but still require a paper prescription.
- **Other e-health and e-pharmacy interventions**, including telemedicine and telehealth, e-Health strategic plans and electronic reminder devices.

Denmark is generally recognised as being at the forefront of e-health initiatives. Technology is used at all levels of the health system. All citizens in Denmark have a unique electronic personal identifier, which is used in all public registries, including health databases. A shared medical card that contains encoded information about each patient’s prescriptions and medicine use — accessible by all relevant health professionals — has been implemented.

As shown in Table 6.6, all countries included in this study utilise e-prescriptions, uptake of which varies between the countries. Uptake is greater than 90% in Sweden and Denmark. The Netherlands (~70%), Spain (~80%) and Norway (~80%) also have high uptake. Use of e-prescriptions is lower in the UK (~50%), and the USA (~60%). France, Japan, Ireland and New Zealand have low penetration of e-prescriptions, with intentions for the services to increase in the future, while uptake in Australia is unclear.

Five of the countries still use a combination of paper-based and electronic systems for their e-prescriptions. In New Zealand, the secure system (NZePS) is used in conjunction with paper-based e-prescriptions. The Netherlands and the UK have a similar approach. In France, GPs can email the prescription to the pharmacy or patient. Japan has noted some implementation difficulties in moving to paperless e-prescriptions. Three of the countries have a completely paperless e-prescription model. In Spain, the information is stored on an individual’s healthcare card, while in Denmark and Sweden the information is stored on national servers which can be accessed by prescribers and pharmacists.
Table 6.6: e-prescription availability and uptake, by country

<table>
<thead>
<tr>
<th>Country</th>
<th>e-prescriptions</th>
<th>e-prescriptions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Availability</td>
<td>Estimated uptake</td>
</tr>
<tr>
<td>Australia</td>
<td>Yes</td>
<td>Unclear</td>
</tr>
<tr>
<td>Canada</td>
<td>Yes</td>
<td>~40%</td>
</tr>
<tr>
<td>Denmark</td>
<td>Yes</td>
<td>&gt;90%</td>
</tr>
<tr>
<td>France</td>
<td>Yes</td>
<td>Low, exact figure unclear</td>
</tr>
<tr>
<td>Ireland</td>
<td>Yes</td>
<td>Limited due to recent introduction</td>
</tr>
<tr>
<td>Japan</td>
<td>Yes</td>
<td>Limited due to recent introduction</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Yes</td>
<td>~70%</td>
</tr>
<tr>
<td>New Zealand</td>
<td>Yes</td>
<td>Limited due to recent introduction</td>
</tr>
<tr>
<td>Norway</td>
<td>Yes</td>
<td>~80%</td>
</tr>
<tr>
<td>Spain</td>
<td>Yes</td>
<td>~80%</td>
</tr>
<tr>
<td>Sweden</td>
<td>Yes</td>
<td>~90%</td>
</tr>
<tr>
<td>UK</td>
<td>Yes</td>
<td>~50%</td>
</tr>
<tr>
<td>United States</td>
<td>Yes</td>
<td>~60%</td>
</tr>
</tbody>
</table>

Source: Deloitte Access Economics research and analysis.

In Australia, My Health Record is the Australian EHR system that connects medical practitioners, hospitals and other health care providers. In the same way as Australia, many countries (including Canada, Denmark, France, the Netherlands, Ireland, Spain, Sweden, the UK and the United States) use EHRs or EHR equivalents within their health system, with varying degrees of uptake. For example, Denmark was the leading country for GP use of EHRs in 2014.

Different functionality within EHR frameworks also exists. For example, Sweden utilises its EHR framework by providing facilities to assist patients to schedule appointments, receive interactive services and sustain full health records and My Care pathways. In Canada, EHRs contain patient history and health information such as test results and prescription medicine. In Canada, e-prescriptions are stored within the EHRs. In 2014, it was estimated that 62% of all Canadians had medicine dispensing profiles in their EHRs.

Countries such as Norway have long-term plans to introduce seamless EHR systems, given that current electronic systems in use are fragmented and have little (if any) interoperability between health care providers. In Japan, EHRs are only used experimentally, with little interoperability between providers. Taking a different route to Australia, Japan is undertaking trials to introduce cloud computing for personal health information, rather than the EHR system. HIEs have been set up across the USA, which allow medical practitioners, including pharmacists, to access a patient’s information. Information such as lab tests, other medical tests and prescriptions can be transferred to other medical practitioners.

Recently in Japan, electronic patient information leaflets have emerged in response to increases in smart phone usage. Community pharmacy chains are developing a leaflet app with value added functions such as data transactions between connected devices, weight scales and pedometers. In Spain, an app for the management of professional services of
community pharmacists enables them to visualise and monitor the health problems of their patients has been developed.

Telemedicine and telehealth for pharmacy services are being increasingly used in a number of countries. These interventions are primarily used to assist with prescribing in rural or remote locations. Some countries, such as Ireland, have rolled out specific e-pharmacy programs that support national medicine product catalogues, e-prescriptions in primary care, hospital group closed loop pharmacy, patient portals, digital record systems and prescribing analytics.

Other technological initiatives have been implemented throughout Canada. One such initiative is a prescription dispensing machine in Ontario. These machines, called PharmaTrust MedCentres, are remote dispensing systems and allow users to communicate with a pharmacist who might be located elsewhere via videoconferencing. They have been installed in rural communities and allow access to pharmacists in communities where pharmacies may be scarce.

In Spain in recent years, a number of community pharmacies have begun to experiment with remote dispensing robots. These machines are placed in a community pharmacy and dispense the required medicines directly to the pharmacist with the touch of a button, with no need for the pharmacist to search for the products.

Additionally, the UK are evaluating the use of robotics in pharmaceutical dispensing. In Wales specifically, the ‘Efficiency Through Technology’ fund has been developed to promote electronic communication between GPs and hospitals with community pharmacies. Other interventions include the Netherlands’ trial of electronic reminder devices to promote adherence to statin treatment (although this was not found to be effective).

# 6.6 Reforms, innovations and trials

Reforms, innovations and trials are necessary to ensure the development and transformation of community pharmacies and the pharmacy industry as a whole. This can lead to increased affordability and quality use of medicines. Global trends in pharmaceutical sector reform have focused on price reforms, increased use of generic medicines and expanding the role of the pharmacist.

Australia recently began implementation of the 2015-2020 PBS Access and Sustainability Package. This includes removal of selected OTC medicines from the PBS, the ability for pharmacies to discount the PBS patient co-payment by $1 and the introduction of the AHI fee in place of the pharmacy mark-up. New Zealand has similarly begun a program of reform in the pharmacy sector, called the Pharmacy Action Plan 2016-2020. Major areas of focus include increasing the role of pharmacists in medicines management services and using technology to improve the efficiency of dispensing and supply services. New Zealand is also preparing to introduce the Therapeutic Products Bill later in 2016. This will include major changes such as removing restrictions on non-pharmacist ownership of pharmacies and the restrictions of pharmacies to physical locations.

Significant health system reform has been undertaken in the USA. Obamacare, or the ACA, aims to increase accessibility of health care for low-income earners through expansion of
Medicaid and increased subsidisations of private insurance. Impacts of this Act on the pharmacy sector have resulted in increased reporting requirements for pharmacy benefits management, increased demand for pharmaceuticals, and accountable care organisations.

Policies to control pharmaceutical expenditure have focussed on increasing uptake of generic medicines in a number of countries. France, Ireland, Sweden and Norway all focus on increasing the penetration and use of generic medicines. In France, both patients and pharmacists have been given strong incentives to accept generic medicine substitution. Pharmacists receive financial incentives, and patients who refuse a generic substitute must pay the full price and claim reimbursement afterwards. Generic substitution is mandatory in Sweden. Swedish pharmacists are required to dispense the least expensive medicine on the market by law. In 2012, Ireland introduced a new pricing and supply model for encouraging such behaviour. Australia currently allows a large amount of consumer choice between generic and branded products. Generic substitution policy in Japan is relatively new. Market share of generics by volume is comparatively low (20.2% in 2009). To encourage the uptake of generic medicines, a new policy was introduced in 2008 allowing community pharmacists to switch to a generic of the prescribed medicine unless specifically stipulated by the prescriber.

Price referencing systems have also been used in some countries to contain the cost of medicines. An external reference pricing based on the average of the three lowest PPP in Sweden, Finland, Denmark, Germany, UK, the Netherlands, Austria, Belgium and Ireland has been used in Norway since 2002. Similarly since 2005, the basis for reimbursement in Denmark was changed to the lowest price paid in the EU. Spain has also introduced reference prices and aggressive generic use policies to rationalise pharmaceutical expenditure. In Sweden, low mark-ups in the distribution chain and the removal of value added tax (VAT) for prescription medicines has been effective in securing low public prices of medicines.

A number of other reforms have been implemented in the pharmacy sector in the countries reviewed. France has implemented reforms to reduce package wastage and reduce low value care. Recent Canadian policy debate has focused on whether or not to provide a pharmaceutical care plan, and whether to implement a number of regulatory and legislative changes throughout the provinces to expand the scope of pharmacists’ services. In April 2016, Japan introduced the “family pharmacist” scheme, where a pharmacist is appointed by a patient as his/her pharmacist. This initiative aims to expand the role of community pharmacists, avoid duplication and reduce waste by establishing a single medicine gatekeeper.

The Irish Pharmacy Act 2007 introduced the requirement for the management and administration of the sale and supply of medicines to be under the personal control of the superintendent pharmacist. The superintendent pharmacist is the person who is in overall control of professional and clinical management, while the supervising pharmacist is the pharmacist who is responsible for day-to-day management of the pharmacy.
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Appendix A: Search terms for systematic search

This appendix details the search topic terms which were used for the systematic search. The following notes apply to the search topic terms:

- **DE = descriptor;** i.e., indexed keywords (subject headings) such as Medical Subject Headings and Emtree terms.
- **TI = title;** i.e., free text terms appearing in titles of articles.
- **AB = abstract;** i.e., free text terms appearing in abstracts of articles.

**TOPIC – Community pharmacy terms**
1. pharmacy/de
2. ("drug store" OR drugstore):de
3. ("community pharmacy" OR "community pharmacies" OR "retail pharmacy" OR "retail pharmacies" OR apothecary OR apothecaries):ti,ab
4. ((Community OR retail) NEXT/1 Pharmaceutic*):ti,ab
5. ("drug store" OR "drug stores" OR drugstore OR drugstores OR chemist OR chemists):ti,ab

**TOPIC ASPECT – Remuneration /regulation terms**
1. remuneration/de
2. reimbursement/de
3. Fee/de
4. Income/de
5. (remuneration OR reimbursement OR subsidy OR subsidies OR payment OR payments OR rebate OR rebates OR fee OR fees OR revenue OR income OR incentive OR incentives OR viability OR wage OR wages):ti,ab
6. "government regulation"/de
7. government/de
8. policy/de
9. law/de
10. "drug legislation"/de
11. (regulation* OR regulatory OR governance OR law OR laws OR legislation OR policy OR policies OR regulators OR "location rules" OR "ownership rules" OR deregulation OR "de regulation"):ti,ab
12. "health care financing"/de
13. funding/de
14. (financing OR funding):ti,ab
15. (Pharmacy NEXT/1 (Agreement* OR negotiation* OR consultation* OR review OR reviews OR inquiry OR inquiries)):ti,ab
16. "pharmacy distribution":de
17. "ambulatory care"/de
18. population/de
19. "population distribution":de
20. "population research":de
city/de
"rural area"/de
"urban area"/exp
"urban population"/de
"geographic distribution"/de
"geographic information system"/de
"indigenous people"/de
"indigenous health care"/de
indigent/de
("ambulatory care" OR "ambulatory service" OR population OR city OR cities OR town OR towns OR rural OR urban OR urbanite* OR urbanity OR suburbia OR suburbs OR suburban OR geographic*):ti,ab
(pharmacy NEAR/3 distribution):ti,ab
(Indigenous OR Aboriginal OR Aborigine* OR indigent OR native OR natives):ti,ab
"health care delivery"/de
"scope of practice"/de
"drug therapy"/de
Vaccination/exp
Pharmacist/de AND prescription/de
Consumer/de
"disease management"/de
"case management"/de
"hospital discharge"/de
"patient care"/de
"treatment outcome"/de
Model/exp
(dispensing OR distribution OR delivery OR accessibility OR "after hours" OR supply):ti,ab
((role OR roles) NEXT/3 (pharmacy OR pharmacies OR pharmacist* OR "drug store" OR "drug stores" OR drugstore OR drugstores OR chemist OR chemists)):ti,ab
(scope NEXT/3 practice):ti,ab
((pharmacy OR professional) NEXT/1 (services OR programs OR programmes)):ti,ab
("medication review" OR "medication reviews" OR "pharmacy vaccination" OR "pharmacy vaccinations" OR "pharmacist prescribing" OR "pharmacy prescribing"):ti,ab
("consumer awareness" OR "continuity of care" OR "continuity of patient care" OR "consumer satisfaction" OR outcome*):ti,ab
("team care arrangement" OR "team care arrangements"):de,ti,ab
(model OR models OR future OR trend OR trends):ti,ab
"drug industry"/de
"drug marketing"/de
contract/de
purchasing/de
(wholesale OR wholesaler OR "wholesaling pharmacy distribution unit" OR "point of supply") :de
(wholesale OR wholesaler* OR wholesaling OR contract OR contracts OR "point of supply" OR manufacturer*):ti,ab
("pharmaceutical industry" OR "pharmaceutical company" OR "pharmaceutical companies" OR "medicine company" OR "medicine companies" OR "medical company" OR "medical companies"):ti,ab
("community service obligation" OR "supply chain"):de,ti,ab
"maintenance chemotherapy"/de
"maintenance therapy"/de
"pharmaceutical care"/de
"medication therapy management"/de
("extemporaneous preparation" OR "extemporaneous preparations" OR "infusion mixture" OR "infusion mixtures" OR "intravenous solution" OR "intravenous solutions" OR "chemotherapy compounding" OR "chemotherapy infusion" OR "chemotherapy infusions"):ti,ab
"health care cost"/de
"drug cost"/de
"health care access"/de
"cost control"/de
"waste"/de
"waste management"/de
(cost OR costs OR expenditure OR expenditures OR "drug expense" OR affordable OR affordability OR "co payment" OR "co payments" OR concession OR charge OR charges OR "drug waste" OR "drug wastage"):ti,ab
"drug use"/exp
"drug utilization"/de
"utilization review"/de
(utilization OR utilisation OR usage OR consumption):ti,ab
"health care policy"/de
"health care quality"/de
"drug quality"/de
("quality use of medicine" OR "quality use of medicines"):de,ti,ab
(reform OR reforms OR innovation OR innovations OR trials):ti,ab
((drug OR drugs) NEXT/1 (strategy OR strategies)):ti,ab
"electronic prescribing"/de
"electronic commerce"/de
"medical record"/exp
telehealth/exp
robotics/de
(electronic OR online OR "e prescribing" OR eprescribing OR "e prescription" OR eprescription OR "e prescriptions" OR eprescriptions OR ehealth OR "e health" OR telehealth OR "tele health" OR telemedicine OR "tele medicine"):ti,ab
("patient controlled health record" OR "patient controlled health records" OR "personally controlled health record" OR "personally controlled health records" OR pchr OR pchrs OR robotics):ti,ab

GEOGRAPHIC ASPECT — Country terms
1 australia/de
2 Australian/de
3 "Australian Aborigine"/exp
4 "Indigenous Australian"/de
5 (australia* OR "new south wales" OR "northern territory" OR queensland OR "south australia" OR tasmania OR victoria OR "western australia"):ti,ab,cy,jt
6 "united states"/de
7 American/de
8 "African American"/de
GEOGRAPHIC ASPECT – Country terms
9 "American Indian"/de
10 "Asian American"/de
11 "European American"/de
12 "North American"/de
13 (american* or usa or "united states" OR georgia or alabama or alaska or appalachia* OR arizona or arkansas or baltimore or boston OR california or chicago or colorado or connecticut OR delaware or florida or hawaii):ti,ab,cy,jt
14 (idaho or illinois OR indiana or iowa or kansas or kentucky OR "los angeles" or louisiana or maine or maryland OR massachusetts or michigan or minnesota OR mississippi or missouri or montana):ti,ab,cy,jt
15 (nebraska OR nevada or "new england" or "new hampshire" OR "new jersey" or "new mexico" or "new york" OR "north carolina" or "north dakota" or ohio OR oklahoma or oregon or pennsylvania OR "rhode island"):ti,ab,cy,jt
16 (*"san francisco" or "south carolina" OR "south dakota" or tennessee or texas or utah OR vermont or virginia or washington OR "west virginia" or wisconsin or wyoming):ti,ab,cy,jt
17 canada/de
18 Canadian/de
19 "Canadian Aboriginal"/de
20 "North American"/de
21 (canada OR canadian* OR alberta OR "british columbia" OR manitoba OR "new brunswick" OR newfoundland OR "nova scotia" OR nunavut OR ontario OR "prince edward island" OR quebec OR saskatchewan OR yukon):ti,ab,cy,jt
22 "new zealand"/de
23 "New Zealander"/de
24 "Maori (people)"/de
25 (*"new zealand" OR "new zealander" OR "new zealanders" OR maori*):ti,ab,cy,jt
26 japan/de
27 "Japanese (people)"/de
28 "Japanese (citizen)"/de
29 (japan* OR tokyo OR "Bonin Islands"):ti,ab,cy,jt
30 "united kingdom"/de
31 "British citizen"/de
32 britons/exp
33 (england or britain or british OR "united kingdom" or uk or scotland OR scottish OR wales OR welsh or london):ti,ab,cy,jt
34 (*"channel islands" OR guernsey OR hebrides or "isle of man" OR "Alderney Island" OR "Jersey Island" OR Sark):ti,ab,cy,jt
35 (britons OR english OR welshman OR welshmen OR scot OR scots OR scotsman OR scotsmen):ti,ab
36 sweden/de
37 "Swede (people)"/de
38 "Swedish citizen"/de
39 france/de
40 Frenchman/de
41 (france or french* OR corsica or paris):ti,ab,cy,jt
GEOGRAPHIC ASPECT – Country terms

42 spain/de
43 Spaniard/de
44 (spain or spanish OR Spaniard* OR Majorca OR Minorca OR "Balearic Islands" OR "Canary Islands"):ti,ab,cy,jt

45 Netherlands/de
46 Dutchman/de
47 (Netherlands OR holland OR dutch*):ti,ab,cy,jt

48 denmark/de
49 "Faroe Islands"/de
50 "Danish citizen"/de
52 (denmark OR danish Ordane OR danes OR "Faeroe Islands"):ti,ab,cy,jt

53 norway/de
54 "Svalbard and Jan Mayen"/de
55 "Norwegian (people)"/de
56 "Norwegian (citizen)"/de
57 (norway OR norwegian* OR Svalbard OR Spitsbergen):ti,ab,cy,jt

58 ireland/de
59 "Irish (citizen)"/de
60 (ireland OR eire OR "Irish republic" OR Irish* OR dublin):ti,ab,cy,jt
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