

# International Comparisons of Pharmacy Models

Wholesaling, distribution & packaging: an international scan of arrangements in Australia, Canada, New Zealand and the UK

Supporting preparations for Australia's 8<sup>th</sup>  
Community Pharmacy Agreement

Final Version - 9 November 2023

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*This document provides a fact-based analysis (based on discussions with industry experts and publicly available information) of the pharmaceutical wholesaling arrangements across comparable countries, and innovations across pharmaceutical distribution and packaging. This is intended to provide information to support the Department of Health and Aged Care in progressing the eight Community Pharmacy Agreement. The information and examples presented are not exhaustive, and should not be viewed or interpreted as providing opinions or recommendations on specific decisions or policies relating to public health or economic responses. These materials do not constitute, and should not be interpreted as policy, reimbursement, compliance, legal, medical, or other regulated advice. The recipient is solely responsible for all of its decisions, use of these materials, and compliance with all applicable laws, rules and regulations. All materials and insights may be subject to the Department's legal and compliance review. The fact-base and analyses presented in this report are current as of Friday 15th September 2023.*

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# 1 Wholesaling arrangements

This chapter is organised in two parts:

- An executive summary which provides the narrative context, and key themes/ findings across what is paid to wholesalers (basis and level of wholesaler payments and profit), what is received (regulations and service requirements), and an indicative rationale for why Australian wholesalers appear to have relatively higher costs.
- A set of tables providing a structured comparison on each component question including references in footnotes.

## 1.1 EXECUTIVE SUMMARY

### 1.1.1 Context: Australia's Community Pharmacy Agreements

**Community Pharmacy arrangements in Australia are currently governed by the 7<sup>th</sup> Community Pharmacy Agreement (CPA).** The 7CPA is an agreement between the Minister for Health and Aged Care (on behalf of the Commonwealth of Australia), Pharmacy Guild of Australia, and the Pharmaceutical Society of Australia that supports all Australians to access safe, affordable medicines and services through community pharmacies. It outlines the Federal government's agreement to reimburse pharmacists and others in the pharmaceutical supply chain for dispensing subsidised medicines on the Pharmaceutical Benefit Scheme and community pharmacy medication management programmes and services. The agreement also includes administration of Community Service Obligation funding, which is provided directly to pharmacy wholesalers.

**The 7CPA is due to expire in June 2025 and the Minister of Health and Aged Care has opened negotiations for an 8<sup>th</sup> agreement early.** In preparation for these negotiations, the Department of Health and Aged Care wishes to better understand revenue levels of wholesalers in Australia and comparator countries and the key drivers of this revenue. Negotiations will conclude by June 2024.

**To inform these negotiations a global scan of pharmacy wholesale arrangements in comparison to Australia has been undertaken.** The scan focused on the wholesale portion of the pharmacy supply chain across Canada, New Zealand (NZ) and the UK. Three broad areas have been considered:

- What is paid (the basis and level of wholesale payments and profit)
- What is received (regulations and service requirements placed on wholesalers)
- An indicative rationale for Australian wholesale costs relative to comparator countries

**Overall, we found that Australia likely has higher wholesale service standards than international comparators, at a higher cost (except for Canada).** These costs are potentially related to higher distribution, labour and investment costs.

### 1.1.2 What is paid: level of wholesaler mark-up revenue and profit

**Australian and Canadian wholesaler mark-up revenue is likely higher than the other comparator countries, but wholesaler profits are not necessarily higher** (than in NZ and the UK).

In Australia, total wholesaler mark-up appears to be ~A\$788M in 2021-22 from PBS medicine sales (excluding ex-manufacturer prices, including CSO funding and after rebates). This translates to likely average revenues of **~A\$30.0 per capita**, **~A\$46.2 per PBS patient** and **~A\$2.5 per prescription**. Wholesalers may apply mark-ups up to 7.52% (with a minimum value of \$0.41 and maximum of \$54.14 per dispense) – stipulated by legislative instrument – before rebates and other incentives are applied. Overall EBITDA margins (Earnings Before Interest, Taxes, Depreciation and Amortisation – a measure of profitability) are likely <4.5%.

In comparison:

- In Canada, total wholesaler mark-up appears to be ~A\$1,610M in 2022. This translates to likely average mark-up revenues of **~A\$41.5 per capita (138% of Australia's total)**, **~A\$62.0 per patient (134% of Australia's total)** and **~A\$2.0 per prescription (80% of Australia's total)**. Mark-ups are likely to be 4-9% post discounts and rebates, depending on Province.
- In NZ, total wholesaler mark-up appears to be ~A\$58M in 2022. This translates to likely averages of **~A\$11.3 per capita (38% of Australia's total)**, **~A\$15.5 per patient (34% of Australia's total)** and **~A\$1.1 per prescription (44% of Australia's total)**. Mark-ups are likely to be 3-4% post discounts and rebates. Overall EBITDA margins are likely less than 2-3% of total revenue.
- In the UK, total wholesaler mark-up appears to be ~A\$1,333M in 2020. This translates to likely averages of **~A\$19.7 per capita (66% of Australia's total)**, **~A\$28.1 per patient (61% of Australia's total)** and **~A\$1.0 per prescription (40% of Australia's total)**. Mark-ups are likely to be 2-3% for innovative medicines and 20-25% for generic medicines post discounts and rebates. Overall, gross margins likely average ~7%.

**Across all countries except Canada, government is the primary payor of wholesalers via prescription payments:**

In Australia a mix of government funding (~90%) and patient co-payments (~10%) appear to ultimately pay for wholesaling services, paid directly (for CSO payments) or via pharmacies paying wholesalers. By comparison:

- In Canada a mix of public (~44%) and private insurance (~37%), along with patient co-payments (~20%) likely ultimately funds wholesaling services, via pharmacies paying wholesalers.
- In NZ and the UK most prescriptions are fully funded by the government (without patient co-payments), via pharmacies paying wholesalers.

### 1.1.3 What is received: regulations and service requirements placed on wholesalers

**Australian and Canadian wholesalers are likely subject to a broader set of regulations and service requirements than wholesalers in NZ and the UK.** Australian wholesaler

regulations appear to be more prescriptive compared to Canada and are largely set by the Federal level of government. Australian regulations include:

- **Accounting for a wholesale mark-up of 7.52%** of ex-manufacturer price (with a minimum value of \$0.41 and maximum of \$54.14) in determining the price paid to pharmacies (Commonwealth Price), set by legislative instrument; and requiring wholesalers to supply PBS medicines to pharmacies at or below this price.
- **Dedicated funding to meet specified service levels** (i.e., Community Service Obligations; see below).
- **Handling of medicines** – wholesalers are responsible for following the code of good wholesaling practice for medicines.

By comparison:

- **Canada's market appears slightly less regulated than Australia**, with regulations covering maximum wholesale mark-ups in some Provinces, and set minimum stocking levels (e.g., in Quebec wholesalers must stock at least 50% of medicines on the Canadian equivalent of the PBS list).
- **In contrast, UK and NZ are less directly regulated.** Beyond the requirement to hold a wholesale licence, direct regulation of wholesalers is constrained to conditions for handing medicines (to protect patient safety).

**The service requirements on wholesalers appear to correspond to these levels of regulation.** I.e., Australian wholesalers are subject to a broad range of regulatory service requirements, while wholesalers in other jurisdictions appear subject to a narrower range of commercially negotiated requirements (mostly defined in commercial contracts between pharmacies and wholesalers).

**Australian requirements stem from Community Service Obligation funding and are defined by government.** These requirements include that wholesalers: (1) supply any Community Pharmacy within a CSO distributor's national or state jurisdiction, (2) supply any brand of any PBS Medicine on request, (3) maintain specific stocks of PBS medicine, (4) supply PBS Medicines at or below the approved price, (5) supply PBS medicines within 24 to 72 hours, and (6) make daily deliveries available to Community Pharmacies within CSO distributor jurisdictions.

By comparison, interviews with industry stakeholders indicate that delivery frequency requirements differ by jurisdiction:

- In Canada, pharmacies in urban areas typically require same day or next day delivery, whereas extreme geographies can expect deliveries 1-2 times per week.
- In NZ, pharmacies are obliged to make 90% of prescription medicines available within one hour, and 100% within two days. This means pharmacies typically require wholesalers to provide same day or next day delivery services and have full pharmaceutical schedule availability throughout the country.
- In the UK, pharmacies typically require two deliveries per day, and will chose wholesalers depending on availability.

#### 1.1.4 Drivers of cost: factors that may contribute to higher wholesaler costs

At a high level, Australia and Canada appear to face higher costs relative to NZ and the UK, which could explain higher levels of mark-up revenue. Exhibit 1 compares factors driving cost and their likely relative strength across jurisdictions.

Higher costs in Australia specifically are likely to be associated with distribution costs arising from the geographical dispersion of pharmacies, the CSO mandate to meet a broad set of service requirements, and comparatively higher labour and investment costs:

- **Geographical factors likely contribute to higher distribution costs in Australia:**
  - Wholesalers in Australia (and Canada) cover significantly larger areas than wholesalers in NZ and the UK, with lower associated volumes as indicated by lower rural population densities. Transport costs appear to be similar across all four countries considered.
  - A further driver of cost in Australia may be higher distribution costs in urban settings. Lower urban population densities in Australia imply couriers must travel relatively greater distances to deliver to pharmacies (where majority of medicine volumes are delivered).
- **Requirements associated with CSO funding will likely add to Australian wholesaler cost burden** compared to wholesalers in NZ and the UK. This is likely driven by higher inventory costs associated with the requirement to maintain specific stocks of PBS medicines and the need to be able to serve the vast majority of Australia with these medicines within 24-72 hours. In NZ and the UK inventories are not mandated.
- **Labour costs are likely to be a major driver of higher costs for Australian wholesalers** given international wage comparisons. Higher labour costs in Canada compared to Australia are likely a major reason for the 38% difference in mark-up revenue between Canada and Australia on a per capita basis.
- **Investment costs are also likely to be higher for Australian wholesalers given less advantageous levels of Purchasing Power Parity (PPP).** This would suggest investments wholesalers make (e.g., in automating warehouses) albeit with the aim of reducing costs overall would be more expensive in Australia than comparator countries.

While this qualitative analysis suggests there is no obvious discrepancy in the pattern between wholesaling revenues and costs (i.e., higher revenue countries tend to be higher cost countries), validating this view would require an analysis of wholesaler economics.

EXHIBIT 1: INDICATORS OF COST ACROSS JURISDICTIONS<sup>1</sup>

Level of cost relative to other jurisdictions:  
■ High ■ Medium ■ Low

Metric	Why this metric matters	Australia	Canada	New Zealand	UK
<b>Structure of the supply chain</b>	<b>Supply chain duplication</b> Indicates level of efficiency across wholesale portion of the supply chain. Fewer national wholesalers or wholesalers with regional focus means duplication of wholesale cost is reduced.	<b>High duplication</b> - 4 major national wholesalers have responsibility across entire country	<b>High duplication</b> - Market is led by 3 major national wholesalers and a range of regional players	<b>Low duplication</b> - 1 national wholesaler has >50% market share while the other 2 major wholesale have regional focus	<b>High duplication</b> - 3 major traditional wholesalers operate across the country with some regional players
<b>How the supply chain is served</b>	<b>Rural population density (# of people/ sq. km)</b> Indicates level of effort required to supply rural populations. Lower densities implies higher levels of effort required to reach rural pharmacies.	<b>Very low</b> - 0.5	<b>Very low</b> - 0.8	<b>Low</b> - 3.1	<b>High</b> - 38.6
	<b>Urban population density (# of people/ sq. km)</b> Indicates level of effort required to supply urban populations (where greatest level of demand exists). High urban density implies a more built up urban area with lower levels of effort required to reach pharmacies	<b>Low</b> - ~1,870	<b>Medium</b> - ~2,280	<b>Medium</b> - ~2,260	<b>High</b> - ~2,480
	<b>Service standards - holding of stocks</b> Indicates levels of cost required to meet service requirements. Higher service standards imply higher cost burden for wholesalers	<b>High</b> - All PBS (\$85) stock must be carried including low volume stock	<b>Medium</b> - stock levels depend on provincial requirements	<b>Medium</b> - National wholesaler carries all major stocks	<b>Medium</b> - ~38% of wholesalers are short-liners with limited high volume stocks. Full line wholesalers represent ~53% of the market
	<b>Service standards - number of deliveries per day</b>	<b>Medium</b> - delivery guaranteed within 24-72 hours based on CSO obligations	<b>Medium</b> - same day or next day delivery industry standard	<b>Medium</b> - same day or next day delivery industry standard	<b>Medium</b> - same day or next day delivery industry standard
	<b>Pharmacy intensity (# of people/ pharmacy)</b> Indicates number of delivery points accounting for population size. High intensity implies less delivery points required of wholesalers, and therefore cost, to satisfy patient demand	<b>Medium</b> - 4,400	<b>High</b> - 3,370	<b>Medium</b> - 4,680	<b>Medium</b> - 4,660
<b>Input costs</b>	<b>Labour costs (Median income per day, international dollars)</b> Higher labour costs imply a wholesalers pay higher wages	<b>High</b> - \$53.05	<b>High</b> - \$55.42	<b>Medium</b> - \$45.14 (adjusted)	<b>Medium</b> - ~\$45.00
<b>PPP (relative to US\$)</b> Lower PPP (shown by higher values) implies wholesalers need relatively more currency to purchase a similar set of goods (e.g., to automate warehouse activities)	<b>Low</b> - 1.419	<b>Medium</b> - 1.225	<b>Low</b> - 1.464	<b>High</b> - 0.68	
<b>Business electricity costs (\$/kWh, PPP adjusted)</b> Higher electricity costs imply higher overall running costs of wholesaler distribution centres	<b>Medium</b> - \$0.18	<b>Low</b> - \$0.13	<b>Medium</b> - \$0.24 (data scaled using household data)	<b>High</b> - \$0.34	
<b>Transport Price Index</b> Higher scores imply higher costs of road, rail, and air transport in country (2017 data)	<b>High</b> - 132.55	<b>High</b> - 125.55	<b>High</b> - 139.05	<b>High</b> - 138.72	
<b>Fuel costs (\$/litre)</b> Fuel costs are a proxy for courier costs; higher fuel costs means cost of distributing medicines to pharmacies will be higher	<b>Low</b> - \$1.97	<b>Low</b> - \$2.08	<b>Medium</b> - \$2.60	<b>High</b> - \$2.90	

<sup>1</sup> This footnote corresponds to each discrete row in exhibit 1:

**Supply chain duplication:** see Table in Chapter 1.

**Rural population density (# of people/ sq. km):** World Bank (n.d.). Land area (sq. km) - Australia, Canada, United Kingdom, New Zealand. [online] World Bank Open Data. Available at: <https://data.worldbank.org/indicator/AG.LND.TOTL.K2?locations=AU-CA-GB-NZ> [Accessed 15 Sep. 2023]; World Bank (n.d.). Population, total - Australia, New Zealand, United Kingdom, Canada. [online] World Bank Open Data. Available at: <https://data.worldbank.org/indicator/SP.POP.TOTL?locations=AU-NZ-GB-CA>; World Bank (n.d.). Urban population (% of total population) - Australia, Canada, United Kingdom, New Zealand. [online] World Bank Open Data. Available at: <https://data.worldbank.org/indicator/SP.URB.TOTL.IN.ZS?locations=AU-CA-GB-NZ> [Accessed 15 Sep. 2023]; World Bank

(n.d.). *Urban land area (sq. km) - Australia, Canada, United Kingdom, New Zealand*. [online] World Bank Open Data. Available at: <https://data.worldbank.org/indicator/AG.LND.TOTL.UR.K2?locations=AU-CA-GB-NZ> [Accessed 15 Sep. 2023].

**Urban population density (# of people/ sq. km):** World Bank (n.d.). *Land area (sq. km) - Australia, Canada, United Kingdom, New Zealand*. [online] World Bank Open Data. Available at: <https://data.worldbank.org/indicator/AG.LND.TOTL.K2?locations=AU-CA-GB-NZ> [Accessed 15 Sep. 2023]; World Bank (n.d.). *Population, total - Australia, New Zealand, United Kingdom, Canada*. [online] World Bank Open Data. Available at: <https://data.worldbank.org/indicator/SP.POP.TOTL?locations=AU-NZ-GB-CA>; **Service standards – holding of stocks:** See Table in Chapter 1.

**Service standards – number of deliveries per day:** See Table in Chapter 1; **Pharmacy intensity (# of people/ pharmacy):** World Bank (n.d.). *Population, total - Australia, New Zealand, United Kingdom, Canada*. [online] World Bank Open Data. Available at: <https://data.worldbank.org/indicator/SP.POP.TOTL?locations=AU-NZ-GB-CA>. Number of pharmacies for Australia can be found: PBS Expenditure and Prescriptions Report 1 July 2021 to 30 June 2022. (2022). Canberra: Department of Health and Aged Care, pp.22; Available at: <https://www.pbs.gov.au/statistics/expenditure-prescriptions/2021-2022/PBS-Expenditure-and-Prescriptions-Report-1-July-2021-to-30-June-2022.PDF>; For New Zealand, please see: FYI. (2019). Total Number of Licenced Pharmacies in NZ - 2019 - a Official Information Act request to Ministry of Health. [online] Available at: <https://fyi.org.nz/request/10183-total-number-of-licenced-pharmacies-in-nz-2019> [Accessed 7 Sep. 2023]; For Canada, please see: NAPRA (2022). National Statistics - NAPRA. [online] [www.napra.ca](http://www.napra.ca). Available at: <https://www.napra.ca/resources/national-statistics/>. For UK, General Pharmaceutical Council (2023). The GPhC register as of 31 May 2022 - Trend data. [online] [Pharmacyregulation.org](http://Pharmacyregulation.org). Available at: <https://www.pharmacyregulation.org/sites/default/files/document/gphc-register-trend-data-may-2022-.docx#:~:text=On%2031%20May%202022%20there> [Accessed 15 Sep. 2023].

**Labour costs (Median income per day, international dollars):** Our World In Data (n.d.). *Median income or consumption per day, 2019*. [online] Our World in Data. Available at: <https://ourworldindata.org/grapher/daily-median-income> [Accessed 15 Sep. 2023]. NB: The median income for New Zealand is missing from the data. The value included for New Zealand is scaled based on average wage data from all four countries.

**PPP (relative to US\$):** OECD (2021). *Conversion rates - Purchasing power parities (PPP) - OECD Data*. [online] OECD. Available at: <https://data.oecd.org/conversion/purchasing-power-parities-ppp.htm> [Accessed 15 Sep. 2023].

**Business electricity costs (A\$/kWh, PPP adjusted):** Australian Energy Council (2022). *International electricity prices: How does Australia compare?* [online] Australian Energy Council. Available at: <https://www.energycouncil.com.au/analysis/international-electricity-prices-how-does-australia-compare/> [Accessed 15 Sep. 2023]; OFX (2018). *Yearly Average Rates & Forex History Data* | OFX. [online] OFX. Available at: <https://www.ofx.com/en-au/forex-news/historical-exchange-rates/yearly-average-rates/> [Accessed 15 Sep. 2023]. NB: The household electricity for New Zealand is missing from the data. The value included for New Zealand is scaled based on average household electricity data from all four countries.

**Transport Price Index:** The Global Economy (2017). *Transport prices - Country rankings*. [online] TheGlobalEconomy.com. Available at: [https://www.theglobaleconomy.com/rankings/transport\\_prices\\_wb/](https://www.theglobaleconomy.com/rankings/transport_prices_wb/) [Accessed 15 Sep. 2023].

**Fuel costs (A\$/litre):** International Energy Agency (2023). *End-Use Prices Data Explorer*. [online] IEA. Available at: <https://www.iea.org/data-and-statistics/data-tools/end-use-prices-data-explorer?tab=Overview> [Accessed 15 Sep. 2023].

## 1.2 TABLES: WHOLESALING ARRANGEMENTS ACROSS AUSTRALIA, CANADA, NEW ZEALAND AND THE UNITED KINGDOM

Questions	AUS	CAN	NZL	UK
<b>How is the wholesale market organised?</b>				
How important are wholesalers in the procurement and delivery of medicines?	<ul style="list-style-type: none"> <li>■ <b>~90%</b> of medicines supplied to pharmacies could be distributed through wholesalers – information based on expert input due to lack of public sources</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>&gt;90%</b> of medicines supplied to pharmacies are distributed through wholesalers or self-distributing pharmacy chains<sup>2</sup></li> </ul>	<ul style="list-style-type: none"> <li>■ <b>&gt;85%</b> of medicines supplied to pharmacies could be distributed through wholesalers – information based on expert input due to lack of public sources</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>~85%</b> of medicines supplied to pharmacies could be distributed through wholesalers – information based on expert input due to lack of public sources</li> </ul>
<p>What is the composition and concentration of players in each market?</p> <p><i>NB: Market shares can shift depending on the year of choice (e.g., recent decision by Chemist)</i></p>	<ul style="list-style-type: none"> <li>■ <b>3 major players</b> likely represent <b>~90%</b> of the wholesale market:<sup>4</sup> <ul style="list-style-type: none"> <li>- <b>EBOS</b> is the largest player with an estimated <b>~40%</b> market share<sup>5</sup></li> <li>- <b>API</b> is the second largest with <b>~30%</b></li> <li>- <b>Sigma Healthcare</b> is the third largest with <b>~20%</b><sup>6</sup></li> <li>- <b>CH2</b> is the final CSO distribution with a likely</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>■ <b>3 major players</b> likely represent <b>~64%</b> of the wholesale market – information based on expert input due to lack of public sources: <ul style="list-style-type: none"> <li>- <b>McKesson</b> is the largest player with a <b>~35%</b> market share (over 1/3<sup>rd</sup> of all medicines in Canada)<sup>8</sup></li> <li>- <b>Matrix Logistics Services</b> and <b>Metro combined</b> represent <b>~29%</b> of the market through its self-distribution model with</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>■ <b>3 major players</b> likely represent <b>~90%</b> of the wholesale market – information based on expert input due to lack of public sources: <ul style="list-style-type: none"> <li>- <b>ProPharma</b> is the largest, representing <b>~55%</b> of the market</li> <li>- <b>CDC</b> is the second largest with <b>~25%</b><sup>10</sup></li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>■ <b>3 major players</b> likely represent <b>~58%</b> of the wholesale market – information based on expert input due to lack of public sources: <ul style="list-style-type: none"> <li>- <b>AAH</b> is the largest player with an estimated <b>~25%</b> market share</li> <li>- <b>Alliance</b> is the second largest with <b>~22%</b></li> <li>- <b>Phoenix</b> is the third largest with <b>~11%</b></li> <li>- <b>All other players</b> individually constitute <b>&lt;5% each</b> of the market</li> </ul> </li> </ul>

2 Canadian Association for Pharmacy Distribution Management (2019). Representing Healthcare Distribution in Canada. [online] Available at: <https://www.capdm.ca/CAP/media/Documents/CAPDM-profile-2019-EN-10-16-19.pdf> [Accessed 7 Sep. 2023].

4 Witcomb, G. (2021). API: turnaround story or value trap? [online] Intelligent Investor. Available at: <https://www.intelligentinvestor.com.au/recommendations/api-turnaround-story-or-value-trap/149845> [Accessed 7 Sep. 2023].

5 EBOS GROUP LIMITED (2022). Macquarie Australia Conference Presentation. [online] Listcorp. Available at: <https://www.listcorp.com/asx/ebo/ebos-group-limited/news/macquarie-australia-conference-presentation-2705025.html> [Accessed 7 Sep. 2023].

6 Witcomb, G. (2021). API: turnaround story or value trap? [online] Intelligent Investor. Available at: <https://www.intelligentinvestor.com.au/recommendations/api-turnaround-story-or-value-trap/149845> [Accessed 7 Sep. 2023].

8 McKesson (n.d.). Retail Banner Services - McKesson Canada - McKesson Canada. [online] Available at: <https://www.mckesson.ca/retail-banner-services> [Accessed 7 Sep. 2023].

10 Exact market share based on industry sources. For details of CDC Pharmaceutical. Please see: CDC Pharmaceuticals Ltd. (n.d.). Our story. [online] Available at: <https://cdc.co.nz/our-story.html> [Accessed 7 Sep. 2023].

Questions	AUS	CAN	NZL	UK
Warehouse to switch providers <sup>3</sup>	market share of <b>less than &lt;10%</b> <sup>7</sup>	Loblaw and Shoppers Drug Mart <sup>9</sup> - Other players include Kohl and Frisch Limited, Cardinal Health, Unipharm and Imperial Distribution	- <b>PWL</b> (Pharmacy Wholesalers Limited) is the smallest player with <b>~10%</b> <sup>11</sup>	Note that there has been some moderate consolidation in the UK market recently with 3 wholesalers serving 4,000 pharmacies going into administration in 2022 <sup>12</sup>
How do wholesalers differentiate themselves in the market?	<ul style="list-style-type: none"> <li> <b>Vertical integration</b> – While the 3 major wholesalers are reportedly not particularly differentiated, each have a stake in a pharmacy business resulting in guaranteed sales volumes (e.g., Sigma Healthcare brand ownership includes Guardian and Amcal+ pharmacies)<sup>13</sup> </li> </ul>	<ul style="list-style-type: none"> <li> <b>Vertical integration</b> – All major wholesalers have a stake in a pharmacy business resulting in guaranteed sales volumes (e.g., McKesson retail banners include Guardian, The Medicine Shoppe Pharmacy and I.D.A.)<sup>15</sup> </li> <li> <b>Self-distribution</b> – Some major pharmacies (e.g., Loblaw, Shoppers Drug Mart, </li> </ul>	<ul style="list-style-type: none"> <li> <b>Vertical integration</b> – CDC and PWL are cooperatives owned by pharmacies, where profits from pharmaceutical wholesale services are released as dividends<sup>19</sup> </li> <li> <b>National footprint</b> – ProPharma is the only national wholesale distributor while CDC and PWL are regional players<sup>20</sup> </li> </ul>	<ul style="list-style-type: none"> <li> <b>Vertical integration</b> – AAH and Phoenix are vertically integrated with Lloyds Pharmacy and Rowlands Pharmacy respectively (Alliance has recently divested from Boots Pharmacy, with a long-term supply agreement until 2031<sup>21</sup>)<sup>22</sup> </li> <li> <b>Exclusive manufacturer contracts</b> – Exclusive distribution agreements between manufacturers and top three wholesalers account for distribution of </li> </ul>

3 Thompson, S., Sood, K. and Rapaport, E. (2023). Sigma Healthcare wins EBOS's Chemist Warehouse contract. [online] Australian Financial Review. Available at: <https://www.afr.com/street-talk/sigma-healthcare-wins-ebos-s-2b-chemist-warehouse-contract-sources-20230606-p5de8v> [Accessed 7 Sep. 2023].

7 Exact market share for CH2 is not publicly reported but likely to be less than <10% through relationship with Ramsay pharmaceutical.

9 Note that this number is calibrated based on expert input combined with publicly available information on pharmacy market share. Shoppers Drug Mart represents ~29% of the pharmacies and drug store market. This is based on information from the Professional Leadership Institute Professional Leadership Institute (2020). Shoppers Drug Mart – Case Study - Professional Leadership Institute. [online] Professional Leadership Institute. Available at: <https://professionalleadershipinstitute.com/case-studies/shoppers-drug-mart-case-study/> [Accessed 14 Sep. 2023].

11 Exact market share based on industry input. For details on PWL, please see here: Pharmacy Wholesalers (Bay of Plenty) Limited. (n.d.). OWNED BY PHARMACY FOR PHARMACY – A TRUE COOPERATIVE. [online] Available at: <https://www.pwl.co.nz/> [Accessed 7 Sep. 2023].

12 Loukou , E. (2022). 3 wholesalers servicing 4,000 pharmacies go into administration. [online] C+D. Available at: <https://www.chemistanddruggist.co.uk/CD136108/3-wholesalers-servicing-4000-pharmacies-go-into-administration> [Accessed 15 Sep. 2023].

13 Sigma Healthcare owns community pharmacy brands Amcal+, Guardian and Discount Drug Stores; EBOS community pharmacies include Terry White and Pharmacy Choice; For EBOS Healthcare source, please refer to footnote 14 and for Sigma source please see here: Sigma Health (n.d.). Brands. [online] [sigmahealthcare.com.au](https://sigmahealthcare.com.au). Available at: <https://sigmahealthcare.com.au/community-pharmacy/brands/> [Accessed 7 Sep. 2023]

15 McKesson (2020). McKesson Canada's IDA®, Guardian®, Remedy's Rx® and The Medicine Shoppe® Pharmacies Ready to Protect Canadians Against the Flu - Press Releases - McKesson Canada - McKesson Canada. [online] Available at: <https://www.mckesson.ca/-/mckesson-canada-s-ida-guardian-remedy-s-rx-and-the-medicine-shoppe-pharmacies-ready-to-protect-canadians-against-the-f-1> [Accessed 7 Sep. 2023].

19 SmartInvestor. (2016). CDC Pharmaceuticals Limited Product Disclosure Statement. [online] Available at: <https://smartinvestor.sorted.org.nz/assets/disclose-documents/6a/80/bb/CDC-Pharmaceuticals-Limited-Product-Disclosure-Statement.pdf> [Accessed 7 Sep. 2023].

20 EBOS Group (n.d.). EBOS Group - Our Business. [online] [www.ebosgroup.com](http://www.ebosgroup.com). Available at: <https://www.ebosgroup.com/our-businesses/community-pharmacy#:~:text=Today%2C%20ProPharma%20is%20the%20largest> [Accessed 7 Sep. 2023].

21 Shaw, I. (2021). Boots' parent company sells wholesale business Alliance Healthcare. [online] The Pharmacist.co.uk. Available at: <https://www.thepharmacist.co.uk/news/boots-parent-company-sells-wholesale-business-alliance-healthcare/> [Accessed 7 Sep. 2023].

22 For detail of AAH and Lloyds Pharmacy and Phoenix and Rowlands please see: Aurelius Group. (2022). AURELIUS completes acquisition of LloydsPharmacy's parent company, McKesson UK. [online] Available at: <https://aurelius-group.com/en/news/aurelius-completes-acquisition-of-lloydspharmacys-parent-company-mckesson-uk/> [Accessed 15 Sep. 2023]. PHOENIX All-in-One. (n.d.). Rowlands Pharmacy - A PHOENIX Group Company. [online] Available at: <https://www.allinone.phoenixmedical.co.uk/company/rowlands-pharmacy/> [Accessed 15 Sep. 2023].

Questions	AUS	CAN	NZL	UK
	<ul style="list-style-type: none"> <li>■ <b>Additional service offerings</b> – EBOS has diversified its offerings to include veterinary medicines along with its core business<sup>14</sup></li> </ul>	<p>Metro pharmacies and Jean Coutru) operate wholesalers who have an exclusive responsibility to distribute to their pharmacies<sup>16</sup></p> <ul style="list-style-type: none"> <li>■ <b>Regional specialisation</b> – Given the differentiated regulatory environment in Canada, wholesalers may distinguish themselves based on their local knowledge, such as in Quebec where players such as Metro are strongest with local knowledge, language and relationships<sup>17</sup></li> <li>■ <b>Specialised services</b> – McKesson, as the largest player in the Canadian market, aims to be a one-stop-shop for all pharmacy needs. This can manifest in a range of add-on services such as automated picking and packing machinery for pharmacies, access to plasma and biologics and cloud platforms to manage pharmacy data and reporting<sup>18</sup></li> </ul>		<p>~40% of innovative medicines (e.g., GSK selected Phoenix for its reduced wholesale model<sup>23</sup>). This model results in most pharmacies having relationships with multiple wholesalers to offer a full range of products</p> <ul style="list-style-type: none"> <li>■ <b>Offer of value-added services</b> – Alliance Healthcare has sought to offer additional services to healthcare practitioners, including medical institutions, doctors and hospitals through such services as training for pharmacists and pharmacy staff, homecare support and business management solutions<sup>24</sup></li> <li>■ <b>Range of SKUs available</b> – Wholesalers have reportedly distinguished themselves based on their SKU availability, broadly falling into two categories: <ul style="list-style-type: none"> <li>- <b>Full line wholesalers</b> tend to hold &gt;30,000 SKUs and are represented by the large wholesalers (e.g., AAH and Phoenix), with twice daily deliveries</li> <li>- <b>Short line wholesalers</b> have emerged as a specialised wholesale offering with ~5,000</li> </ul> </li> </ul>

14 EBOS Group. (n.d.). Animal Care EBOS Group. [online] Available at: <https://www.ebosgroup.com/our-businesses/animal-care> [Accessed 7 Sep. 2023].

16 Metro (2022). Annual Report 2022. [online] Annualreports.com, p.2. Available at: [https://www.annualreports.com/HostedData/AnnualReports/PDF/TSX\\_MRU-A\\_2022.pdf](https://www.annualreports.com/HostedData/AnnualReports/PDF/TSX_MRU-A_2022.pdf) [Accessed 14 Sep. 2023].

17 Insight based on industry expert with knowledge of geographic concentration of players. Insight is further confirmed by location of distribution centres for metro which is placed in Quebec and Ontario. See here for distribution centres: Metro (2023). Metro distribution centres. [online] Metro.ca. Available at: <https://careers.metro.ca/go/Distribution-Centres-Jobs/2639117/> [Accessed 14 Sep. 2023].

18 McKesson (n.d.). Specialty Pharmacy in Health Systems | McKesson. [online] [www.mckesson.com](http://www.mckesson.com). Available at: <https://www.mckesson.com/Pharmacy-Management/Specialty-Pharmacy-Health-Systems/> [Accessed 13 Sep. 2023].

23 PHOENIX All-in-One. (2018). GlaxoSmithKline UK Pharmaceuticals selects PHOENIX in new Reduced Wholesale Model distribution agreement. [online] Available at:

<https://www.allinone.phoenixmedical.co.uk/news/glaxosmithkline-uk-pharmaceuticals-selects-phoenix-in-new-reduced-wholesale-model-distribution-agreement/> [Accessed 7 Sep. 2023].

24 Alliance Healthcare. (n.d.). Prescription Delivery | Alliance Healthcare UK. [online] Available at: <https://www.alliance-healthcare.co.uk/pharmacy-solutions/added-value-services> [Accessed 7 Sep. 2023].

Questions	AUS	CAN	NZL	UK
				high volume SKU and deliveries once a day <sup>25</sup>
Where do the benefits of vertical integration accumulate?	<ul style="list-style-type: none"> <li>■ <b>Wholesale</b> - From our research the main benefit of vertical integration is guaranteed demand for wholesaling services in Australia. However, we did not come across any information that would suggest differences in rebate levels between pharmacies and wholesalers on the basis of vertical integration (i.e., we did not find information that a vertically integrated pharmacy pays higher or lower prices compared to non-vertically integrated pharmacies for Australia)</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>Pharmacy (for self-distribution)</b> – In Canada, self-distribution represents a significant proportion (~29%) of the market where the wholesaler serves only its own pharmacies, and therefore likely retains the benefits of vertical integration</li> <li>■ <b>Wholesale (for Traditional wholesale)</b> – Our research has seen no explicit data showing differences in rebate levels or price based on vertical integration in Canada. This is likely because the Competition Bureau Canada (CBC) does place restrictions on the relationship between vertically integrated wholesalers and pharmacies. This was seen in 2016 when McKesson (~33% of the wholesale market) purchased Rexall Pharmacy Group. As part of the purchase, the CBC required McKesson to "restrict the transmission of commercially sensitive information between its pharmaceutical wholesale business and the Rexall retail business, to ensure that competition is preserved for the wholesale and retail supply of</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>Pharmacies</b> - In NZ ~35% of the wholesale market operates through collectives where the wholesaler profits are distributed back to pharmacies. As such, the benefits of integration go to pharmacies in this model. See question above and references for more details of collectivist organisational structure</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>Wholesalers</b> – In the UK, under the national pharmacy contractual framework, pharmacies are guaranteed purchase profit income (In England, it is GBP800 million per year).<sup>27</sup> This suggests the benefits of vertical integration would likely be received in the wholesaling component of the supply chain, through how funds are distributed would depend on contract negotiations between wholesalers and pharmacies</li> </ul>

<sup>25</sup> British Association of European Pharmaceutical Distributors (2020). British Association of European Pharmaceutical Distributors – Written Evidence (UST0019). [online] Committees Parliament UK, p.5. Available at: <https://committees.parliament.uk/writtenevidence/7760/pdf/>.

<sup>27</sup> Community Pharmacy England (2023). Retained margin (Category M). [online] Community Pharmacy England. Available at: <https://cpe.org.uk/funding-and-reimbursement/pharmacy-funding/funding-distribution/retained-margin-category-m/> [Accessed 13 Oct. 2023].

Questions	AUS	CAN	NZL	UK
		<p>pharmaceutical products and services in local markets across Canada.". In their report, the CDC outline how their approach was designed to ensure the benefits of vertical integration did not translate to differences in fees or rebates between McKesson-owned pharmacies and other pharmacies.<sup>26</sup></p>		
<p>What are the government policy objectives for the wholesaling portion of the pharmacy value chain?</p>	<p><b>The National Medicines Policy sets out an overarching objective of "Achiev[ing] the world's best health, social and economic results for all Australians".</b> This includes central pillars of:<sup>28</sup></p> <ul style="list-style-type: none"> <li>- <b>Fair, timely, safe and reliable access</b> to medicines and medicines services, at affordable prices</li> <li>- Medicines are <b>high quality, effective and as safe as possible</b></li> <li>- Medicines are <b>used correctly and safely</b></li> <li>- Medicines industry and researchers that work together are <b>innovative</b></li> </ul>	<p><b>Provincial governments each run discrete drug programmes with aligned policy aims.</b> For example, the Ontario Public Drug Programme is committed to "striving to meet the needs of Ontarians, as patients, consumers and taxpayers" and "making funding decisions on drugs on the best clinical and economic evidence available"<sup>29</sup></p> <p>Wholesale policy at the Federal level is constrained to maintaining the safety of prescription drugs supplied to the public (see next question).</p> <p>There are plans to legislate for universal pharmacare before the end</p>	<p><b>The Medicines New Zealand strategy outlines three core outcomes for the medicines system:</b><sup>31</sup></p> <ul style="list-style-type: none"> <li>■ <b>Quality, safety and efficacy</b> – medicines are safe, of high quality and effective</li> <li>■ <b>Access</b> – citizens have access to the medicines they need regardless of ability to pay</li> <li>■ <b>Optimal use</b> – choices about medicines, the ways the system delivers medicines, and the ways individuals use medicines result in optimal outcomes</li> </ul> <p>Otherwise, wholesale policy is constrained to maintaining the safety of</p>	<p><b>The Medicines and Healthcare products Regulatory Agency has a mandate to:</b><sup>32</sup></p> <ul style="list-style-type: none"> <li>■ Ensure medicines meet acceptable safety standards</li> <li>■ Secure a safe supply chain for medicines</li> <li>■ Collaborate with UK and international partners to enable early access to safe medicines to protect public health</li> </ul> <p>Associated regulation is described in the next question.</p>

26 Please see here for CBC ruling: <https://ised-isde.canada.ca/site/competition-bureau-canada/en/how-we-foster-competition/education-and-outreach/position-statements/acquisition-katz-groups-healthcare-mckesson>

28 National Medicines Policy. Pg. 5. Available at: <https://www.health.gov.au/resources/publications/national-medicines-policy?language=en> [Accessed 11 Sep. 2023].

29 Ontario (n.d.). Ontario Public Drug Programs — Executive Officer Communications | ontario.ca. [online] [www.ontario.ca](http://www.ontario.ca). Available at: <https://www.ontario.ca/page/ontario-public-drug-programs-executive-officer-communications> [Accessed 13 Sep. 2023].

31 Ministry of Health (2015). *Implementing Medicines New Zealand 2015 to 2020*. [online] Ministry of Health. Available at: [https://www.health.govt.nz/publication/implementing-medicines-new-zealand-2015-2020#:~:text=Medicines%20New%20Zealand%20\(the%20New,optimal%20use](https://www.health.govt.nz/publication/implementing-medicines-new-zealand-2015-2020#:~:text=Medicines%20New%20Zealand%20(the%20New,optimal%20use) [Accessed 15 Sep. 2023].

32 Medicines and Healthcare Products Regulatory Agency (n.d.). *About us*. [online] GOV.UK. Available at: <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about#our-corporate-documents> [Accessed 15 Sep. 2023].

Questions	AUS	CAN	NZL	UK
	<p><b>and sustainable.</b> They also have the ability and skills to meet health needs now and in the future</p> <p>Otherwise, wholesalers operate in a regulated market where margins, handling and service agreements are significantly influenced by government (see next question).</p>	of 2023. Details have not yet been published. <sup>30</sup>	prescription drugs supplied to the public (see next question).	
In what ways do governments regulate wholesalers?	<p><b>Regulations are largely set by the Federal government.</b> Regulations include:</p> <ul style="list-style-type: none"> <li>■ <b>Accounting for a wholesale mark-up of 7.52%</b> of ex-manufacturer price in determining the price paid to pharmacies (with minimum and maximum thresholds applied)<sup>33</sup></li> <li>■ <b>Dedicated funding to meet specified service levels</b> – ~40% of government funding to wholesalers is conditional on meeting certain service levels set out in CSOs (see next question for more detail)<sup>34</sup></li> </ul>	<p><b>Regulations are largely set by Provincial governments.</b> While differing significantly by Province, direct regulations include:</p> <ul style="list-style-type: none"> <li>■ <b>Maximum wholesale mark-ups</b> – in Quebec, Newfoundland, Labrador and Saskatchewan wholesale mark-ups are set by government for Public Drug Plans:<sup>37</sup> <ul style="list-style-type: none"> <li>- Quebec and Newfoundland set a maximum wholesale mark-up percentage (e.g., 6.5% and 8.5% respectively)</li> <li>- Saskatchewan differentiates its mark-up by the type of drug (e.g.,</li> </ul> </li> </ul>	<p><b>Direct regulations are set by the Central government.</b> Pharmacy-specific regulations likely have a significant impact on the pricing and service levels of wholesalers.</p> <p>Direct wholesaler regulations include:</p> <ul style="list-style-type: none"> <li>■ Requirement to have a <b>wholesale licence</b><sup>44</sup></li> <li>■ <b>Handling of medicines</b> – Wholesalers are responsible for adhering to the New Zealand Code of Good Manufacturing Practice for manufacture and distribution of therapeutic goods. This includes guidelines on buildings and</li> </ul>	<p><b>Direct regulations are set by the UK government.</b> However, wholesale standards are reportedly largely set through industry norms and behaviours. Direct wholesaler regulations include:</p> <ul style="list-style-type: none"> <li>■ Requirement to have a <b>wholesale licence</b><sup>49</sup></li> <li>■ <b>Handling of medicines</b> – Government imposes regulations related to the transportation and storage of medicines through the Good Distribution Practice (GDP) guidelines. This includes standards on the types of delivery trucks, and the conditions of medicines storage<sup>50</sup></li> </ul>

30 Wilson, J. (2023). Universal pharmacare legislation to pass this year: health minister. [online] Human Resources Director. Available at: <https://www.hcamag.com/ca/specialization/benefits/universal-pharmacare-legislation-to-pass-this-year-health-minister/456755> [Accessed 15 Sep. 2023].

33 Australian Government Department of Health and Aged Care. (2023). Seventh Community Pharmacy Agreement (7CPA). [online] Available at: <https://www.health.gov.au/topics/primary-care/what-we-do/7cpa> [Accessed 7 Sep. 2023].

34 7CPA sets out ~A\$1.1b for CSO and NDSS funding along with A\$1.7b for traditional wholesale mark-up funding leading to ~40% from CSO obligations – See pg. 7 of 7CPA agreement.

37 Health Canada (2023). Mark-up Policies in Public Drug Plans, 2020/21. [online] Available at: <https://www.canada.ca/en/patented-medicine-prices-review/services/npduis/analytical-studies/supporting-information/markup-policies-public-drug.html> [Accessed 7 Sep. 2023].

44 Ministry of Health NZ (n.d.). How to get a licence. [online] Ministry of Health NZ. Available at: <https://www.health.govt.nz/our-work/regulation-health-and-disability-system/psychoactive-substances-regulation/how-get-licence> [Accessed 15 Sep. 2023].

49 Medicines and Healthcare products Regulatory Agency (2014). Apply for manufacturer or wholesaler of medicines licences. [online] GOV.UK. Available at: <https://www.gov.uk/guidance/apply-for-manufacturer-or-wholesaler-of-medicines-licences> [Accessed 15 Sep. 2023].

50 GOV.UK (2020). Good manufacturing practice and good distribution practice. [online] Available at: <https://www.gov.uk/guidance/good-manufacturing-practice-and-good-distribution-practice> [Accessed 7 Sep. 2023].

Questions	AUS	CAN	NZL	UK
	<ul style="list-style-type: none"> <li>■ <b>Handling of medicines</b> – wholesalers are responsible for following the Australian code of good wholesaling practice for medicines. This outlines wholesaler responsibilities for the “effective, efficient and safe handling, storage and distribution of those medicines”<sup>35</sup></li> </ul> <p><b>Wholesalers are also responsible for adhering to any state or territory laws such as holding a state or territory license to hold medicines</b> (e.g., in Victoria, wholesalers must register with the Victorian Department of Health, pay certain license fees and adhere to license conditions<sup>36</sup>)</p>	<p>5% for insulin vs. 6.5% for most other drugs)</p> <ul style="list-style-type: none"> <li>■ <b>Setting minimum stocking standards</b> – In the case of Quebec, wholesalers are required to stock at least 50% of medicines that appear on the Drug List<sup>38</sup></li> <li>■ <b>Setting limits on rebates</b> – Ontario and Quebec have some restrictions on the use of rebates on generic drugs between manufacturer, wholesaler and pharmacy with only some regulated prompt payment/volume discount from the manufacturer allowed (limited to 10% total)<sup>39</sup></li> </ul> <p>Indirect regulations impacting wholesaler revenue include:</p> <ul style="list-style-type: none"> <li>■ <b>Restrictions on pharmacy mark-ups</b> – Some provinces place restrictions on the mark-up of the total drug price for pharmacies. This mark-up limit may incorporate payments to</li> </ul>	<p>facilities, personnel, stock handling and controls and transportation<sup>45</sup></p> <p>Indirect regulations impacting wholesaler revenue include:</p> <ul style="list-style-type: none"> <li>■ <b>Setting maximum reimbursement to pharmacies</b> – While prices charged by wholesalers are determined by the wholesaler, reimbursement schemes to pharmacies can provide a constraint on the amount wholesalers can charge pharmacies for medicines (i.e., there is an implicit ceiling).<sup>46</sup> The current Integrated Community Pharmacy Agreement (ICPSA) sets a maximum mark-up of 3-4% on the ex-manufacturer price for pharmacies. This places an implicit ceiling on the price of wholesaling services (e.g., if the ex-manufacturer price is \$100, a pharmacy can only charge \$103</li> </ul>	<p>Indirect regulations impacting wholesaler revenue include:</p> <ul style="list-style-type: none"> <li>■ <b>Price gauging and hoarding rules</b> – While the UK government does not explicitly set maximum prices for wholesalers, the Competition and Market Authority (CMA) rules can prevent the withholding of supply to increase prices (a recent allegation by CMA was brought against Alliance Pharmaceuticals for alleged restriction of competition)<sup>51</sup></li> </ul>

35 TGA (2010). Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 & 8. [online] Available at: <https://www.tga.gov.au/resources/publication/publications/australian-code-good-wholesaling-practice-medicines-schedules-2-3-4-8#:~:text=Wholesalers%20are%20responsible%20for%20the,appropriate%20standards%20to%20be%20applied.> [Accessed 7 Sep. 2023].

36 Victorian Government. (2023). Medicines and poisons – licence and permit fees schedule. [online] Available at: <https://www.health.vic.gov.au/drugs-and-poisons/medicines-and-poisons-licence-and-permit-fees-schedule> [Accessed 7 Sep. 2023].

38 Quebec Legislature (2023). Regulation respecting the conditions governing the accreditation of manufacturers and wholesalers of medications. [online] Available at: <https://www.legisquebec.gouv.qc.ca/en/document/cr/a-29.01,%20r.%202> [Accessed 7 Sep. 2023].

39 Two sources have been utilised: (1) Shoppers Drug Mart v. MINISTER OF HEALTH AND LONG-TERM CARE and LIEUTENANT GOVERNOR-IN-COUNCIL OF ONTARIO and ATTORNEY GENERAL OF ONTARIO [2016] 4; 40 (Supreme Court of Canada) Available at: [https://www.scc-csc.ca/WebDocuments-DocumentsWeb/34649/FM010\\_Appellants\\_Shoppers-Drug-Mart-Inc-et-al.pdf](https://www.scc-csc.ca/WebDocuments-DocumentsWeb/34649/FM010_Appellants_Shoppers-Drug-Mart-Inc-et-al.pdf) [Accessed 14 Sep. 2023] & (2) Ontario Provincial Government (2014). O. Reg. 220/10: GENERAL. [online] Ontario.ca. Available at: <https://www.ontario.ca/laws/regulation/r10220> [Accessed 14 Sep. 2023].

45 Medsafe New Zealand Medicines and Medical Devices Safety Authority. (n.d.). New Zealand Code of Good Manufacturing Practice for Manufacturing and Distribution of Therapeutic Goods. [online] Available at: <https://www.medsafe.govt.nz/downloads/GMPParts4and5.pdf> [Accessed 7 Sep. 2023].

46 SmartInvestor (2016). CDC Pharmaceuticals Limited Product Disclosure Statement. P15 [online] Available at: <https://smartinvestor.sorted.org.nz/assets/disclose-documents/6a/80/bb/CDC-Pharmaceuticals-Limited-Product-Disclosure-Statement.pdf> [Accessed 7 Sep. 2023].

51 GOV.UK. (2023). Pharmaceuticals: anti-competitive agreements. [online] Available at: <https://www.gov.uk/cma-cases/pharmaceuticals-suspected-anti-competitive-agreements> [Accessed 7 Sep. 2023].

Questions	AUS	CAN	NZL	UK
		<p>wholesalers (e.g., Ontario caps pharmacy mark-ups to 6-8%, which is then used to fund wholesalers)<sup>40</sup></p> <ul style="list-style-type: none"> <li>■ <b>Setting of drug list prices</b> – Provinces and pan-Canadian Pharmaceutical Alliance will typically negotiate with manufacturers to determine the maximum reimbursement price they are willing to pay for public drug programme medicines, thereby potentially influencing the margins of pharmacies and wholesalers<sup>41</sup></li> </ul> <p>Additionally, the Federal government regulations include:</p> <ul style="list-style-type: none"> <li>■ Requirement to have a <b>drug establishment licence</b><sup>42</sup></li> <li>■ <b>Regulations on the storage and handling of medicines.</b> These regulations guarantee that wholesalers comply with the safety conditions for drug storage, including cold storage, ventilation and sanitation<sup>43</sup></li> </ul>	<p>maximum, leading to a maximum wholesaler charge of \$3)<sup>47</sup></p> <p>Indirect guidance impacting operations of wholesalers include the Integrated Community Pharmacy Services Agreement (ICPSA), which stipulates that:<sup>48</sup></p> <ul style="list-style-type: none"> <li>■ 90% of prescription items should be available to the patient within one hour of the prescription being presented to the pharmacy</li> <li>■ 99% by the end of the next business day</li> <li>■ 100% within two business days</li> </ul>	

40 Marchese Health Care (n.d.). Pharmacy Dispensing Fees. [online] Available at: <https://marchesehealthcare.ca/2020/04/pharmacy-dispensing-fees/> [Accessed 7 Sep. 2023].

41 Memedovich, K.A., Manns, B., Beall, R., Hollis, A. and Clement, F. (2019). The impact of pharmaceutical rebates on patients' drug expenditures. *Canadian Medical Association Journal*, 191(11), pp.E308–E312. doi:<https://doi.org/10.1503/cmaj.181041>.

42 Canada Health (2011). Drug establishment licences. [online] [www.canada.ca](http://www.canada.ca). Available at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/drug-establishment-licences.html> [Accessed 13 Sep. 2023].

43 Canada Health (2020). Guidelines for environmental control of drugs during storage and transportation (GUI-0069). [online] Available at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/guidance-documents/guidelines-temperature-control-drug-products-storage-transportation-0069.html#s3.2.1> [Accessed 7 Sep. 2023].

47 Integrated Community Pharmacy Services Agreement Fees and Payments -from 1 October 2022. (2022). p.1 [online] <https://www.tewhātuora.govt.nz/>. Available at: <https://www.tewhātuora.govt.nz/assets/For-the-health-sector/Community-pharmacy/Procedures-and-payments/Integrated-Community-Pharmacy-Services-Agreement-Fees-and-Payments-from-October-2022-September-2023-v2.pdf> [Accessed 7 Sep. 2023].

48 Tewhātuora. (2023). Community Pharmacy Agreement – Te Whatu Ora - Health New Zealand. P83 [online] Available at: <https://www.tewhātuora.govt.nz/for-the-health-sector/community-pharmacy/community-pharmacy-agreement/> [Accessed 7 Sep. 2023].

Questions	AUS	CAN	NZL	UK
<b>What roles do wholesalers play?</b>				
What are the major service requirements of wholesalers?	<p>Australian requirements of wholesalers stem from Community Service Obligation funding and are defined by the government. These include.<sup>52</sup></p> <ul style="list-style-type: none"> <li>■ <b>Delivery frequency –</b> Wholesalers are expected to supply certain PBS Medicines (s85) promptly within 24 to 72 hours (except for 9 remote postcodes that are exempt, e.g., Norfolk Island)</li> <li>■ <b>SKU availability –</b> wholesalers should have the ability to supply any brand of any PBS Medicine on request</li> <li>■ <b>Ability to supply any Community Pharmacy</b> within a wholesaler's national or state jurisdiction, including rural and remote pharmacies</li> </ul>	<p><b>Service requirements are mostly defined in commercial contracts between pharmacies and wholesalers</b> (excluding some provincial mandates such as in Quebec), and details are not publicly available given commercial sensitivity. Industry experts indicate that service requirements generally include:</p> <ul style="list-style-type: none"> <li>■ <b>Delivery frequency –</b> same day or next day delivery for most urban areas with reduced frequency the more rural a pharmacy gets (i.e., minimum for extreme locations may be once a week)<sup>54</sup></li> <li>■ <b>Rebates based on threshold of sales or repayment timelines</b> (e.g., pharmacies repaying within a certain number of days results in a rebate). Note that some rebates have been restricted in Quebec</li> </ul>	<p><b>Service requirements are mostly defined in commercial contracts between pharmacies and wholesalers</b>, although requirements of pharmacies significantly shape the nature of wholesaler agreements (as described above). Exact service agreements are commercially sensitive; however, industry experts indicate that agreements tend to include:</p> <ul style="list-style-type: none"> <li>■ <b>Delivery frequency –</b> Next day delivery is standard, with orders made before the end of day subsequently packed in the evening for a next day delivery by 10:00am<sup>57</sup></li> <li>■ <b>SKU availability –</b> Full Pharmaceutical Schedule availability is expected given the delivery speed requirements for pharmacies<sup>58</sup></li> </ul>	<p><b>Service requirements are mostly defined in commercial contracts between pharmacies and wholesalers</b> and details are not publicly available given commercial sensitivity. Industry experts indicate that these agreements will tend to include:</p> <ul style="list-style-type: none"> <li>■ <b>Delivery frequency –</b> Twice daily delivery with orders placed before noon delivered in the afternoon and orders after this hour delivered early the next morning</li> <li>■ <b>SKU availability –</b> I.e., the number of SKUs to be delivered as part of the agreement with full line wholesalers offering a wide range of products and short line wholesalers select options</li> <li>■ Compliance with <b>storage and transportation requirements</b></li> </ul>

<sup>52</sup> Department of Health and Aged Care. (2022). Community Service Obligation Operational Guidelines. [online] Available at: <https://www.health.gov.au/sites/default/files/documents/2022/10/community-service-obligation-cso-for-pharmaceutical-wholesalers-funding-pool-operational-guidelines-guidelines.pdf> [Accessed 7 Sep. 2023].

<sup>54</sup> CAPM identify same day delivery as the industry norm in the following reference: CAPDM. (n.d.). CAPDM - Canadian Association for Pharmacy Distribution Management. [online] Available at: <https://www.capdm.ca/#howebenefit> [Accessed 7 Sep. 2023].

<sup>57</sup> Please see page 7 of the following reference for detail of standard delivery: Notice of proposed merger, PURSUANT TO SECTION 66(1) OF THE COMMERCE ACT 1986, NOTICE IS HEREBY GIVEN SEEKING CLEARANCE FOR A PROPOSED MERGER. (2014). [https://comcom.govt.nz/\\_data/assets/pdf\\_file/0021/76512/CDC-Pharmaceuticals-Limited-and-Pharmacy-Wholesalers-Central-Limited-Clearance-Application-18-June-2014-public-version.pdf](https://comcom.govt.nz/_data/assets/pdf_file/0021/76512/CDC-Pharmaceuticals-Limited-and-Pharmacy-Wholesalers-Central-Limited-Clearance-Application-18-June-2014-public-version.pdf).

<sup>58</sup> Notice of proposed merger, PURSUANT TO SECTION 66(1) OF THE COMMERCE ACT 1986, NOTICE IS HEREBY GIVEN SEEKING CLEARANCE FOR A PROPOSED MERGER. (2014). [https://comcom.govt.nz/\\_data/assets/pdf\\_file/0021/76512/CDC-Pharmaceuticals-Limited-and-Pharmacy-Wholesalers-Central-Limited-Clearance-Application-18-June-2014-public-version.pdf](https://comcom.govt.nz/_data/assets/pdf_file/0021/76512/CDC-Pharmaceuticals-Limited-and-Pharmacy-Wholesalers-Central-Limited-Clearance-Application-18-June-2014-public-version.pdf).

Questions	AUS	CAN	NZL	UK
	<ul style="list-style-type: none"> <li>■ <b>Maintaining specific stocks</b> of PBS medicines</li> <li>■ Supply PBS Medicines <b>at or below the approved price</b> to pharmacies</li> <li>■ <b>Adhere to the Code of Good Wholesaling Practices</b> for Medicines<sup>53</sup></li> </ul>	<p>and Ontario since 2013 so this applies to other provinces<sup>55</sup></p> <ul style="list-style-type: none"> <li>■ Compliance with <b>storage and transportation requirements</b></li> <li>■ <b>Other value-added services</b> may be included such as packaging requirements, supply of medical materials or expert support or advice (e.g., McKesson offering strip packing inspection technology<sup>56</sup>)</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>Compliance with storage, transportation and handling requirements</b> – New Zealander wholesalers are responsible for adhering to the Good Manufacturing Practice code for distribution of Therapeutic Goods<sup>59</sup></li> </ul>	
What channels (and associated volumes) are used to distribute medicines? <sup>60</sup>	<p>This information is largely based on expert input due to lack of public sources.</p> <ul style="list-style-type: none"> <li>■ <b>Traditional wholesaler, exclusive wholesaler or direct distribution</b> – likely &gt;90% of the market<sup>61</sup></li> <li>■ <b>Direct distribution using a third-party logistics provider</b> – likely &lt;10% of</li> </ul>	<p>This information is largely based on expert input due to lack of public sources.</p> <ul style="list-style-type: none"> <li>■ <b>Traditional wholesaler</b> – likely ~62% of all medicines through this channel<sup>65</sup></li> <li>■ <b>Self-distribution without wholesalers</b> – likely represents ~29% with the highest</li> </ul>	<p>This information is largely based on expert input due to lack of public sources.</p> <ul style="list-style-type: none"> <li>■ <b>Traditional wholesaler</b> – likely &gt;85% of overall market occurs through traditional wholesalers (includes hospital and pharmacy distribution)</li> <li>■ <b>Direct distribution with a third-party logistics provider</b> – likely distribute &lt;15% to hospitals –</li> </ul>	<p>This information is largely based on expert input due to lack of public sources.<sup>68</sup></p> <ul style="list-style-type: none"> <li>■ <b>Traditional wholesaler</b> – likely ~70% of generic medicines and ~20% of innovative medicines sent to pharmacies, and ~30% of generic medicines sent to hospital</li> <li>■ <b>Direct distribution</b> – likely ~30% of generic medicines and ~40% of innovative medicines sent to</li> </ul>

53 Department of Health and Aged Care (2020). Community Service Obligation (CSO) for Pharmaceutical Wholesalers funding pool operational guidelines. [online] Available at:

<https://www.health.gov.au/resources/publications/community-service-obligation-cso-for-pharmaceutical-wholesalers-funding-pool-operational-guidelines?language=en> [Accessed 7 Sep. 2023].

55 Ontario Provincial Government (2014). O. Reg. 220/10: GENERAL. [online] Ontario.ca. Available at: <https://www.ontario.ca/laws/regulation/r10220> [Accessed 14 Sep. 2023].

56 McKesson (n.d.). Strip Packaging Inspection - McKesson Canada - McKesson Canada. [online] [www.mckesson.ca](http://www.mckesson.ca). Available at: <https://www.mckesson.ca/strip-packaging-inspection> [Accessed 7 Sep. 2023].

59 New Zealand Ministry of Health (1995). New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods. [online] Available at: <https://www.medsafe.govt.nz/downloads/GMPParts4and5.pdf> [Accessed 7 Sep. 2023]

60 Distribution models largely fit under 5 archetypes:

Traditional wholesaler – wholesaler buys stock from manufacturers and sell it to retail and hospital channels; players are usually vertically integrated.

Direct distribution – typically for higher-margin, low-volume drugs, manufacturers often pair with wholesalers as logistics partner who do not own stock and are paid on \$-per-pack basis.

Direct distribution without wholesaler – Manufacturer pair with non-wholesaler logistics partner; commonly for expensive medicines that require special handling.

Exclusive wholesaler agreements – Manufacturers contract with 1-2 wholesalers exclusively with wholesaler owning stock and selling it; allows manufacturers to negotiate better terms and wholesalers to attract volume for innovative medicines.

61 Exact split between reduced wholesale and traditional wholesalers are not segmented and, as such, grouped together

65 Sources based on Canadian industry expert with knowledge of breakdown across geographies

68 Exact numbers based on UK expert interviews with knowledge of the composition of distribution

Questions	AUS	CAN	NZL	UK
	<p>pharmaceuticals; this will typically be sent through this channel with major manufacturers moving from this model in recent years (e.g., Pfizer Australia in 2021<sup>62</sup>).</p> <ul style="list-style-type: none"> <li>■ <b>Direct to government</b> – Some medicines are delivered directly from manufacturers to government who manage distribution to healthcare professions (e.g., for vaccines or medicines on the national medical stockpile<sup>63</sup>).<sup>64</sup></li> </ul>	<p>concentration in Quebec (~50%)<sup>66</sup></p> <ul style="list-style-type: none"> <li>■ <b>Direct distribution with a third-party logistics</b> – likely represent a small component of the market with ~9%<sup>67</sup></li> </ul>	<p>information based on expert input due to lack of public sources</p>	<p>pharmacies, and 15% of innovative medicines sent to hospitals</p> <ul style="list-style-type: none"> <li>■ <b>Exclusive wholesaler agreements</b> – likely account for ~40% of innovative medicines going to pharmacies and ~15% going to hospitals</li> <li>■ <b>Direct distribution with a third-party logistics provider</b> likely distributes the remaining ~70% of generic and innovative medicines to hospitals</li> </ul>
How do governments regulate packaging?	<p><b>Labelling and packaging rules are regulated by the Therapeutic Goods Administration (TGA) and include requirements for:</b><sup>69</sup></p> <ul style="list-style-type: none"> <li>■ Tamper-evident packaging</li> <li>■ Child-resistant packaging</li> <li>■ Standard data matrix codes and medicine serialisation</li> </ul>	<p><b>Labelling and packaging rules are set by Health Canada and include requirements for:</b><sup>70</sup></p> <ul style="list-style-type: none"> <li>■ Restrictions on the language used on labels to promote health benefits (i.e., superlatives or undue emphasis phrases)</li> <li>■ Legible font sizes – recommended 10 pt font</li> </ul>	<p><b>Labelling and packaging is regulated by the New Zealand Medicines and Medical Devices Safety Authority and includes requirements for:</b><sup>71</sup></p> <ul style="list-style-type: none"> <li>■ Legible and durable labels</li> <li>■ Minimum information, such as name of medicine, batch numbers, expiry dates, etc.</li> <li>■ English to be used on all labels</li> </ul>	<p><b>Labelling and packaging is regulated and approved by the Medicines and Healthcare products Regulatory Agency and include requirements for:</b><sup>72</sup></p> <ul style="list-style-type: none"> <li>■ Clear, easy to read labels</li> <li>■ Patient information leaflets (PIL), unless on the packet</li> <li>■ Braille on labelling and in PIL for the name of the medicine</li> </ul>

62 Pfizer Australia (2021). Pfizer Australia transitions to wholesaler distribution model. [online] Available at: [https://www.pfizer.com.au/files/2021-05-19-MEDIA-RELEASE-Pfizer-AU-transitions-to-wholesaler-distribution-model\\_FINAL.pdf](https://www.pfizer.com.au/files/2021-05-19-MEDIA-RELEASE-Pfizer-AU-transitions-to-wholesaler-distribution-model_FINAL.pdf).

63 Department of Health and Aged Care (2023). National Medical Stockpile. [online] Australian Government Department of Health and Aged Care. Available at: <https://www.health.gov.au/our-work/national-medical-stockpile>.

64 In Australia, there are various conditions placed on pharmacies including their location (e.g., certain restrictions on pharmacies being placed within 1.5km from the nearest approved premises (DHAC Pharmacy Location Rules, August 2022 V1.7) and on their ownership (e.g., an applicant must be a pharmacist or a partnership of registered pharmacists or a pharmacists' body corporate (ABLIS, Available at: [https://ablis.business.gov.au/service/nsw/pharmacy-registration/31976#:~:text=Eligibility%20requirements,Securities%20and%20Investment%20Commission%20\(ASIC\)](https://ablis.business.gov.au/service/nsw/pharmacy-registration/31976#:~:text=Eligibility%20requirements,Securities%20and%20Investment%20Commission%20(ASIC)))

66 Self-distribution is analogous to traditional wholesaling with an exclusive distribution arrangement with pharmacies that are vertically integrated

67 Sources based on Canadian industry expert with knowledge of breakdown across geographies

69 TGA (n.d.). Labelling & packaging. [online] Therapeutic Goods Administration (TGA). Available at: <https://www.tga.gov.au/labelling-packaging>.

70 Health Canada (2013). Guidance Document: Labelling of Pharmaceutical Drugs for Human Use. [online] [www.canada.ca](https://www.canada.ca). Available at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/labelling-pharmaceutical-drugs-human-use-2014-guidance-document.html#a521> [Accessed 7 Sep. 2023].

71 MEDSAFE (2023). Guideline on the Regulation of Therapeutic Products in New Zealand. [online] Available at: <https://www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/Part5.pdf> [Accessed 7 Sep. 2023].

72 GOV.UK (2014). Medicines: packaging, labelling and patient information leaflets. [online] GOV.UK. Available at: <https://www.gov.uk/guidance/medicines-packaging-labelling-and-patient-information-leaflets>.

Questions	AUS	CAN	NZL	UK
		<ul style="list-style-type: none"> <li>Limits on advertising and promotion materials on packaging</li> </ul>		<ul style="list-style-type: none"> <li>Warning labels and child-resistant packaging</li> </ul>
<b>What are the payment arrangements?</b>				
Who ultimately pays for wholesaling services?	<p><b>A mix of government funding (~90%) and patient payments (~10%)</b> ultimately pay for wholesaling services:<sup>73</sup></p> <ul style="list-style-type: none"> <li>Government funding is made directly, through CSO funding, and indirectly through subsidies to pharmacies (at a level that provides wholesalers with up to a 7.52% mark-up with minimum and maximum thresholds of A\$0.41 to A\$54.14)</li> <li>Patient payments occur indirectly through their payments to pharmacies<sup>74</sup></li> </ul>	<p><b>A mix of public spending (~45%), private insurance (~35%) and direct patient costs (~20%)</b> ultimately pay for wholesaling services:<sup>75</sup></p> <ul style="list-style-type: none"> <li>Provincial governments are responsible for managing public drug plan budgets paying pharmacies fees for those eligible for Drug Benefit programmes</li> <li>Insurance providers cover private plans and will negotiate on the claimable cost of medicines (~2/3rds of Canadians have private insurance that cover such things as outpatient prescription drugs<sup>76</sup>)</li> </ul>	<p><b>Historically a mix of public (~68%) and private sources (~32%)</b> have ultimately paid for wholesaling services:<sup>79</sup></p> <ul style="list-style-type: none"> <li>Government funding is paid indirectly via payments provided to pharmacies as part of the ICPSA agreement. Payments to pharmacies are limited to NZ\$1.4976B in FY23<sup>80</sup></li> <li>Patient payments occur indirectly through their co-payments to pharmacies</li> </ul> <p><b>From July 2023 standard co-payments have been scrapped</b>, while prescriptions from specialists and non-publicly funded prescribers still attract a NZ\$15 co-</p>	<p><b>A mix of government funding (&gt;90%) and patient payments (&lt;10% in England only<sup>82</sup>)</b> ultimately pay for wholesaling services:</p> <ul style="list-style-type: none"> <li>Government funding is made indirectly through the payments to pharmacies who then pay traditional wholesalers for their services</li> <li>Patient co-payments also contribute £9.65 per prescription item in England depending on the eligibility of the patients (e.g., free for those over the age of 65, under 16 or based on medical conditions).<sup>83</sup></li> </ul>

73 Calculation based on 7CPA where a total of ~A\$3.1b is allocated to remuneration to wholesalers. Of this, ~A\$320 is patient funded. See 7CPA for more details: Seventh Community Pharmacy Agreement (7CPA). (2020). [online] Department of Health and Aged Care, Australia: Department of Health, p.7. Available at: <https://www.health.gov.au/resources/publications/7cpa> [Accessed 7 Sep. 2023].

74 Seventh Community Pharmacy Agreement (7CPA). (2020). [online] Department of Health and Aged Care, Australia: Department of Health, p.7. Available at: <https://www.health.gov.au/resources/publications/7cpa> [Accessed 7 Sep. 2023].

75 Zhang, Y. (2022). Mark-up Policies of Canada's Public Drug Plans. In: WHO. [online] WHO webinar series on country pharmaceutical pricing policies. WHO. Available at: [https://cdn.who.int/media/docs/default-source/who-aap-pricing-webinars/webinar-slides---2022-07.pdf?sfvrsn=bcdb863f\\_1](https://cdn.who.int/media/docs/default-source/who-aap-pricing-webinars/webinar-slides---2022-07.pdf?sfvrsn=bcdb863f_1) [Accessed 7 Sep. 2023].

76 Tikkanen, R., Osborn, R., Mossialos, E., Djordjevic, A. and Wharton, G. (2020a). Canada | Commonwealth Fund. [online] [www.commonwealthfund.org](http://www.commonwealthfund.org). Available at: <https://www.commonwealthfund.org/international-health-policy-center/countries/canada>.

79 OECD/WHO (2018), How Pharmaceutical Systems are organized in Asia and the Pacific, WHO, Geneva/OECD Publishing, Paris, pp.32. <https://doi.org/10.1787/9789264291706-en>.

80 Pharmac (n.d.). Budget bid information. [online] Pharmac | New Zealand Government. Available at: <https://pharmac.govt.nz/medicine-funding-and-supply/the-funding-process/budget-bid-information/> [Accessed 7 Sep. 2023].

82 Tikkanen, R., Osborn, R., Mossialos, E., Djordjevic, A. and Wharton, G.A. (2020). England | Commonwealth Fund. [online] The Commonwealth Fund. Available at: <https://www.commonwealthfund.org/international-health-policy-center/countries/england>.

83 Department of Health & Social Care (n.d.). Aligning the upper age for NHS prescription charge exemptions with the State Pension age. [online] GOV.UK. Available at:

<https://www.gov.uk/government/consultations/aligning-the-upper-age-for-nhs-prescription-charge-exemptions-with-the-state-pension-age/aligning-the-upper-age-for-nhs-prescription-charge-exemptions-with-the-state-pension-age#:~:text=Prescribing%20data>.

Questions	AUS	CAN	NZL	UK
		<ul style="list-style-type: none"> <li>Private citizens without insurance pay pharmacies themselves assuming they are not eligible for public plans<sup>77</sup></li> </ul> <p>Note that the current federal government has committed to introduce a Pharmacare bill by the end of 2023 which would significantly change the mix of spending sources and potentially reshape the regulatory landscape<sup>78</sup></p>	payment meaning this split will change in the next year <sup>81</sup>	
Who decides how much is paid to wholesalers?	<p><b>Government and pharmacies</b> – Payment terms are broadly determined by government with some scope for negotiation between wholesalers and pharmacies:</p> <ul style="list-style-type: none"> <li><b>Government</b> – Wholesaler allowances are set in the Seventh Community Pharmacy Agreement including the wholesaler mark-up level (currently 7.52% with dispensing range of A\$0.41 to A\$54.14) and are paid through pharmacies<sup>84</sup></li> <li><b>Pharmacies</b> – Rebates will typically be decided based on</li> </ul>	<p><b>Province dependent</b> – Pharmacies are ultimately responsible for setting service terms with wholesalers. The results of this agreement are shaped significantly by government and insurance providers:</p> <ul style="list-style-type: none"> <li><b>Provincial governments</b> – will provide an explicit or implicit ceiling on wholesaler margins through regulations on wholesalers or pharmacies (described in the question above). Governments can also exert significant influence through their direct negotiations with manufacturers for drug prices and setting of maximum reimbursements from</li> </ul>	<p><b>Pharmacies, limited by government</b> – wholesalers are paid directly through agreements and contracts with pharmacies, with pharmacy income largely paid for by government.</p>	<p><b>Pharmacy or manufacturer</b> – Depending on the nature of the agreement, pharmacies or manufacturers are responsible for direct payments to wholesalers and the associated terms.</p> <ul style="list-style-type: none"> <li><b>Manufacturer</b> – Wholesalers are paid by manufacturers through contracts for exclusive distribution (e.g., AstraZeneca direct distribution with AAH in 2019<sup>88</sup>)</li> <li><b>Pharmacy</b> – Traditional wholesalers are paid by pharmacies through service agreements<sup>89</sup></li> </ul>

77 Government of Canada, S.C. (2022). The Daily — Study: Inequities in pharmaceutical access and use. [online] www150.statcan.gc.ca. Available at: <https://www150.statcan.gc.ca/n1/daily-quotidien/221102/dq221102a-eng.htm>.

78 Major, D. (2023). New health minister says pharmacare legislation is coming this fall. [online] CBC. Available at: <https://www.cbc.ca/news/politics/mark-holland-health-minister-pharmacare-1.6938470> [Accessed 13 Sep. 2023].

81 Verrall, A. (2023). Helping with health costs: Prescription charge scrapped, providing cheaper medicine. [online] The Beehive. Available at: <https://www.beehive.govt.nz/release/helping-health-costs-prescription-charge-scrapped-providing-cheaper-medicine>.

84 Australian Government Department of Health and Aged Care. (2023). Seventh Community Pharmacy Agreement (7CPA). [online] Available at: <https://www.health.gov.au/topics/primary-care/what-we-do/7cpa> [Accessed 7 Sep. 2023].

88 Lewis, G. (2019). AAH secures exclusive direct-to-pharmacy deal for AstraZeneca products. [online] C+D. Available at: <https://www.chemistanddruggist.co.uk/CD005938/AAH-secures-exclusive-direct-to-pharmacy-deal-for-AstraZeneca-products> [Accessed 15 Sep. 2023].

89 Based on input from industry expert with knowledge of wholesale and pharmacy relationships

Questions	AUS	CAN	NZL	UK
	<p>contractual negotiations between pharmacies and wholesalers with higher volume pharmacies typically able to extract greater margin. Industry experts indicate that:<sup>85</sup></p> <ul style="list-style-type: none"> <li>- <b>Small independent pharmacies</b> experience little to no rebates against the 7.52% mark-up</li> <li>- <b>Moderately sized franchises</b> will be able to capture a ~1-1.5% reductions depending on size</li> <li>- <b>Larger players</b> are able to extract the largest rebates, often greater than &gt;1.5%</li> </ul> <ul style="list-style-type: none"> <li>■ <b>Manufacturer</b> – rebates or incentives from manufacturers will typically range from 3-10% depending on the contractual terms<sup>86</sup></li> </ul>	<p>pharmacies. There are also some restrictions placed on allowable rebates with Ontario and Quebec outlawing the practice</p> <ul style="list-style-type: none"> <li>■ <b>Pharmacies and insurers</b> – For private payers, the wholesale margins are a matter of negotiation between the pharmacy and wholesaler. In turn, this is dependent on the maximum reimbursements that insurers will pay<sup>87</sup></li> </ul>		

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<sup>85</sup> Given exact rebates are commercial in confidence, numbers have been estimated through expert interviews

<sup>86</sup> Given exact rebates are commercial in confidence, numbers have been estimated through expert interviews

<sup>87</sup> Reguly, T.A., McMahon, E.M. and Singh, M. (2021). Drug pricing and reimbursement: The role of provinces and hospitals in pharmaceutical pricing | Insights | Torys LLP. [online] www.torys.com. Available at: <https://www.torys.com/en/our-latest-thinking/publications/2021/02/pricing-and-reimbursement-the-role-of-provinces-and-hospitals-in-pharmaceutical-pricing> [Accessed 13 Sep. 2023].

Questions	AUS	CAN	NZL	UK
<p>How much is paid to wholesalers?</p> <p><i>All numbers are indicative only and estimated using multiple sources, including expert interviews given data is typically not</i></p>	<ul style="list-style-type: none"> <li>Estimated <b>~A\$788M</b> wholesaler post rebate Mark-Up Revenue (MUR)<sup>90</sup> from PBS excluding ex-manufacturer prices (including CSO funding): <ul style="list-style-type: none"> <li><b>~A\$457M</b> wholesaler mark-up as agreed in 7CPA</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Estimated <b>~A\$1,610M (CA\$1,440M)</b> wholesaler post rebate MUR<sup>101</sup></li> <li><b>Wholesaler mark-ups are 4-9%</b> depending on Province (e.g., Ontario is 4-8%, British</li> </ul>	<ul style="list-style-type: none"> <li>Estimated <b>~A\$58M (NZ\$62M)</b> wholesaler post rebate MUR<sup>107</sup></li> <li><b>Wholesaler mark-ups are likely 3-4%</b> post discounts and rebates<sup>108</sup></li> </ul>	<ul style="list-style-type: none"> <li>Estimated <b>~A\$1,333M (£716M)</b> wholesaler post rebate MUR<sup>115</sup></li> <li><b>Wholesaler mark-ups are likely 2-3%</b> for innovative medicines and <b>20-25%</b> for generic medicines post discounts and rebates<sup>116</sup></li> </ul>

90 Note that the term “wholesaler post rebate mark-up revenue” has been used to create a like-for-like comparison across different countries. This term includes revenues, all net rebates from manufacturers and pharmacies minus the cost of purchasing the drugs. The number therefore excludes a range of other non-drug manufacturer costs that would be applied before gross profit is determined.

101 Wholesale mark-up has been calculated based on the overall size of the Canadian pharmaceutical at ~CAN\$37bn of which \$30.5bn focuses on the retail/community pharmacy component. Based on an average wholesaler mark up of ~6.5% and an overall share of the total cost of drug of ~4.7%, this was assumed to lead to a wholesaler post-rebate MUR of CAN\$1,440M.

Sources: Total size of market – Overall size of the market is based a combination of expert input combined with verified public data sources. The publicly available market size come from: Hofmeister, M., Sivakumar, A., Clement, F., Hayes, K.N., Law, M., Guertin, J.R., Neville, H.L. and Tadrous, M. (2022). Trends in Canadian prescription drug purchasing: 2001–2020. Journal of Pharmaceutical Policy and Practice, 15(1). doi:<https://doi.org/10.1186/s40545-022-00420-4>. Wholesaler mark-up post rebates – Leverages Quebec regulated mark-up: 101 A-29.01, r. 2 - Regulation respecting the conditions governing the accreditation of manufacturers and wholesalers of medications. SCHEDULE II [online] Available at: <https://www.legisquebec.gouv.qc.ca/en/document/cr/A-29.01,%20r.%202?langCont=en#sc-nb:2> [Accessed 7 Sep. 2023]. Proportion of the supply chain – Estimated based on spending referenced in: Zhang, Y. (2022). Mark-up Policies of Canada’s Public Drug Plans. In: WHO. [online] WHO webinar series on country pharmaceutical pricing policies. WHO. Available at: [https://cdn.who.int/media/docs/default-source/who-aap-pricing-webinars/webinar-slides---2022-07.pdf?sfvrsn=bcdb863f\\_1](https://cdn.who.int/media/docs/default-source/who-aap-pricing-webinars/webinar-slides---2022-07.pdf?sfvrsn=bcdb863f_1) [Accessed 7 Sep. 2023].

107 Calculation has been calibrated using two approaches with the first used throughout the analysis and the second providing a lower bound and sense check.

Total wholesaler post rebate mark-up revenue has been identified through the financial statements of major wholesaler CDC Pharmaceuticals and scaled up based on their market share for New Zealand (~25% based on expert input). CDC was found to have a total of NZ\$561,698 receipts from customers in 2022 and costs to suppliers/manufacturers of NZ\$543,787. The remaining amount is then scaled up to account for CDC’s market share along with accounting for non-subsidised medicines that may be distributed by the wholesaler.

Please note for (1) that CDC Pharmaceutical is a cooperative wholesaler (i.e., owned by pharmacists) with profits distributed to pharmacies. The nature of both rebates and profits being distributed to pharmacies suggests that the overall post rebate mark-up revenue figure for New Zealand is an upper limit as there may be an incentive for CDC and other co-operatives to offer lower rebates and higher profit/ dividend payments, resulting in a higher post rebate mark-up revenue than otherwise.

To stress test (1), a lower limit was identified through decomposing PHARMAC’s budget into components for the wholesaler and pharmacy. PHARMAC’s total pharmaceutical budget of ~NZ\$1.29b in 2023 (including spending on subsidised medicines based on the Pharmaceutical Schedule Information and excluding special programs, rebates, etc.). Total dispensing fees was ~NZ\$474M through multiplying total dispensing events by a \$5.45 dispensing fee. The pharmacy mark-up was calculated as ~NZ\$42.5M based on a 3-4% mark-up on the final price of drugs. Industry experts indicate that the pharmacy mark-up is typically captured by the wholesaler along with some proportion of the total dispensing fee. This suggests a lower limit of NZ\$42.5M for wholesaling post rebate mark-up revenue.

For first methodology, please see CDC financial statement here: CDC Pharmaceutical (2023). Annual Report 2023. [online] p.10. Available at:

<https://app.companiesoffice.govt.nz/companies/app/service/services/documents/824AA7FE081A6A7DBBD133B40F0B295D> [Accessed 15 Sep. 2023].

For the second methodology, sources for the pharmaceutical products are based on the PHARMAC Community Schedule which lists out the drugs provided by government and the subsidised amount. Please find the link here: Government, P. | N.Z. (2023). Schedule Online. [online] Pharmac | New Zealand Government. Available at: <https://schedule.pharmac.govt.nz/ScheduleOnline.php> [Accessed 15 Sep. 2023]. Additionally, quantity of drugs supplied can be found at: Te Whatu Ora (n.d.). Pharmaceutical Data web tool. [online] [tewhatuora.shinyapps.io](https://tewhatuora.shinyapps.io). Available at: <https://tewhatuora.shinyapps.io/pharmaceutical-data-web-tool/> [Accessed 15 Sep. 2023]. and the regulations that are used to determine the wholesale lower bound revenue is the Integrated Community Pharmacy Services Agreement Fees and Payments -from 1 October 2022. (2022). p.1 [online] <https://www.tewhatuora.govt.nz/>. Available at: <https://www.tewhatuora.govt.nz/assets/For-the-health-sector/Community-pharmacy/Procedures-and-payments/Integrated-Community-Pharmacy-Services-Agreement-Fees-and-Payments-from-October-2022-September-2023-v2.pdf> [Accessed 7 Sep. 2023].

108 Figure triangulated by NZ wholesale expert and Sapere 2015 research report where 3.5% is used: <https://srgexpert.com/wp-content/uploads/2017/11/Sapere-pharmaceuticalmarginsFinal-Report-09102015-public-as-sent.pdf>.

115 Estimates taken from 2020 IQVIA market data combined with expert insights around expected returns for different segments of the wholesale market (i.e., disaggregating hospital and community pharmacy market shares). Total pharmacy distribution value chain is estimated to be ~£10.4b with retail Bx and GX drugs accounting for ~75% of the market (i.e., totalling ~£7.9bn) and gross profit pools are estimated to be ~£540M. The wholesaler post rebate mark-up revenue is taken from the ~£540M gross profit pool and any non-manufacturing COGS (~£152M). The total is assumed to grow at a rate of 1.4% based on the IBIS World report on the pharmaceutical wholesaling industry. This totals ~£716M for the UK market in 2022

116 Given commercial sensitivity of the number, numbers are based on wholesale experts from relevant country.

Questions	AUS	CAN	NZL	UK
<u>reported explicitly. Public sources are provided in footnotes</u>	<ul style="list-style-type: none"> <li>- <b>~A\$214M</b> in funding to wholesalers as a result of CSO funding pool<sup>91</sup></li> <li>- <b>~A\$117M</b> in net rebates from an estimated ~3% rebate from manufacturers and average 1% rebate to pharmacies<sup>92</sup></li> </ul> <ul style="list-style-type: none"> <li>■ Wholesalers may apply <b>mark-ups up to 7.52%</b> (with a minimum value of \$0.41 and maximum of \$54.14<sup>93</sup>) – stipulated by legislative instrument – before rebates and other incentives are applied.</li> </ul>	<p>Columbia is 5-9% and Quebec is 6.5%)<sup>102</sup></p> <p>Accounting for country-specific factors, post rebate MUR benchmarks show:</p> <ul style="list-style-type: none"> <li>■ <b>~A\$41.5 per capita</b> (covering ~38.8m people and a population density of 4 per km<sup>2</sup>)<sup>103</sup></li> <li>■ <b>~A\$61.2 per patient</b> (covering ~26m patients ~67% of the population)<sup>104</sup></li> </ul>	<ul style="list-style-type: none"> <li>■ Overall EBITDA margin ranges around <b>2-3%</b> of total revenue<sup>109</sup></li> </ul> <p>Accounting for country-specific factors, post rebate MUR benchmarks show:</p> <ul style="list-style-type: none"> <li>■ <b>~A\$11.3 per capita</b> (covering ~5.1m people and a population density of 20 per km<sup>2</sup>)</li> <li>■ <b>~A\$15.2 per patient</b> (covering ~3.8m patients ~75% of the population)<sup>110</sup></li> <li>■ <b>~A\$1.11 per prescription of medicine</b> (with ~52M scripts of medicine for New Zealand)<sup>111</sup></li> </ul>	<ul style="list-style-type: none"> <li>■ Overall, <b>gross margins likely average ~6.9%</b> of total revenue</li> <li>■ <b>EBITDA margins</b> (as a percent of revenue) <b>tend to be moderate to low</b> with AAH achieving a <b>~2.4%</b> EBITDA margin (as a percentage of turnover) in 2022<sup>117</sup></li> </ul> <p>When accounting for country-specific factors, the following benchmarks show:</p> <ul style="list-style-type: none"> <li>■ <b>~A\$19.7 per capita</b> (covering ~67.7m people and a population density of 280 per km<sup>2</sup>)</li> </ul>

91 PBS Expenditure and Prescriptions Report 1 July 2021 to 30 June 2022. (2022). Canberra: Department of Health and Aged Care, pp.22; Available at: <https://www.pbs.gov.au/statistics/expenditure-prescriptions/2021-2022/PBS-Expenditure-and-Prescriptions-Report-1-July-2021-to-30-June-2022.PDF>

92 ~\$117M has been calculated based on the assumption of a 3% rebate from manufacturers to wholesalers on a total drug spend of ~A\$6.083b which gives a value of ~A\$182.5M, a ~1% rebate to pharmacies from wholesalers have also been applied on the total cost of drugs to the pharmacy (i.e., 1% of A\$6.54b). Together these yield a net rebate of ~A\$117M. Exact rebate percentages have been based on industry experts while total cost of drug spending and price to pharmacy is based on PBS expenditure and prescriptions report: PBS Expenditure and Prescriptions Report 1 July 2021 to 30 June 2022. (2022). Canberra: Department of Health and Aged Care, pp.22; Available at: <https://www.pbs.gov.au/statistics/expenditure-prescriptions/2021-2022/PBS-Expenditure-and-Prescriptions-Report-1-July-2021-to-30-June-2022.PDF>

93 Minimum dispensing amount will apply where the ex-manufacturer price is up to and including \$5.50 while \$54.14 will apply for ex-manufacturer prices above \$720 accord to 7CPA.

102 Given commercial sensitivity of the number, numbers are based on wholesale experts from relevant country. Please note that for private plans, wholesale mark-ups are not regulated and, as such, are a result of negotiations between wholesalers and pharmacies.

103 Worldometers (2023). Canada Population (2019) - Worldometers. [online] Worldometers.info. Available at: <https://www.worldometers.info/world-population/canada-population/> [Accessed 13 Sep. 2023].

104 Smith, L. and Cortes, K. (2022). Pharmaceutical access and use during the pandemic. [online] www150.statcan.gc.ca. Available at: <https://www150.statcan.gc.ca/n1/pub/75-006-x/2022001/article/00011-eng.htm>.

109 Range estimated based on CDC Pharmaceutical and EBOS EBITDA/Revenue figures released in investor reports. For CDC Pharmaceutical, please see CDC Pharmaceutical (2023). Annual Report 2023. [online] p.10. Available at: <https://app.companiesoffice.govt.nz/companies/app/service/services/documents/824AA7FE081A6A7DBBD133B40F0B295D> [Accessed 15 Sep. 2023]. For EBOS, please see

110 3.77 million individuals each access funded medicines each year in New Zealand. Cross reference with Australia definition may be required to ensure consistent denominator: Pharmac (n.d.). Home. [online] Pharmac | New Zealand Government. Available at: <https://pharmac.govt.nz>. For EBOS please see: INVESTOR PRESENTATION Interim Financial Results Half year ended 31 December 2022.

(2023). [online] EBOS Group, Australia: EBOS Group Limited, p.4. Available at: [https://investor.ebosgroup.com/static-files/77d25199-0b45-4932-be39-ebfd8fe2276e#:~:text=Underlying%20EBITDA%20margin%20improved%20to%204.71%25%20\(from%203.95%25\).&text=Net%20Finance%20Costs%20increased%20to,a%20higher%20interest%20rate%20environment.&text=Underlying%20NPAT%20and%20EPS%20increased,%25%20and%2012.0%25%20C%20respectively%20and%20https://investorcentre.sigmahealthcare.com.au/financial-information/financial-fundamentals-snapshot](https://investor.ebosgroup.com/static-files/77d25199-0b45-4932-be39-ebfd8fe2276e#:~:text=Underlying%20EBITDA%20margin%20improved%20to%204.71%25%20(from%203.95%25).&text=Net%20Finance%20Costs%20increased%20to,a%20higher%20interest%20rate%20environment.&text=Underlying%20NPAT%20and%20EPS%20increased,%25%20and%2012.0%25%20C%20respectively%20and%20https://investorcentre.sigmahealthcare.com.au/financial-information/financial-fundamentals-snapshot) [Accessed 7 Sep. 2023].

111 Based on calculation conducted on NZ Pharmaceutical data web tool. Note that New Zealand refers to number of prescriptions as initial dispensing which refers to the number of medicines prescribed to a patient and not accounting for repeats). See data source here: Health New Zealand (n.d.). Pharmaceutical Data web tool. [online] tewhatuora.shinyapps.io. Available at: <https://tewhatuora.shinyapps.io/pharmaceutical-data-web-tool/> [Accessed 13 Sep. 2023].

117 AAH (2022). Annual report and financial statements for the year ended [online] p.3. Available at: <https://hallohealthcaregroup.com/wp-content/uploads/2023/04/FY22-AAHP-Stats-16022023.pdf> [Accessed 15 Sep. 2023].

Questions	AUS	CAN	NZL	UK
	<ul style="list-style-type: none"> <li>■ <b>Rebates</b> will range from <b>0% to &gt;1.5%</b> for pharmacies (as outlined in the question above)<sup>94</sup></li> <li>■ <b>Overall EBITDA margins are &lt;4.5%</b> of total revenue (e.g., Sigma Healthcare and EBOS EBITDA margins were 1.7% and 4% respectively in FY22 – NB: other non-wholesaling components have not been removed)<sup>95</sup></li> </ul> <p>Accounting for country-specific factors, MUR benchmarks show:</p> <ul style="list-style-type: none"> <li>■ <b>~A\$30.0 per capita</b> (covering ~26.2m people and a</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>~A\$2.0 per prescription</b> (~806m prescriptions per year)<sup>105</sup></li> <li>■ <b>~A\$140,000 per pharmacy</b> (~11,554 registered pharmacies)<sup>106</sup></li> </ul>	<ul style="list-style-type: none"> <li>■ <b>~A\$0.66 per dispensing event</b> (covering ~87m dispensing events per year)<sup>112</sup></li> <li>■ <b>~A\$53,000 per pharmacy</b> (covering ~1,100 registered pharmacies)<sup>113</sup></li> </ul> <p>Note that wholesaler margins will typically range between 3-4% post rebates. Wholesalers may offer discounts for adherence to terms of trade (e.g., payment within certain thresholds – ranging from 2.5-6.7%) and have high baseline margins (e.g., 10.4% margins on manufacturing costs<sup>114</sup>)</p>	<ul style="list-style-type: none"> <li>■ <b>~A\$28.1 per patient.</b> covering ~47.4m patients (~70% of the populations)<sup>118</sup></li> <li>■ <b>~A\$1.01 per prescription</b> (with ~1.316b prescriptions per year)<sup>119</sup></li> <li>■ <b>~A\$93,000 per pharmacy</b> (with ~14,383 registered pharmacies)<sup>120</sup></li> </ul>

94 Given that negotiations are commercial in confidence, rebate ranges have been estimated based on expert input

95 INVESTOR PRESENTATION Interim Financial Results Half year ended 31 December 2022. (2023). [online] EBOS Group, Australia: EBOS Group Limited, p.4. Available at:

[https://investor.ebosgroup.com/static-files/77d25199-0b45-4932-be39-ebfd8fe2276e#:~:text=Underlying%20EBITDA%20margin%20improved%20to%204.71%25%20\(from%203.95%25\).&text=Net%20Finance%20Costs%20increased%20to,a%20higher%20interest%20rate%20environment.&text=Underlying%20NPAT%20and%20EPS%20increased,%25%20and%2012.0%25%20C%20respectively%20and%20https://investorcentre.sigmahealthcare.com.au/financial-information/financial-fundamentals-snapshot](https://investor.ebosgroup.com/static-files/77d25199-0b45-4932-be39-ebfd8fe2276e#:~:text=Underlying%20EBITDA%20margin%20improved%20to%204.71%25%20(from%203.95%25).&text=Net%20Finance%20Costs%20increased%20to,a%20higher%20interest%20rate%20environment.&text=Underlying%20NPAT%20and%20EPS%20increased,%25%20and%2012.0%25%20C%20respectively%20and%20https://investorcentre.sigmahealthcare.com.au/financial-information/financial-fundamentals-snapshot) [Accessed 7 Sep. 2023].

105 Health Canada (2019). A Prescription for Canada: Achieving Pharmacare for All - Final Report of the Advisory Council on the Implementation of National Pharmacare - Canada.ca. [online] Canada.ca.

Available at: <https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/implementation-national-pharmacare/final-report.html>.

106 NAPRA (2022). National Statistics - NAPRA. [online] [www.napra.ca](http://www.napra.ca). Available at: <https://www.napra.ca/resources/national-statistics/>.

112 Based on total number of dispensing for 2022 including repeat appearance and for same medication. Please see: Te Whatu Ora - Health New Zealand (2023). Pharmaceutical Data web tool. [online] [tewhatauora.shinyapps.io](https://tewhatauora.shinyapps.io). Available at: <https://tewhatauora.shinyapps.io/pharmaceutical-data-web-tool/>.

113 FYI. (2019). Total Number of Licenced Pharmacies in NZ - 2019 - a Official Information Act request to Ministry of Health. [online] Available at: <https://fyi.org.nz/request/10183-total-number-of-licenced-pharmacies-in-nz-2019> [Accessed 7 Sep. 2023].

114 Moore, D. (2015). Strategic think piece on pharmaceutical margins. [online] Sapere. Available at: <https://srgexpert.com/wp-content/uploads/2017/11/Sapere-pharmaceuticalmarginsFinal-Report-09102015-public-as-sent.pdf> [Accessed 12 Sep. 2023].

118 Zhang, F., Mamtani, R., Scott, F.I., Goldberg, D.S., Haynes, K. and Lewis, J.D. (2015). Increasing use of prescription drugs in the United Kingdom. *Pharmacoepidemiology and Drug Safety*, 25(6), pp.628–636. doi:<https://doi.org/10.1002/pds.3947>.

119 Based on NHS figure of £1.11bn prescriptions in 2020-21 period for England representing 84% of the population; prescriptions have been scaled up assuming similar uptake of prescriptions in other regions: NHSBSA (2022). Prescription Cost Analysis – England – 2021/22 | NHSBSA. [online] Available at: <https://www.nhsbsa.nhs.uk/statistical-collections/prescription-cost-analysis-england/prescription-cost-analysis-england-202122#:~:text=The%20number%20of%20prescription%20items>.

120. General Pharmaceutical Council (2023). The GPhC register as of 31 May 2022 - Trend data. [online] [Pharmacyregulation.org](http://www.pharmacyregulation.org). Available at:

<https://www.pharmacyregulation.org/sites/default/files/document/gphc-register-trend-data-may-2022-.docx#:~:text=On%2031%20May%202022%20there> [Accessed 15 Sep. 2023].

Questions	AUS	CAN	NZL	UK
	<p>population density of 3.4 per km<sup>2</sup>)<sup>96</sup></p> <ul style="list-style-type: none"> <li>■ <b>~A\$46.2 per patient</b> (covering 17.1M patients – 65% of the populations)<sup>97</sup></li> <li>■ <b>~A\$2.50 per prescription</b><sup>98</sup> (covering ~315m prescriptions per year)<sup>99</sup></li> <li>■ <b>~A\$134,000 per pharmacy</b> (covering ~5,901 registered pharmacies).<sup>100</sup></li> </ul>			
On what basis are these payments made?	<ul style="list-style-type: none"> <li>■ <b>Mark-up on manufacturer prices</b> – The price wholesalers charge pharmacies is determined by a mark-up of up to 7.52% of the ex-manufacturer price (with an upper and lower limit of A\$0.41 to A\$54.14 per dispense)</li> <li>■ <b>Volume of distribution (if compliant)</b> – The basis of</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>Mark-up on manufacturer prices</b> – Payments may be paid based on: <ul style="list-style-type: none"> <li>- (1) the quantity of drugs distributed to pharmacies</li> <li>- (2) A percentage or mark-up on the price of Medicines<sup>123</sup></li> </ul> </li> <li>■ <b>Inventory management fees and added services-</b></li> </ul>	<ul style="list-style-type: none"> <li>■ <b>Mark-up on manufacturer prices</b> – Wholesalers can apply a mark-up on the medicines distributed based on the results of contractual negotiations. Margins typically differ depending on the buying power of the pharmacy and whether the product is Rx and Gx or OTC</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>Mark-up on manufacturer price</b> – Traditional wholesalers are likely paid based on a mark-up between the cost of acquisition and delivery price</li> <li>■ <b>Fee per package/ medicine</b> – Exclusive wholesalers are typically paid based on contractual negotiations between the manufacturer and wholesaler. This would result in a dollar amount paid per package delivered to pharmacies</li> </ul>

96 Population density sourced from Worldometers: Worldometers (2023). World Population Clock. [online] Worldometers. Available at: <https://www.worldometers.info/world-population/>; Australian Bureau of Statistics (2023). Population | Australian Bureau of Statistics. [online] [www.abs.gov.au](https://www.abs.gov.au). Available at: <https://www.abs.gov.au/statistics/people/population> [Accessed 13 Sep. 2023].

97 Total patient population calculated by the total population of Australia multiplied by the percentage receiving prescriptions. See the following source for detail: Australian Institute of Health and Welfare (2022). Medicines in the health system. [online] Australian Institute of Health and Welfare. Available at: <https://www.aihw.gov.au/reports/medicines/medicines-in-the-health-system>.

98 Please note that the definition and duration of prescriptions will differ by country regulations (e.g., the maximum expiry date of a prescription may change resulting in differences in the total number of prescriptions per year a patient may require

99 PBS Expenditure and Prescriptions Report 1 July 2021 to 30 June 2022. Pg. 2 (2022). Canberra: Department of Health and Aged Care; Available at: <https://www.pbs.gov.au/statistics/expenditure-prescriptions/2021-2022/PBS-Expenditure-and-Prescriptions-Report-1-July-2021-to-30-June-2022.PDF>

100 Based on total prescriptions and pharmacies including those above and below co-payment thresholds - PBS Expenditure and Prescriptions Report 1 July 2021 to 30 June 2022. (2022). Canberra: Department of Health and Aged Care, pp.2; 18

123 CAPDM Submission to the PMPRB December 2022 Revised Guidelines Consultation. (2022). [online] CAPDM.CA, pp.1–3. Available at: <https://www.capdm.ca/CAP/media/Documents/CAPDM-Response-to-PMPRB-Consultations-2022.pdf> [Accessed 7 Sep. 2023].

Questions	AUS	CAN	NZL	UK
	<p>government CSO payments are:<sup>121</sup></p> <ul style="list-style-type: none"> <li>- CSO – NDSS: CSO distributors are entitled to receive A\$1 per unit fee for each NDSS product they supply</li> <li>- CSO – PBS: Payment is based on proportion of volumes of sales of PBS medicines and total CSO funding pool for that month (~A\$220m per year total)</li> </ul> <ul style="list-style-type: none"> <li>■ The basis for patient payments is set through the maximum co-payment amount. The co-payment cap has fallen recently from \$42.50 to \$30 as of the 1<sup>st</sup> of January 2023 such that customers will pay a maximum of \$30 out of pocket for PBS medicines<sup>122</sup></li> <li>■ The basis for government subsidies is the gap between the allowed price charged by pharmacies for the medicines when wholesale mark-ups and pharmacy charges are accounted for against the co-payment limits (\$30 currently). The government will cover the</li> </ul>	<p>Wholesalers may be able to make further revenue from inventory management fees, added services (e.g., assembling of packs or packages) or exclusive distribution models for high-end innovative medicines<sup>124</sup></p>		<ul style="list-style-type: none"> <li>■ <b>Surcharges</b> – Traditionally wholesalers may also apply a surcharge to pharmacies in regional or remote areas if certain order volume or value conditions are not met</li> </ul> <p>Please note that pharmacies in the UK will typically <b>be served by several wholesalers with live price comparison portals</b> used to determine the distributing wholesaler (for example, Drug Comparison is one example service in the UK<sup>125</sup>). According to UK experts, this live purchasing has reduced the prevalence of end-of-month rebates between wholesalers and pharmacies.</p> <p>Information based on expert input given commercial sensitivity of information</p>

121 Department of Health and Aged Care (2022). Community Service Obligation - Operational Guidelines. [online] p68-75; Available at: <https://www.health.gov.au/sites/default/files/documents/2022/10/community-service-obligation-cso-for-pharmaceutical-wholesalers-funding-pool-operational-guidelines-guidelines.pdf> [Accessed 15 Sep. 2023].

122 Department of Health and Aged Care (n.d.). Pharmaceutical Benefits Scheme (PBS) | Changes to the PBS to make medicines more affordable. [online] www.pbs.gov.au. Available at: <https://www.pbs.gov.au/info/news/2023/01/changes-to-the-pbs-to-make-medicines-more-affordable#:~:text=PBS%20Co%2DPayment%20Reduction.>

124 Based on knowledge from industry expert with knowledge of relationships between wholesalers, manufacturers and pharmacies

125 Drug Comparison. (n.d.). Drug Comparison. [online] Available at: <https://www.drugcomparison.co.uk/> [Accessed 15 Sep. 2023].

Questions	AUS	CAN	NZL	UK
	gap between these numbers as needed			
How do payments and service levels differ by location (e.g., metro, rural, remote)?	<p>In Australia, service levels and cost of delivery are mandated by the government, resulting in <b>very little difference in service quality and costs across geographically dispersed pharmacies.</b></p> <p>For further details, please see question “What are the major service requirements of wholesalers?” on page 17 which outlines the requirements of wholesalers to supply pharmacies.</p>	<p>In Canada, <b>service levels and costs of delivery will vary for rural pharmacies.</b> In particular, they will experience:</p> <ul style="list-style-type: none"> <li>■ <b>Less frequent deliveries –</b> Compared to metro areas which can expect same day or next day deliveries, Canada industry experts indicate that Canadian rural pharmacies can experience much lower service levels (e.g., at worst would be weekly deliveries)</li> <li>■ <b>Additional fees for excess deliveries -</b> Where thresholds may not be achieved, an excess cost may be imposed on deliveries</li> </ul> <p>Please note that while our expert conversations did not note the occurrence of minimum thresholds requirements, this could be a feature of particular agreements between wholesalers and pharmacies</p>	<p>In New Zealand, expert input indicates that <b>excess fees are not experienced by rural pharmacies.</b></p> <p>Instead, the biggest distinction in wholesale cost will be between independent pharmacies and larger chains where larger chains can extract better deals.</p>	<p>In the UK, rural and remote pharmacies <b>experience a mix of additional costs or diminished service levels</b> such as:</p> <ul style="list-style-type: none"> <li>■ <b>Less frequent deliveries –</b> Compared to metro areas which can expect same day or next day deliveries, rural and regional locations at worst may experience deliveries once a week but more likely next day or 2 days</li> <li>■ <b>Minimum quantity thresholds –</b> before additional deliveries outside of agreed timeframes are made a minimum threshold to trigger deliveries may be required</li> <li>■ <b>Additional fees for excess deliveries -</b> Where thresholds may not be achieved, an excess cost may be imposed on deliveries</li> </ul> <p>The value of fees will depend on service level agreements where small independent pharmacies are more likely to face higher costs or lower service levels relative to larger pharmacies or chains with greater bargaining power.</p> <p>Please note that the UK government does provide some specific support for rural pharmacies through its GBP20 million Pharmacy Access Scheme (PhAS) which provides payments to pharmacies in areas with limited pharmacy coverage.<sup>126</sup></p>

126 Community Pharmacy England (2023). Pharmacy Access Scheme (PhAS). [online] Community Pharmacy England. Available at: <https://cpe.org.uk/quality-and-regulations/the-pharmacy-contract/pharmacy-access-scheme-phas/> [Accessed 13 Oct. 2023].

Questions	AUS	CAN	NZL	UK
What are the general conditions that are required to be met to receive the funds?	<b>Conditions for these payments are set out in CSO guidance and the 7CPA (described above)</b>	<b>Conditions dependent on Province</b> <ul style="list-style-type: none"> <li>■ Conditions are mainly set out in commercial service agreements (described above)</li> <li>■ Some conditions are set by Provincial governments. In Quebec, wholesalers commit as a result of government regulations to:<sup>127</sup> <ul style="list-style-type: none"> <li>- Respect the manufacturer's guaranteed selling price and apply up to 6.5% margin</li> <li>- Must maintain a drug inventory that includes at least 50% of the medicines outlined in the public drug schedule</li> </ul> </li> </ul>	<b>No conditions</b>	<ul style="list-style-type: none"> <li>■ In the UK and New Zealand, wholesalers do not receive significant special payments from sources other than pharmacies or manufacturers. Conditions are set out in service agreements described above<sup>128</sup></li> </ul>
<b>What outcomes are achieved?</b>				
How do wholesalers perform in terms of speed, access and quality?	Public information on the typical percentage of products damaged for wholesalers has not been found <ul style="list-style-type: none"> <li>■ Wholesalers in Australia have a strong track record with <b>~98% compliance with CSO</b></li> </ul>	Information is based on industry expert given commercial sensitivity of information <ul style="list-style-type: none"> <li>■ <b>Percentage of products that arrive in unacceptable condition</b> – An estimated 1-1.5% of products are damaged on arrival at the pharmacy</li> </ul>	Information is based on industry expert given commercial sensitivity of information <ul style="list-style-type: none"> <li>■ <b>Percentage of products that arrive in unacceptable condition</b> – A NZ pharmacy expert indicated that destroyed products were <b>rare</b> for wholesalers</li> </ul>	Information is based on industry expert given commercial sensitivity of information <ul style="list-style-type: none"> <li>■ <b>Percentage of products that arrive in unacceptable condition</b> – An estimated ~2% of products are damaged on arrival at the pharmacy</li> <li>■ <b>Lead time for deliveries</b> – wholesalers reportedly provide <b>same</b></li> </ul>

127 A-29.01, r. 2 - Regulation respecting the conditions governing the accreditation of manufacturers and wholesalers of medications. SCHEDULE II [online] Available at: <https://www.legisquebec.gouv.qc.ca/en/document/cr/A-29.01,%20r.%202?langCont=en#sc-nb:2> [Accessed 7 Sep. 2023].

128 Based on conversations with industry experts with knowledge of UK and NZL wholesaler financial arrangements. Further validation taken through CDC financial statements which show limited to no revenues from sources beyond payments from customers. See financial statement here: CDC Pharmaceutical (2023). Annual Report 2023. [online] p.10. Available at: <https://app.companiesoffice.govt.nz/companies/app/service/services/documents/824AA7FE081A6A7DBBD133B40F0B295D> [Accessed 15 Sep. 2023].

Questions	AUS	CAN	NZL	UK
	<p>requirements from 2017-2019<sup>129</sup></p>	<ul style="list-style-type: none"> <li>■ <b>Lead times for delivery</b> – wholesalers reportedly offer <b>same day or next day</b> delivery in urban areas</li> <li>■ <b>DIFOT</b> – Anecdotally, wholesalers achieve a <b>~90% on time</b> delivery rate (within a 2-hour window) and a <b>~98% delivery in full</b> rate</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>Lead times for delivery</b> – wholesalers typically provide <b>same day or next day</b> delivery (orders placed before midday arrive in the afternoon and remaining orders are delivered the next day)</li> <li>■ <b>DIFOT</b> – Anecdotally, while wholesalers are expected to meet DIFOT requirements over 99% of the time, actual <b>performance varies</b> with some below target delivery outcomes reported</li> </ul>	<ul style="list-style-type: none"> <li>■ <b>day or next day</b> delivery (orders placed before midday arrive in the afternoon and remaining orders are delivered the next day)</li> <li>■ <b>DIFOT</b> – UK industry experts suggest that wholesalers achieve <b>~86-87%</b> DIFOT rates</li> </ul>

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<sup>129</sup> Department of Health Annual Report 2018. (2018). [online] Health.gov, p.87. Available at: [https://www.health.gov.au/sites/default/files/documents/2019/10/department-of-health-annual-report-2018-19\\_0.pdf](https://www.health.gov.au/sites/default/files/documents/2019/10/department-of-health-annual-report-2018-19_0.pdf) [Accessed 7 Sep. 2023].

## 2 Distribution and packaging approaches and innovation

This chapter is organised in three parts:

- An executive summary which provides the narrative context and overview of innovations found.
- A summary of aged care packaging and distribution arrangements across Australia, Canada, New Zealand and the UK
- A set of deep dives containing descriptions of each type of innovation found, case studies, and notes on the potential applicability to Australia.

### 2.1 EXECUTIVE SUMMARY

In December 2022, DoHAC published the second edition of the National Medicines Policy. **This includes an aim to ensure equitable, timely, safe and reliable access to medicines** and medicines-related services, at a cost that individuals and the community can afford. This policy intent is implemented via Community Service Obligations (CSOs) that are reflected in the Community Pharmacy Agreements (CPAs). The CSOs aim to ensure that all Australians have access to the PBS medicines and NDSS products they require, regardless of the cost of the medicine, or where they live.

**The 7CPA is due to expire in June 2025 and the Minister of Health and Aged Care has opened negotiations for an 8<sup>th</sup> agreement early.** In preparation for these negotiations, the Department of Health and Aged Care wishes to better understand innovations in distribution and packaging approaches seen in comparable countries, to better serve vulnerable populations (with a particular focus on residents in aged care facilities). Negotiations will conclude by June 2024.

**To inform these negotiations an international scan of distribution and packaging arrangements in aged care facilities as been undertaken, with limited innovation or distinctiveness found across the four countries:**

- In general, aged care providers form agreements with pharmacies to provide medicines on a regular basis, including any packaging requirements.
- Australia has seen the greatest level of policy development as a result of the Royal Commission into Aged Care Quality and Safety. If recommendations are implemented fully, the role of the pharmacist will be further integrated into aged care facilities (e.g., on-site pharmacists) and, consequently, distribution would become more personalised.
- Packaging is similarly standardised across aged care facilities across countries with a mix of Dose Administration Aids (DDA) and regular packaging provided to the aged care facility staff from the pharmacist. Exact packaging regulations vary by country, but generally includes requirements for clear descriptions of the medicine, patient and pharmacy identifiable information, and timing for use of medicines.

This scan is detailed in section 2.2.

**Additionally, an international scan of innovations across distribution and packaging has been undertaken.** The scan covers arrangements and innovations in Canada, NZ and the UK, along with notable innovations seen elsewhere. These innovations are listed in Exhibit 2 and detailed in section 2.3.

## EXHIBIT 2: INNOVATIONS ACROSS DISTRIBUTION AND PACKAGING

Approach	Innovation	Description	Benefits to vulnerable cohorts	Countries
Distribution	<b>Medication Synchronisation</b>	Aligns prescription repeat dates to simplify medication management, reducing the frequency of pharmacy visits	Adherence, Convenience	United States, United Kingdom, Canada
	<b>Online Pharmacies</b>	Allows prescriptions to be purchased online and have them delivered to your door	Access, Availability, Convenience, Adherence, Literacy	United Kingdom, Canada, New Zealand, United States
	<b>Remote Kiosks</b>	Dispenses medication using automated, self-serving machines or terminals, also referred to as vending machines	Accessibility, Convenience, Adherence	United States, United Kingdom, Canada
	<b>Smart Lockers</b>	Dispenses medication securely using storage units that securely provide patients medications at appropriate times	Convenience, Accessibility, Safety	Portugal, United Kingdom, United States
	<b>Drone Delivery</b>	Transports medications to homes/ distribution centres using unmanned aerial vehicles (drones)	Availability, Accessibility, Adherence	United Kingdom, United States, Australia
	<b>Physician Dispensing</b>	Dispenses medications to patients directly from physicians rather than patients obtaining medications from a pharmacy	Adherence, Convenience, Cost	Switzerland, United Kingdom, United States
Packaging	<b>Accessible Packaging</b>	Enables patient use including through simplified opening mechanisms, accessible labels (e.g. Braille, font-size) and Dose Administration Aids	Safety, Independence, Literacy	United States, United Kingdom, European Union, Canada, New Zealand, Australia
	<b>Smart Packaging</b>	Integrates sensors, connectivity and data processing to support patients via dose tracking, temperature monitoring, medication reminders	Adherence, Safety, Literacy	United States, Germany
	<b>Anti-counterfeit Packaging</b>	Uses advanced technologies like invisible signatures, holograms and RFID tags to safeguard medication authenticity	Safety, Adherence, Cost	European Union, United Kingdom, United States, Germany, Australia
	<b>Sustainable Packaging</b>	Focus on environmentally responsible materials and practices to minimise waste while maintaining product safety and integrity	Cost	United States, European Union, United States, New Zealand, United Kingdom

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## 2.2 DISTRIBUTION AND PACKAGING IN AGED CARE FACILITIES

Questions	AUS	CAN	NZL	UK
How are medicines used in Aged Care facilities distributed?	<p>Although the exact relationships between pharmacies and aged care facilities will differ based on the exact needs of the facility, they will typically include:</p> <ul style="list-style-type: none"> <li>■ <b>Delivery through aged care staff</b> – community pharmacist will provide the medicine to the aged care provider with limited to no face-to-face interaction with the patient (i.e., actual delivery of the medicines to patients will occur through staff at the facility)<sup>130</sup></li> </ul> <p>Additionally, as a result of recommendations from the Royal Commission into Aged Care Quality and Safety, it is likely that the following forms of distribution will become more prominent:</p> <ul style="list-style-type: none"> <li>■ <b>On-site pharmacists</b> – Pharmacist, employed by the aged care facility, are</li> </ul>	<p>Although the exact relationships between pharmacies and aged care facilities will differ based on the exact needs of the facility, they will typically include:</p> <ul style="list-style-type: none"> <li>■ <b>Delivery through aged care staff</b> – Aged care facilities will typically contract with a community pharmacy for the delivery of medicines with limited to no face-to-face interactions with patients <ul style="list-style-type: none"> <li>- Resident medications are typically <b>delivered on a weekly basis</b> with the opportunity for on-demand emergency access as needed<sup>134</sup></li> </ul> </li> <li>■ <b>Medication Management Portfolios</b> – A tracker of existing and previous medicines prescribed which is used to ensure personalised treatment and safe usage of medicines <ul style="list-style-type: none"> <li>- Some technology tools may be used to update this portfolio</li> </ul> </li> </ul>	<p>Although the exact relationships between pharmacies and aged care facilities will differ based on the exact needs of the facility, they will typically include:</p> <ul style="list-style-type: none"> <li>■ <b>Delivery through aged care staff</b> – Aged care facilities will typically contract with a community pharmacy for the delivery of medicines with limited to no face-to-face interactions with patients <ul style="list-style-type: none"> <li>- This will typically range from once a day to weekly deliveries with a month's supply provided<sup>137</sup></li> </ul> </li> <li>■ <b>Ad-hoc on-site visits</b> – Pharmacist will sometimes conduct site visits to review medication, provide education to staff and any other relevant advice</li> </ul>	<p>Although the exact relationships between pharmacies and aged care facilities will differ based on the exact needs of the facility, they will typically include:</p> <ul style="list-style-type: none"> <li>■ <b>Delivery through aged care staff</b> – Aged care facilities will typically contract with a community pharmacy for the delivery of medicines with limited to no face-to-face interactions with patients<sup>139</sup></li> <li>■ <b>Ad hoc on-site visits</b> - Some pharmacists will visit aged care facilities to provide medicines reviews, staff trainings and advice on proper use of medicines<sup>140</sup> <ul style="list-style-type: none"> <li>- Current quality standards from the National Institute for Health and Care Excellence (NICE) may result in more visits as it recommends that Pharmacists be involved in a multidisciplinary team to</li> </ul> </li> </ul>

130 Pagone, T. and Briggs, L. (2021). Royal Commission into Aged Care Quality and Safety Final Report: Care, Dignity and Respect Volume 2 The current system. [online], P123 Available at: [https://agedcare.royalcommission.gov.au/sites/default/files/2021-03/final-report-volume-2\\_0.pdf](https://agedcare.royalcommission.gov.au/sites/default/files/2021-03/final-report-volume-2_0.pdf) [Accessed 20 Sep. 2023].

134 The Neighbourhood Pharmacy Association of Canada (2020). A Primer on the Value of Pharmacy Services in Long- Term Care Settings in Canada. [online] p22 Available at: <https://neighbourhoodpharmacies.ca/sites/default/files/2021-01/Pharmacy%20Services%20in%20LTC%20F.pdf> [Accessed 20 Sep. 2023].

137 Parkside Pharmacy (n.d.). Pharmacy Services | Rest Homes & Aged Care. [online] Parkside Pharmacy. Available at: <https://www.parksidepharmacy.co.nz/> [Accessed 20 Sep. 2023].

139 Waghmare, P.-H., Lindsey, R., Reed, J.B., Gao, S. and Zillich, A.J. (2023). Systematic Review of the Impact of Medication Synchronization on Healthcare Utilization, Economic, Clinical, and Humanistic Outcomes. JACCP: JOURNAL OF THE AMERICAN COLLEGE OF CLINICAL PHARMACY. doi:<https://doi.org/10.1002/jac5.1815>.

140 Royal Pharmaceutical Society England (2016). Shaping pharmacy for the future: pharmacists improving medicines use in care homes SHAPING PHARMACY FOR THE FUTURE: PHARMACISTS IMPROVING MEDICINES USE IN CARE HOMES. [online] Available at: <https://www.rpharms.com/Portals/0/Care%20Homes%20Policy%20Briefing%20Feb%202016.pdf> [Accessed 20 Sep. 2023].

Questions	AUS	CAN	NZL	UK
	<p>responsible for reviewing medication and dispensing with the rest of the health team<sup>131</sup></p> <ul style="list-style-type: none"> <li>■ <b>Drop-in visits</b> – Where an on-site pharmacist is not present, some pharmacist may visit the facility to review medication, provide education to staff and any other relevant advice</li> </ul> <p>Other services provided include:</p> <ul style="list-style-type: none"> <li>■ <b>Medication Management Review</b> – While only ~30% of aged care residents have a plan, pharmacist may meet with the patient to review medicines and ensure proper dosing or as part of a multidisciplinary team<sup>132</sup></li> <li>■ <b>Synchronisation of medicines</b> – Pharmacists are typically responsible for sending the medicines to the aged care carers (e.g., nurses) who would then</li> </ul>	<p>over time and ensure “live 24/7” medication management<sup>135</sup></p> <ul style="list-style-type: none"> <li>■ <b>Synchronisation of medicines</b> – Pharmacists are typically responsible for sending the medicines to the aged care carers (e.g., nurses) who would then provide the medicines to patients. As such, pharmacists are responsible for picking and packing the specific medication to be used (see next question for detail of packaging)</li> <li>■ <b>Regulations around storage of medicines in aged care facility</b> – Aged care facilities and pharmacy professionals are responsible for the safe storage, usage and disposal of medicines as required. Typically, these standards are set out on a province level (e.g., in Saskatchewan the College of Pharmacy Professionals set out standards of care for residents of long-term facilities<sup>136</sup>)</li> </ul>	<ul style="list-style-type: none"> <li>■ There is no evidence of any widespread special medication management plans that pharmacists uniquely provide to aged care residents relative to other sections of the population</li> <li>■ <b>Synchronisation of medicines</b> – Pharmacists are typically responsible for sending the medicines to the aged care carers (e.g., nurses) who would then provide the medicines to patients. As such, pharmacists are responsible for picking and packing the specific medication to be used (see next question for detail of packaging)</li> <li>■ <b>Regulations around storage of medicines in aged care facility</b> – According to the New Zealand Ministry of Health, aged care facilities are responsible for the safe storage, usage and disposal of medicines as required<sup>138</sup></li> </ul>	<p>review medications periodically<sup>141</sup></p> <ul style="list-style-type: none"> <li>■ <b>On-site pharmacist</b> – Through the NHS Medicines Optimisation in Care Homes program, pharmacists are required to spend at least 0.4 FTE in aged care to be eligible for funding resulting in significant on-site time.<sup>142</sup> Note that the program concluded in 2021 but there are ongoing roles provided at some aged care facilities, suggesting some continued prominence<sup>143</sup></li> <li>■ <b>Synchronisation of medicines</b> – Pharmacists are typically responsible for sending the medicines to the aged care carers (e.g., nurses) who would then provide the medicines to patients. As such, pharmacists are responsible for picking and packing the specific medication to be used (see next question for detail of packaging)</li> </ul>

131 Department of Health and Aged Care (2023). Aged care on-site pharmacist. [online] Australian Government Department of Health and Aged Care. Available at: <https://www.health.gov.au/our-work/aged-care-on-site-pharmacist> [Accessed 20 Sep. 2023].

132 Pagone, T. and Briggs, L. (2021). Royal Commission into Aged Care Quality and Safety Final Report: Care, Dignity and Respect Volume 2 The current system. [online], P79 Available at: [https://agedcare.royalcommission.gov.au/sites/default/files/2021-03/final-report-volume-2\\_0.pdf](https://agedcare.royalcommission.gov.au/sites/default/files/2021-03/final-report-volume-2_0.pdf) [Accessed 20 Sep. 2023].

The Neighbourhood Pharmacy Association of Canada (2020). A Primer on the Value of Pharmacy Services in Long- Term Care Settings in Canada. [online] p22 Available at: <https://neighbourhoodpharmacies.ca/sites/default/files/2021-01/Pharmacy%20Services%20in%20LTC%20F.pdf> [Accessed 20 Sep. 2023].

136 Saskatchewan college of pharmacy professionals (2021). STANDARDS FOR PHARMACY PROFESSIONALS CARING FOR RESIDENTS OF LONG-TERM CARE FACILITIES. [online] p.7. Available at: [https://scp.in1touch.org/document/3622/REF\\_LongTermCareStnds\\_20140603.pdf](https://scp.in1touch.org/document/3622/REF_LongTermCareStnds_20140603.pdf) [Accessed 20 Sep. 2023].

138 Ministry of Health (2011). Medicines care guides for residential aged care. [online] p14 Available at: <https://www.health.govt.nz/system/files/documents/publications/medicines-care-guides-for-residential-aged-care-may11.pdf> [Accessed 20 Sep. 2023].

141 NICE (2015). Medicines management in care homes Quality standard. [online] p43, Available at: <https://www.nice.org.uk/guidance/qs85/resources/medicines-management-in-care-homes-pdf-2098910254021> [Accessed 20 Sep. 2023].

142 NHS England (2018). Medicines optimisation in care homes Programme overview. [online] p.10. Available at: <https://www.england.nhs.uk/wp-content/uploads/2018/03/medicines-optimisation-in-care-homes-programme-overview.pdf> [Accessed 20 Sep. 2023].

143 Careers in Pharmacist (n.d.). Care Home Pharmacist. [online] Pharmacy Careers. Available at: <https://careersinpharmacy.uk/job-roles/care-home-pharmacist/> [Accessed 21 Sep. 2023].

Questions	AUS	CAN	NZL	UK
	<p>provide the medicines to patients. As such, pharmacists are responsible for picking and packing the specific medication to be used (see next question for detail of packaging)</p> <p><b>Regulations around storage of medicines in aged care facility –</b> Aged care facilities are responsible for the safe storage, usage and disposal of medicines as required<sup>133</sup></p>	<p>Please note that the responsibilities of pharmacist within aged care facilities varies by province with some requiring greater pharmacist engagement (e.g., authentication of how medicines are dispensed and administered to patients to ensure safe and secure medication management). See question “How do governments regulate packaging?” in wholesaling table for relevant body regarding packaging.</p>		<p>■ <b>Regulations around storage of medicines in aged care facility –</b> According to the Care Quality Commission, aged care facilities are responsible for the safe storage, usage and disposal of medicines as required<sup>144</sup></p>
How are medicines used in Aged Care facilities packaged?	<p>■ <b>Dose Administration Aid<sup>145</sup> (DAA)</b> – Specialized multi-dose packaging products are used to improve adherence and medication management, ensuring correct dose and time, in a safe and hygienic manner. Given the often-large number of medicines patients in aged care will take, it is a common way of delivery medicines</p> <p>■ <b>Standardised information present</b> – DAAs are required to be labelled with a range of information including patient name, pharmacy contact details, directions for use of</p>	<p>■ <b>Dose Administration Aid –</b> Specialised multi-dose packaging products are used to improve adherence and medication management, ensuring correct dose and time, in a safe and hygienic manner. Usage is higher for patients with larger prescriptions in aged care</p> <p>■ <b>Standardised information present</b> – Health Canada outlines in its guidance document “Labelling of Pharmaceutical Drugs for Human Use” the requirement of multi-dose containers (i.e., DAAs) to include: the brand and manufacturer name</p>	<p>■ <b>Dose Administration Aid –</b> Specialized multi-dose packaging products are used to improve adherence and medication management, ensuring correct dose and time, in a safe and hygienic manner. Usage is higher for patients with larger prescriptions in aged care<sup>148</sup></p> <p>■ <b>Standardised information present</b> – With Medico Pak’s widely used across New Zealand typical information will include the full description of medicines contained in the</p>	<p>■ <b>Mixed Dose Administration Aid uptake</b> – A mix of DAAs and regular dispensing is used in the UK to provide medicines to patients in care facilities.</p> <p>- The Care Quality Commission has recommended some restraint in overutilisation of DAA usage. It argues, in general, DAAs should be used in situations where large numbers of medicines are provided to one patient and the aged care facility has</p>

<sup>133</sup> Department of Health and Aged Care (2023). Revised Aged Care Quality Standards Draft for Pilot. [online] Available at: <https://www.health.gov.au/sites/default/files/2023-05/strengthened-aged-care-quality-standards-pilot-program.pdf> [Accessed 20 Sep. 2023].

<sup>144</sup> Care Quality Commission (2022). Storing medicines in care homes | Care Quality Commission. [online] [www.cqc.org.uk](https://www.cqc.org.uk). Available at: <https://www.cqc.org.uk/guidance-providers/adult-social-care/storing-medicines-care-homes> [Accessed 20 Sep. 2023].

<sup>145</sup> According to the Pharmaceutical Society of Australia, DDAs are “A tamper-evident, well-sealed device or packaging system that allows for organising doses of medicine according to the time of administration”. Please see sources here: Pharmaceutical Society of Australia (2017). Guidelines for pharmacists providing dose administration aid services. [online] Available at: <https://www.ppaonline.com.au/wp-content/uploads/2019/01/PSA-Dose-Admin-Aid-Guidelines.pdf> [Accessed 20 Sep. 2023].

<sup>148</sup> Examples of services provided can be found on most pharmacist website, including the following: Parkside Pharmacy. (n.d.). Pharmacy Services | Rest Homes & Aged Care. [online] Available at: <https://www.parksidepharmacy.co.nz/>.

Questions	AUS	CAN	NZL	UK
	<p>each medicine, brand and active ingredient names, strength and form of all medicines supplied, identifiable information for each medicine, date of packing and expiry date of the DAA<sup>146</sup></p> <p>Please note that while many aged care residents take multiple medications and therefore use DAAs, some patients will use traditional forms of packaging for single doses which are subject to standard regulations around packaging (e.g., font size, types of information and personally identifiable information).</p>	<p>of the drug, the potency of the drug, lot number and expiry date<sup>147</sup></p> <ul style="list-style-type: none"> <li>Please note that while many aged care residents take multiple medications and therefore use DAAs, some patients will use traditional forms of packaging for single doses which are subject to standard regulations around packaging (e.g., font size, types of information and personally identifiable information).</li> </ul> <p>Additionally, packaging may not be seen by patients in aged care subject to the medium of delivery chosen by the staff (e.g., medicines may be distributed in an unmarked cup for patients with the aged care staff responsible for reviewing the package and ensure the right medicines are provided to the correct person).</p>	<p>pack, dose strength and timing clearly printed<sup>149</sup></p> <p>Please note that while many aged care residents take multiple medications and therefore use DAAs, some patients will use traditional forms of packaging for single doses which are subject to standard regulations around packaging (e.g., font size, types of information and personally identifiable information).</p> <p>Additionally, packaging may not be seen by patients in aged care subject to the medium of delivery chosen by the staff (e.g., medicines may be distributed in an unmarked cup for patients with the aged care staff responsible for reviewing the package and ensure the right medicines are provided to the correct person).</p>	<p>deemed DAAs necessary to increase accuracy<sup>150</sup></p> <ul style="list-style-type: none"> <li><b>Standardised information present</b> – Given that DAAs involve the removal of the original manufacturer's packaging, there is a requirement that all packages include clear descriptors of each medicine for clear identification.<sup>151</sup></li> </ul> <p>Please note that while many aged care residents take multiple medications and therefore use DAAs, some patients will use traditional forms of packaging for single doses which are subject to standard regulations around packaging (e.g., font size, types of information and personally identifiable information).</p>
How are DAAs charged between pharmacies and aged care facilities/residents?	<ul style="list-style-type: none"> <li><b>Do not charge</b> – According to The Pharmacy Guild of Australia, packing and delivering of medicines in the form of DAAs are provided free of charge<sup>152</sup></li> </ul>	<ul style="list-style-type: none"> <li><b>Mixed (a number of major players do not charge)</b> - In Canada, the cost of the DAA packs will vary based on the individual pharmacy. Canada's largest pharmacy chains such as Shoppers Drug Mart and</li> </ul>	<ul style="list-style-type: none"> <li><b>Mixed</b> - For the general public, patients will be charged for the DAAs based on the rates set by the pharmacy (e.g., in 3 pharmacies in Auckland, the cost ranged from \$2.5-\$5)</li> </ul>	<ul style="list-style-type: none"> <li><b>Mixed (government regulations restrict charging of certain groups)</b> - In the UK, pharmacies may charge for DAAs subject to government regulations around accessibility and safe usage of the medicines, which renders a substantial number of aged care</li> </ul>

146 Pharmaceutical Society of Australia (2017). Guidelines for pharmacists providing dose administration aid services. [online] P11, Available at: <https://www.ppaonline.com.au/wp-content/uploads/2019/01/PSA-Dose-Admin-Aid-Guidelines.pdf>.

147 Health Canada (2013). Guidance Document: Labelling of Pharmaceutical Drugs for Human Use. [online] [www.canada.ca](http://www.canada.ca). Available at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/labelling-pharmaceutical-drugs-human-use-2014-guidance-document.html#a363> [Accessed 20 Sep. 2023].

149 Medico Pak (n.d.). Medico Pak - How Does it Work? [online] [www.medicopak.co.nz](http://www.medicopak.co.nz). Available at: <http://www.medicopak.co.nz/doctorshowdoesitwork/> [Accessed 20 Sep. 2023].

150 Care Quality Commission (2022). Multi-compartment compliance aids (MCAs) in adult social care. [online] [www.cqc.org.uk](http://www.cqc.org.uk). Available at: <https://www.cqc.org.uk/guidance-providers/adult-social-care/multi-compartment-compliance-aids-mcas-adult-social-care> [Accessed 20 Sep. 2023].

151 NHS (2019). Multi-compartment Compliance Aids (Blister packs) Frequently Asked Questions for prescribers. [online] Available at: <https://www.panmerseyapc.nhs.uk/media/2274/blisterpacks.pdf>.

152 The Pharmacy Guild of Australia (2023). Looming aged care medicine crisis. [www.guild.org.au](http://www.guild.org.au). [online] Available at: <https://www.guild.org.au/news-events/news/2023/looming-aged-care-medicine-crisis> [Accessed 13 Oct. 2023].

Questions	AUS	CAN	NZL	UK
		<p>The Medicine Shoppe Pharmacy provide the service for free<sup>153</sup></p>	<p>depending on the size of the DAA pack)<sup>154</sup></p> <ul style="list-style-type: none"> <li>■ For aged care centres, this will depend on the exact contract between the pharmacy and the aged care centre with an expectation of some discounting or free of charge service in exchange for an exclusive supplying contract with the aged care centre</li> </ul>	<p>residents eligible for free sorting and provision of DAAs.</p> <ul style="list-style-type: none"> <li>- Under the Equality Act (2010), pharmacies have an obligation to supply DAAs free of charge for a patient that:               <ol style="list-style-type: none"> <li>(1) qualifies under the Equality Act; and</li> <li>(2) if a DAA is deemed the most appropriate adjustment in the interest of the patient.</li> </ol> <p>To qualify under the Equality Act, a person is regarded as having a physical or mental impairment, which impedes on their ability to carry out day to day activities and safely administer the medicines</p> </li> <li>- Given these requirements, a substantial number of aged care residents would qualify for free offerings<sup>155</sup></li> <li>■ Additionally, where the Equality Act (2010) does not apply, there are several pharmacies in the UK that provide the service for free as part of their standard service delivery<sup>156</sup></li> </ul>

153 Please note assertion that Shoppers Drug Mart, one of the largest pharmacies in Canada does not charge is based on a data base provided by Toronto Central Healthline which lists out several Shoppers Drug Marts that offer free picking of DAA - please see example here: Toronto Central Healthline (2023). Shoppers Drug Mart - Toronto - St Clair Ave W (St Clair and Bathurst) - torontocentralhealthline.ca. [online] www.torontocentralhealthline.ca. Available at: <https://www.torontocentralhealthline.ca/display/service.aspx?id=120785> [Accessed 11 Oct. 2023].

For The Medicine Shoppe Pharmacy, please see here: The Medicine Shoppe Pharmacy (n.d.). Our Services – The Medicine Shoppe Pharmacy – Courtenay BC. [online] The Medicine Shoppe Pharmacy. Available at: <https://medicineshoppecourtenay.ca/pharmacy-services/> [Accessed 11 Oct. 2023].

154 This was based on an anonymous call to three pharmacies in Auckland

155 For details of Equality Act recommendations please see here: Courtside Surgency NHS (n.d.). Dosette Boxes. [online] www.courtside.nhs.uk. Available at: <https://www.courtside.nhs.uk/dosette-boxes> [Accessed 11 Oct. 2023].

156 Spirit Pharmacy (n.d.). Blister Packs. [online] Spirit Pharmacy. Available at: <https://spirit-pharmacy.co.uk/blister-packs/> [Accessed 11 Oct. 2023]. and Time Pharmacy (n.d.). Dosette Box Service! [online] Time Pharmacy. Available at: <https://timepharmacy.co.uk/service/free-dosette-box-service/> [Accessed 11 Oct. 2023].

Questions	AUS	CAN	NZL	UK
				<p>It should be noted that UK medical guidance in recent years has questioned the effectiveness and safety of DAAs. This has resulting in some major pharmacies no longer offering DAA or blister pack services to patients and aged care facilities. For example, Boots pharmacy have begun limiting their usage of DAA packaging.<sup>157</sup></p>

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<sup>157</sup> Greene, J. and Ogden, S. (2019). Blister packs are being withdrawn - what's really happening? [online] Medication Training. Available at: <https://medicationtraining.co.uk/are-blister-packs-disappearing/> [Accessed 11 Oct. 2023]. and Pharmacy Magazine (2022). Boots responds to criticism of decision to stop blister pack service. [online] [www.pharmacymagazine.co.uk](http://www.pharmacymagazine.co.uk). Available at: <https://www.pharmacymagazine.co.uk/news/boots-responds-to-criticism-of-decision-to-stop-blister-pack-service> [Accessed 11 Oct. 2023].

## 2.3 INNOVATION DEEP DIVES

In this section information on **10 innovations** that could enhance access to pharmaceutical products for vulnerable cohorts (e.g., people with a disability, older citizens, those living in remote settings, and those on low income) is provided, each with discrete advantages across access, adherence, availability, convenience, cost, literacy, independence and safety, organised by innovation type. Based on the analysis conducted, there are no innovations that are explicitly designed for older citizens or those resident in aged care facilities. However, the range of innovations profiled here have aged care-related use cases in addition to offering support for other vulnerable cohorts, including people with disabilities and the elderly. These have been explicitly called out where relevant.

For each innovation, information is organised across three categories:

- Innovation description
  - What is the innovation and how does it work?
  - What benefits and/ or improvements does the innovation bring to vulnerable cohorts?
  - How has government enabled this innovation?
  - What are the associated risks with this innovation and how could they be mitigated?
- Specific innovation case study
- Applicability to Australia
  - What is the typical/ current approach in Australia?
  - What considerations affect whether this can be adopted/ scaled in Australia?

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### 2.3.1 Medication Synchronisation

Figure 1: Illustration of Medication (Prescription) Synchronisation Developed by Port St. John Discount Pharmacy in Florida, USA<sup>158</sup>



#### 2.3.1.1 INNOVATION DESCRIPTION

##### What is the innovation and how does it work?

- **Innovation overview:** Medication synchronisation is a pharmacy service that aims to streamline and simplify the process of managing multiple prescription medications for patients. The method eliminates the confusion, missed doses and unnecessary trips often associated with the traditional approach to managing prescriptions, which involves patients having different refill dates for different medications.<sup>159</sup>
- **How it works:** The primary goal of medication synchronisation is to align the refill dates for multiple medications to a single day each month. It works in the following way:<sup>160</sup>
  - **Assessment:** The patient's current medication regimen is assessed, and information is gathered on the medications the patient is taking, their dosages and their existing refill dates.
  - **Selection:** Medications which can be synchronised are selected. Not all medications may be suitable for synchronisation due to varying factors such as the patient's medical needs or medication type.

<sup>158</sup> Cocoa, N. (n.d.). Medication Synchronization. [online] [www.discountpharmacyfl.com](http://www.discountpharmacyfl.com). Available at: <https://www.discountpharmacyfl.com/services/medication-synchronization> [Accessed 7 Sep. 2023].

<sup>159</sup> Renfro, C., Patti, M., Ballou, J.M. and Ferreri, S.P. (2018). Development of a medication synchronization common language for community pharmacies. *Journal of the American Pharmacists Association*, 58(5), pp.515-521.e1. doi:<https://doi.org/10.1016/j.japh.2018.04.032>.

<sup>160</sup> Krumme, A.A., Isaman, D.L., Stolpe, S.F., Dougherty, S. and Choudhry, N.K. (2016). Prevalence, effectiveness, and characteristics of pharmacy-based medication synchronization programs. *PubMed*, 22(3), pp.179, 185.

- **Adjustment:** For the chosen medications, the pharmacist calculates and modifies the prescription periods so that they all end on the same day each month. In some cases, to align the medications with the desired refill schedule, partial refills or quantities may be provided. This means that patients may receive a portion of their usual medication supply to cover the period until the next synchronised refill date.
- **Synchronisation:** A specific day of the month is chosen as the synchronisation date. This is the day when all the selected medications will be refilled and when the patient will have to collect their medication going forward.
- **Education:** Patients are educated about the new refill schedule and any changes made to their medications.
- **Monitoring:** After the initial synchronisation, patients' progress is monitored to ensure that the new refill schedule is working effectively. Adjustments are made where necessary.

### What benefits and/ or improvements does the innovation bring to vulnerable cohorts?

- In the last ten years, numerous peer-reviewed studies evaluating the effects of medication synchronisation have reported improved medication adherence and greater convenience:<sup>161</sup>
  - **Adherence:** Medication synchronisation can simplify medication routines, reducing confusion, the risk of missed refills and disruptions in medication regimen. Vulnerable populations, including patients managing chronic conditions and polypharmacy which especially affects the elderly and those in aged care, frequently encounter such challenges when it comes to dealing with multiple medications. These challenges are exacerbated by the cognitive load associated with intricate dosing schedules and the need to keep track of numerous prescriptions. Medication synchronisation can not only simplify their healthcare routine but may also significantly contribute to better adherence, enhanced treatment outcomes and even a reduction in hospitalisations.
  - **Convenience:** Medication synchronisation enhances patient convenience by reducing trips to the pharmacy and simplifying medication management. With this approach, patients no longer need to keep track of various refill dates for their medications. Pharmacists take on the responsibility of managing refill schedules and, in some cases, can send reminders to patients. This streamlined process is particularly beneficial for older patients, individuals in rural areas and those lacking reliable transportation, such as many in aged care communities. It ensures that these individuals have easier access to their essential medications, promoting better health outcomes and a higher quality of life.

### How has government enabled this innovation?

- **United States:** In the US, the Centres for Medicare and Medicaid Services (CMS) regulations and state-level legislation has enabled medication synchronisation by:<sup>162</sup>

<sup>161</sup> U.S. Government Accountability Office (GAO) (2019). Medicare: Limited Information Exists on the Effects of Synchronizing Medication Refills. [online] U.S. Government Accountability Office, p.10. Available at: <https://www.gao.gov/assets/gao-19-520.pdf> [Accessed 7 Sep. 2023].

<sup>162</sup> Ibid. Medication Synchronisation is also permitted and available in Canada and the UK. See, e.g., Medsync (n.d.). The New Model. [online] MEDSYNC®. Available at: <https://medsync.ca/our-solution/the-new-model/> [Accessed 12 Sep. 2023]; Claypath and University Medical Group (n.d.). How to synchronise your repeat prescriptions – Claypath and University Medical Group. [online] Durham Student Health UK. Available at: <https://durhamstudenthealth.co.uk/how-to-synchronise-your-repeat-prescriptions/#:~:text=What%20is%20synchronisation%3F> [Accessed 12 Sep. 2023].

- Centres for Medicare and Medicaid Services (CMS) regulations:
  - **Regulation for short fills:** The prorated co-payment system introduced by CMS facilitates medication synchronisation by preventing patients from paying the full prescription charge when they require short (partial) fills.
- **State-level legislation:** Various states, including Georgia, Illinois, Maine, Texas, and Washington, have enacted laws since 2015 that support medication synchronisation efforts.<sup>163</sup> These laws enable synchronisation in several ways:
  - **Prorated cost sharing:** Similar to CMS's regulation, some state laws have mandated health plans to prorate patients' cost-sharing (e.g., co-payments) for short fills. This practice eases the financial burden on patients during the initial stages of medication synchronisation, promoting their participation.
  - **Short fill coverage:** Laws in some of these states mandate insurance coverage for medication short fills. This requirement supports synchronisation by permitting health plans and pharmacies to bypass quantity limits imposed on medication refills. This can be important when patients need short fills to synchronise multiple medications effectively.
  - **Mandated synchronisation processes:** Texas and Washington state laws require health plans to create processes to synchronise medication. These regulations cover pharmacists, prescribing physicians, health plans and patients in evaluating the appropriateness of synchronisation, ensuring patient-centric decision-making.

#### What are the associated risks with this innovation and how could they be mitigated?

- **Cost:** Some patients may experience increased out-of-pocket costs when they synchronise their medications. This can happen if their insurance plan has different co-payments or coverage rules for medications, including for short fills. As outlined above, in some areas in the US this has been mitigated through prohibiting full charges for partial or short falls as well as co-payments or prorating cost-sharing.<sup>164</sup>
- **Consultation:** Reducing the number of visits, often to once a month, may mean that consultations with pharmacists are reduced. While this can lead to increased convenience, it may also result in less frequent monitoring of a patient's overall health and medication-related issues. To mitigate this risk, pharmacists and healthcare providers patients should actively engage in open communication with their patients. Regularly reporting any changes in their health status, new symptoms or concerns about medication side effects is crucial. Additionally, pharmacies may bridge the gap between in-person visits by offering telehealth or phone consultation options.<sup>165</sup>

<sup>163</sup> U.S. Government Accountability Office (GAO) (2019). Medicare: Limited Information Exists on the Effects of Synchronizing Medication Refills. [online] U.S. Government Accountability Office, p.10. Available at: <https://www.gao.gov/assets/gao-19-520.pdf> [Accessed 7 Sep. 2023].

<sup>164</sup> Ibid.

<sup>165</sup> Holdford, D.A. and Saxena, K. (2015). Impact of appointment-based Medication Synchronization on existing users of Chronic Medications. *Value in Health*, 18(3), pp.663–64. doi:<https://doi.org/10.1016/j.jval.2015.03.1513>.

### 2.3.1.2 SPECIFIC INNOVATION CASE STUDY

#### Thrifty White Pharmacy – Medication Synchronisation Programme<sup>166</sup>

- **Overview:** In the United States, Thrifty White Pharmacy introduced an ABM programme to enhance patient adherence to chronic medications. The programme synchronised prescription refills to a single day of the month, aiming to combat inconsistent medication use.
- **How it works:**
  - **Participant selection:** Eligibility for participation was determined based on specific criteria, including enrolment and having a minimum of two refills for medications within six chronic medication categories.
  - **Date alignment:** The core strategy of the programme involved synchronising prescription refills for chronic medications to a single day of the month.
  - **Monthly pickup:** Patients participating in the ABM programme were assigned a specific day each month for medication pickup. This regular schedule ensured predictability and convenience for patients.
  - **Personalised support:** Participants received individualised phone calls to clarify any questions or concerns regarding their medication needs. This personalised support aimed to enhance medication management.
  - **Impact assessment:** The effectiveness of the ABM programme was evaluated using patient data from the pharmacy's prescription claims database and outcomes from a control group. The programme demonstrated a notable enhancement in patient adherence and a decrease in non-persistence for chronic medications during the evaluated period compared to the control group:
    - **Adherence:** The proportion of days covered (PDC), a metric for adherence rates, revealed that patients in the ABM programme had higher rates of compliance with various medication classes. Patients also showed, on average, 3.4 to 6.1 times higher odds of adherence.
    - **Persistence:** Patients exhibited a 52% to 73% lower likelihood of non-persistence (i.e., not continuing their medication treatment) compared to controls, depending on the drug category.

### 2.3.1.3 APPLICABILITY TO AUSTRALIA

#### What is the typical/ current approach in Australia?

- **Synchronisation is unavailable:** Australia does not have a formalised medication synchronisation programme. Instead, the typical approach to managing multiple prescriptions for a single patient appears to be contingent on the patient self-organising renewal or refill dates of medications.<sup>167</sup>

#### What considerations affect whether this can be adopted/ scaled in Australia?

- **Cost and infrastructure** constraints are unlikely to be a challenge to adopting or scaling medication synchronisation. For instance, The American Pharmacists

<sup>166</sup> Holdford, D. and Inocencio, T. (2012). Appointment-Based Model (ABM) Data Analysis Report: Prepared for Thrifty White Pharmacy. [online] MPHA, pp.1–8. Available at: <https://cdn.ymaws.com/www.mpha.org/resource/resmgr/imported/Thrifty-White-Med-Adherence-Study.pdf> [Accessed 7 Sep. 2023]. See also Blank, C. (2017). Thrifty White Program Improves Medication Adherence in Diabetes. [online] Drug Topics. Available at: <https://www.drugtopics.com/view/thrifty-white-program-improves-medication-adherence-diabetes> [Accessed 7 Sep. 2023].

<sup>167</sup> See, e.g., NPS MedicineWise (n.d.). Managing your medicines. [online] NPS MedicineWise. Available at: <https://www.nps.org.au/consumers/managing-your-medicines> [Accessed 14 Sep. 2023].

Association Foundation in its 'Implementation Guide for Pharmacy Practices' on Appointment Based Models emphasised the low implementation difficulty, observing that "the ABM does not require any integration or modification of pharmacy management systems and necessitates a very low investment, if any, to implement."<sup>168</sup>

- **Collaboration between prescribers and dispensers** ensures that the patient's medication regimen aligns with their medical needs, prescribed dosages, and treatment goals. Pharmacists typically review the patient's prescriptions and may contact the prescribers to discuss the synchronisation plan or request adjustments to prescription durations. In this context, a well-established and cooperative relationship between prescribers and pharmacists is likely an important factor in the successful adoption and expansion of medication synchronisation.
- **Variability in medication pack sizes** may influence the adoption of medication synchronisation in Australia as they play a pivotal role in such programmes. Specifically, the presence of varying sizes may impede the consistency of medication synchronisation, making it challenging for patients to synchronise their medications effectively and, in turn, disrupting pharmacy inventory management.
- **Stakeholder engagement** would be required with healthcare professionals, pharmacists, pharmacies, technology providers and patient advocacy groups to address potential concerns and build confidence in the effectiveness of the innovation.

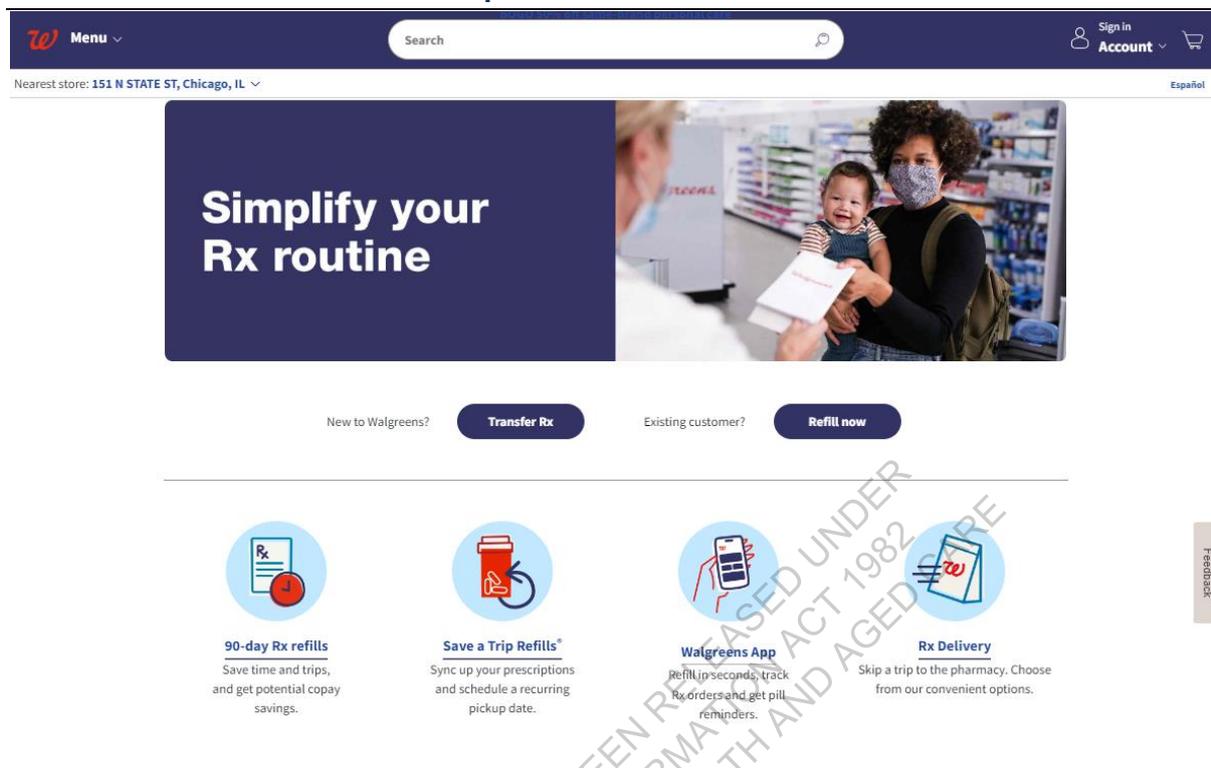
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<sup>168</sup> Watson, L.L. and Bluml, B.M. (2013). Pharmacy's Appointment Based Model: A prescription synchronization program that improves adherence. [online] APhA Foundation, American Pharmacists Association Foundation, p.5. Available at: <https://www.aphafoundation.org/sites/default/files/ckeditor/files/ABM%20White%20Paper%20-%20Final%20-%2020130830.pdf>.

## 2.3.2 Online Pharmacies

**Figure 2: Walgreens allows patients to manage, refill and transfer prescriptions online as well as have them delivered to patients' homes<sup>169</sup>**



### 2.3.2.1 INNOVATION DESCRIPTION

#### What is the innovation and how does it work?<sup>170</sup>

- **Innovation overview:** Online pharmacies, also referred to as ePharmacies, are digital platforms where individuals can order a wide range of prescription medicines which are subsequently delivered to their residence. While online pharmacies have been in existence for some time in Australia, their widespread adoption and scaling have remained somewhat limited.
- **How it works:**
  - **Website access:** Users visit the online pharmacy's website, where they can browse and search for various medicines, selecting the quantity and dosage they need.
  - **Guidance and support:** Users access online pharmacists or healthcare professionals who can answer medication-related queries and offer guidance on proper usage and potential side effects.
  - **Prescription verification:** Users upload or email a valid prescription from a licensed healthcare provider. In turn, the online pharmacy verifies its authenticity and reviews it for potential interactions with other medicines.

<sup>169</sup> Walgreens (n.d.). *Pharmacy Landing*. [online] Walgreens. Available at: <https://www.walgreens.com/rx-checkout/pharmacy-landing> [Accessed 14 Sep. 2023].

<sup>170</sup> Gray, N.J. (2011). The Evolution of Online Pharmacies. *SelfCare*, [online] 2(3), p. 76-86. Available at: <https://selfcarejournal.com/wp-content/uploads/2015/09/Gray-2.376-86.pdf>.

- **Purchase and confirmation:** Users proceed to checkout, where they provide shipping information and payment details. The online pharmacy ensures secure payment processing. Once approved, users receive a confirmation email or message with order details, including the total cost and estimated delivery date.
- **Medication dispensing:** The online pharmacy team or partnered pharmacy fills the prescription and packages the medication safely.
- **Delivery:** The medication is dispatched for delivery to the user's specified address. Users receive a tracking number to monitor the shipment's progress and can contact customer support with any inquiries.
- **Receipt of medication:** Upon arrival, users inspect the package to ensure it matches their order and follow any provided instructions for proper medicine usage and storage.

### What benefits and/ or improvements does the innovation bring to vulnerable cohorts?<sup>171</sup>

- **Benefits differ across services provided:** Online pharmacies offer a range of supporting services, including online ordering, medication management, direct GP lodgement of prescriptions with pharmacists electronically (e.g., E-Scribe), by fax or by email, online pharmacist support, specialised medication packaging and home deliveries. Although the precise services may differ across online pharmacy providers, they benefit vulnerable cohorts, including the elderly and patients with disabilities, in several ways:
  - **Access and availability:** Online pharmacies streamline the medication ordering process, ensuring prompt delivery to Aged care facilities, homes and residences, saving time and effort, beyond the traditional approach of in-person, one-to-one discussions and management (e.g., MedsCheck in Australia which involves the provision of an in-Pharmacy one-on-one discussion and medication review provided by a pharmacist or at an Aged Care facility).<sup>172</sup> With a broad medication selection and 24/7 accessibility, these pharmacies ensure that residents have timely access to the medications they need, promoting better healthcare management, including within aged care facilities.
  - **Convenience:** Online uploading of a patient's prescriptions, ordering and home delivery reduces the burden of physical travel to pharmacies, providing a convenient way for patients with limited mobility to access medicines. Quick digital access to a patient's active medications and prescription details, order history and shipping status makes it easier to track and organise medications, especially for polypharmacy.
  - **Adherence:** Online ordering, delivering and specialised packaging services which variously sort medications (e.g., by date and time) promote better medication adherence among vulnerable individuals because they are given access to a continuous and easily accessible supply of medicines which can auto renew.<sup>173</sup>
  - **Literacy:** Online access to pharmacists ensures patients as well as carers of vulnerable cohorts can receive immediate expert advice without the need to

171 Prashanti, G., Sravani, S. and Noorie, S. (2017). A Review on Online Pharmacy. IOSR Journal of Pharmacy and Biological Sciences, [online] 12(03), p. 33. doi:<https://doi.org/10.9790/3008-1203043234>.

172 Pharmacy Programs Administrator (2019). MedsCheck and Diabetes Medscheck - Pharmacy Programs Administrator. [online] AHA. Available at: <https://www.ppaonline.com.au/programs/medication-management-programs/medscheck-and-diabetes-medscheck> [Accessed 13 Sep. 2023].

173 Thalkari, A.B., Karwa, P.N. and Gawli, C.S. (2018). A Review on Online Pharmacy: Views and Counterinterviews. Asian Journal of Pharmacy and Technology, 8(2), p.108. doi:<https://doi.org/10.5958/2231-5713.2018.00017.x>.

physically attend a pharmacy. This is particularly helpful for elderly people who might value expert reassurance or support during an online activity.

### How has government enabled this innovation?

- **Safety programmes:** To combat the potential risks of fraud, some governments have launched initiatives designed to promote the legitimacy, validity and certification of online pharmacies.<sup>174</sup> The US, for example, has established:
  - **'Safe Pharmacy' Initiative:** The National Association of Boards of Pharmacy (NABP) has enabled consumers to check whether an ePharmacy website is verified using NABP's Safe Site Search Tool. Likewise, the NABP provides a search function to identify NABP-accredited digital pharmacies, which comply with criteria that address the customers' right to privacy, authentication and security of prescription orders, adherence to a recognised quality assurance policy, and provision of meaningful consultation between customers and pharmacists.
  - **BeSafeRx:** The US Food and Drug Administration (FDA) also runs the 'BeSafeRx' campaign, a public awareness campaign designed to educate citizens on how to safely buy prescription medicines online. This includes the ability to check whether an online pharmacy is in the respective state's board of pharmacy license database.
- **Guidelines:** To reduce the safety risks of online pharmacies, guidelines have been published in some countries. In the UK, for example:
  - In 2019, the UK's General Pharmaceutical Council (GPhC), the UK regulatory body overseeing pharmacy and medications, released guidelines for pharmacy owners on conducting risk assessments, appropriate training, secure and cogent website building, and transparency. The guidelines, grouped under five principles, hold that such factors should be considered before deciding whether any services can be provided safely and effectively on the internet. This response formed part of a UK-wide regulatory push across healthcare services, medicines and health professionals over the potential risks of online primary care, including inappropriate access to medications and the configuration of some providers' services to evade regulatory oversight.

### What are the associated risks with this innovation and how could they be mitigated?<sup>175</sup>

- **Potential Quality Use of Medicines (QUM) risks:** The Pharmacy Guild of Australia has expressed "concerns relating to online medicine sales and QUM".<sup>176</sup> Specifically, they have identified certain risks, notably the absence of personal contact and the encouragement of dispensing multiple repeats. These risks relate to the QUM strategy

174 Fincham, J.E. (2021). Negative Consequences of the Widespread and Inappropriate Easy Access to Purchasing Prescription Medications on the Internet. *American Health & Drug Benefits*, [online] 14(1), pp.22–28. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8025924/>.

175 See, e.g., Health Canada (2021). Choosing a safe online pharmacy. [online] [www.canada.ca](https://www.canada.ca/en/health-canada/topics/buying-using-drug-health-products-safely/safe-use-online-pharmacies.html). Available at: <https://www.canada.ca/en/health-canada/topics/buying-using-drug-health-products-safely/safe-use-online-pharmacies.html>.

176 The Pharmacy Guild of Australia (2011). Pharmacy Guild submission in response to The Productivity Commission- Issues Paper: The Economic Structure and Performance of the Australian Retail Industry. [online] Productivity Commission, p. 3. Available at: <https://www.pc.gov.au/inquiries/completed/retail-industry/submissions/sub072.pdf> [Accessed 11 Sep. 2023].

which focuses on selecting management options wisely, choosing suitable medicines if a medicine is considered necessary and using medicines safely and effectively:<sup>177</sup>

- **Lack of personal contact:** It has been argued that online pharmacies could lead to the unsuitable supply of medicines, inappropriate adverse effects and interactions with other medicines because they compromise essential communication or personal contact between pharmacists and patients.<sup>178</sup> To mitigate this risk, online pharmacies can implement measures such as online consultations with healthcare professionals. For instance, for Amazon Pharmacy US-licensed pharmacists check every order and are available 24/7 to answer any questions about patients' medications.<sup>179</sup>
- **Supply of multiple repeats:** The online supply of medicines, including the promotion of multiple repeats by some online pharmacies for cost-saving or convenience reasons has been suggested to raise potential concerns about medicine misuse and patient safety.<sup>180</sup> This risk may be mitigated through limitations on the promotion of multiple repeats and robust patient education on responsible medication use.
- **Limited reference to QUM:** Beyond this, there appears to be limited explicit reference to the potential risks which online pharmacies pose to QUM principles. One related research paper, published in 2023, evaluated the safety of prescription request applications in Australia and observed that two apps “did not utilise a standard general health questionnaire and therefore did not have a comprehensive or consistent information-gathering process.”<sup>181</sup> In relation to QUM principles, it noted that, “[t]his is concerning as the quality use of medicines relies on prescribers being aware of patients' general health information in order to prescribe medications that are appropriate and safe.”<sup>182</sup> Otherwise, no literature was identified that discussed the QUM risks of online pharmacies.
- **Lack compliance:** The global operation of online pharmacies potentially makes it challenging to ensure compliance with local regulations (e.g., operating without the necessary licenses). Mitigating these challenges can involve mandatory licensing and auditing procedures, and the creation of a transparent public database of accredited pharmacies.

<sup>177</sup> Department of Health and Aged Care (2002). *National Strategy for Quality Use of Medicines - Plain English Edition*. [online] Department of Health and Aged Care, p.1. Available at: [https://www.health.gov.au/sites/default/files/documents/2022/04/national-strategy-for-quality-use-of-medicines\\_0.pdf](https://www.health.gov.au/sites/default/files/documents/2022/04/national-strategy-for-quality-use-of-medicines_0.pdf) [Accessed 14 Sep. 2023].

<sup>178</sup> The Pharmacy Guild of Australia (2011). Pharmacy Guild submission in response to The Productivity Commission- Issues Paper: The Economic Structure and Performance of the Australian Retail Industry. [online] Productivity Commission, pp.3–4. Available at: <https://www.pc.gov.au/inquiries/completed/retail-industry/submissions/sub072.pdf> [Accessed 11 Sep. 2023]. Cf Ilardo, M.L. and Speciale, A. (2020). The Community Pharmacist: Perceived Barriers and Patient-Centered Care Communication. *International Journal of Environmental Research and Public Health*, [online] 17(2), pp. 2-3. doi:<https://doi.org/10.3390/ijerph17020536>. This paper notes this point, albeit without explicit reference to QUM principles: “The growing use of online and mail-order pharmacies has certainly facilitated the customers but has also deprived them of the physical encounter with professionals in pharmacy”

<sup>179</sup> Amazon (2023a). Amazon's full-service online pharmacy makes it easy and affordable to shop for medication. Here's how it works. [online] US About Amazon. Available at: <https://www.aboutamazon.com/news/retail/how-does-amazon-pharmacy-work> [Accessed 6 Sep. 2023].

<sup>180</sup> The Pharmacy Guild of Australia (2011). Pharmacy Guild submission in response to The Productivity Commission- Issues Paper: The Economic Structure and Performance of the Australian Retail Industry. [online] Productivity Commission, pp.3–4. Available at: <https://www.pc.gov.au/inquiries/completed/retail-industry/submissions/sub072.pdf> [Accessed 11 Sep. 2023].

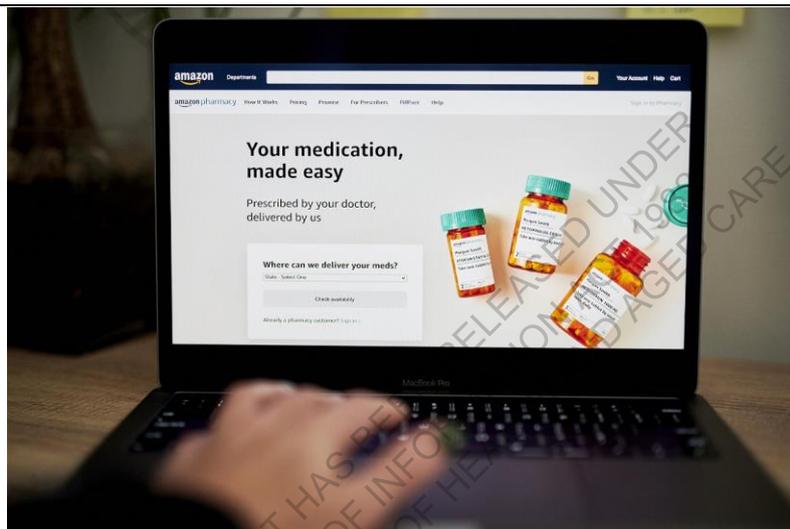
<sup>181</sup> This is a category of eHealth app which allows consumers to request prescriptions for specific prescription-only medications without necessarily interacting with a prescriber: Amin, R., Cato, M., Rahavi, S., Tran, K., Lee, K., Lobo, E., Mill, D., Page, A. and Salter, S. (2023). Is It Safe to Buy Medications from an App? Evaluation of Medication Prescribing Applications Available in Australia. *Pharmacy*, 11(2), p.49. doi:<https://doi.org/10.3390/pharmacy11020049>.

<sup>182</sup> Amin, R., Cato, M., Rahavi, S., Tran, K., Lee, K., Lobo, E., Mill, D., Page, A. and Salter, S. (2023). Is It Safe to Buy Medications from an App? Evaluation of Medication Prescribing Applications Available in Australia. *Pharmacy*, 11(2), p.49. doi:<https://doi.org/10.3390/pharmacy11020049>.

- Fraudulent practices:** Engaging with deceptive online pharmacies could pose a threat to the security of personal and financial information, potentially leading to theft. To combat this risk, governments may take a multifaceted approach including enacting legal measures for swift actions. For instance, the FDA has publicly issued warning letters informing various website operators of rogue online pharmacies that they are engaged in illegal activity in violation of the US Food, Drug, and Cosmetic Act.<sup>183</sup> Establishing consumer-friendly cyber-security reporting systems and collaborating with financial institutions to monitor and block suspicious transactions could also potentially be effective.

### 2.3.2.2 SPECIFIC INNOVATION CASE STUDY

#### Figure 3: Amazon Pharmacy provides secure, discreet packaging and 2-day medication delivery as part of its online pharmacy service<sup>184</sup>



### Amazon Pharmacy

- Overview:** Launched in the United States in November 2020, Amazon Pharmacy is Amazon's pharmacy e-commerce business. Amazon Pharmacy allows users to purchase both prescription (Rx) and over the counter (OTC) medications through the Amazon online store and have them delivered to their home.<sup>185</sup>
  - Area of Operation:** Amazon currently operates only in the United States where it delivers medications to all 50 US States.<sup>186</sup> In 2020, the company filed to trademark "Amazon Pharmacy" in Australia, Brazil, Canada, China, Egypt, the EU, India, Israel, Japan, Mexico, Singapore, Taiwan, Turkey, UAE and the UK.<sup>187</sup> However, filing a trademark does not necessarily indicate an intent to expand internationally. In fact, Amazon withdrew its trademark application in Australia in

183 FDA (2021). Internet Pharmacy Warning Letters. [online] FDA. Available at: <https://www.fda.gov/drugs/drug-supply-chain-integrity/internet-pharmacy-warning-letters>.

184 Dr. Vin Gupta, C.M.O. (2023) Introducing RxPass from Amazon Pharmacy, a \$5 prescription subscription that helps prime members who take multiple medications save time and money, US About Amazon. Available at: <https://www.aboutamazon.com/news/retail/introducing-rxpass-from-amazon-pharmacy-a-5-prescription-subscription-that-helps-prime-members-who-take-multiple-medications-save-time-and-money> (Accessed: 06 September 2023).

185 Amazon (2023a). Amazon's full-service online pharmacy makes it easy and affordable to shop for medication. Here's how it works. [online] US About Amazon. Available at: <https://www.aboutamazon.com/news/retail/how-does-amazon-pharmacy-work> [Accessed 6 Sep. 2023].

186 Ibid.

187 Farr, C. (2020). Amazon just filed a bunch of international trademarks for 'Amazon Pharmacy'. [online] CNBC. Available at: <https://www.cnbc.com/2020/01/21/amazon-files-trademarks-for-amazon-pharmacy-in-uk-australia-canada.html>.

2021.<sup>188</sup> The reasons behind this decision are unknown although the registration was opposed by The Pharmacy Guild of Australia.<sup>189</sup>

#### ■ **How it works:**<sup>190</sup>

- **Medication selection:** Customers can choose from different supply options, including 30-day, 90-day, and 6-month supplies. They have the flexibility to purchase medications privately or using their insurance.
- **Price comparison:** Before making a purchase, customers can compare the cost of their medication with insurance co-pays, the price without insurance, and any available savings. This is particularly beneficial for Amazon Prime members.
- **PillPack service:** Amazon Pharmacy also provides a unique service called PillPack. This service organises medications into packets based on the date and time they should be taken.
- **User-friendly interface:** The platform is designed with Amazon's signature user-friendly interface, making it familiar and easy to navigate for customers.
- **Prescription handling:** Healthcare providers can send new prescriptions or existing ones directly to Amazon Pharmacy for fulfilment. This streamlines the prescription process and ensures a smooth experience for customers.
- **Pharmacist support:** For any medication-related questions or concerns, customers can reach out to a pharmacist 24/7. This ensures that they have professional guidance whenever they need it.

#### 2.3.2.3 APPLICABILITY TO AUSTRALIA

##### What is the typical/ current approach in Australia?

- **Low use:** In Australia, online pharmacies are permitted to dispense drugs although customer use is low. In one Australian study, only 3% of those surveyed visited an online only pharmacy for prescription medicines, and only 4% visited an online only pharmacy for other products and services.<sup>191</sup>
- **No safe list:** Australia does not have an official online pharmacy 'safe list'.<sup>192</sup>
- **Sector reluctance:** The Pharmacy Board of Australia has held that the supply of medicines through the internet and mail-order dispensing is "less than the optimal way of delivering a pharmacy service because communication, including opportunities for counselling, may be compromised".<sup>193</sup> Nevertheless, the Board has acknowledged their utility: "...the Board recognises that particular patient circumstances may exist where these forms of communication [indirect supply of medicines, such as Internet and mail-order dispensing] necessary or appropriate (e.g., in remote areas). The Board

188 Payne, H. (2021). Amazon bins pharmacy aspirations • The Medical Republic. [online] The Medical Republic. Available at: <https://www.medicalrepublic.com.au/amazon-bins-pharmacy-aspirations/47075> [Accessed 11 Sep. 2023].

189 IP Australia (2021). Trade Mark 2062013 | IP Australia | Trade Mark Search. [online] search.ipaustralia.gov.au. Available at: <https://search.ipaustralia.gov.au/trademarks/search/view/2062013?s=63e835b5-05f8-43ea-b7ea-15bdd298fd0a> [Accessed 11 Sep. 2023].

190 Amazon (2023a). Amazon's full-service online pharmacy makes it easy and affordable to shop for medication. Here's how it works. [online] US About Amazon. Available at: <https://www.aboutamazon.com/news/retail/how-does-amazon-pharmacy-work> [Accessed 6 Sep. 2023].

191 Out of over 1,000 consumers surveyed who were "representative of the adult population of Australian": NAB (2021). NAB Pharmacy Survey 2021. p.6.

192 Mitchell, C. (2016). Online pharmacy 'safe list' needed. [online] InSight+. Available at: <https://insightplus.mja.com.au/2016/17/online-pharmacy-safe-list-needed/> [Accessed 6 Sep. 2023].

193 See Pharmacy Board (2019). Pharmacy Board of Australia – Guidelines for dispensing of medicines. [online] Available at: <https://www.pharmacyboard.gov.au/codes-guidelines.aspx>.

also recognises that some consumers may prefer to access particular pharmacy services in this way.”<sup>194</sup>

### What considerations affect whether this can be adopted/ scaled in Australia?

- **Building customer trust** is one factor that could promote use of online channels. Trust could be built via transparency in pricing and rigorous quality assurance. Provision of easily accessible ways to check online pharmacy accreditation could also build patient trust. Such tools or checks could build upon the existing availability of information published by the TGA on buying medicines or medical devices legitimately online.<sup>195</sup>
- **Existing regulations and guidelines:** Facilitating the scaling of ePharmacies may require government to review existing regulation e.g., CPA rules on pharmacy ownership and location as well as, among others, relevant Commonwealth and State legislation and The Pharmacy Board Guidelines for Dispensing of Medicines.<sup>196</sup> Furthermore in 2015, the Productivity Commission outlined various “concerns about the costs and anticompetitive effects of pharmacy location and ownership regulations [which] are longstanding and have been widely raised.” In response to these factors, the Productivity Commission stated: “Removing location and ownership restrictions would benefit the community. [...] In the long term, reform is inevitable. Ongoing developments in technology, including the Internet, are already shaping consumers’ expectations about how medicines can be bought. Consumers will increasingly question why they cannot purchase pharmaceuticals in the same way that people in other countries do — for example, in New Zealand, the United Kingdom and United States, consumers can [...] fill prescriptions online. Removing location and ownership restrictions now would give Australian pharmacists the opportunity and incentive to adjust to these developments.”<sup>197</sup>
- **QUM principles:** Ensuring online pharmacies are safe and can adhere to QUM principles is a concern expressed by the Pharmacy Guild of Australia.<sup>198</sup> The potential risks posed by online pharmacies to QUM principles have not been explicitly highlighted elsewhere, as detailed above.<sup>199</sup>

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194 Ibid.

195 TGA (2022). Buying medicines and medical devices online. [online] Therapeutic Goods Administration (TGA). Available at: <https://www.tga.gov.au/safety/buying-health-products-online-has-risks/buying-medicines-and-medical-devices-online>.

196 Productivity Commission (2015). Efficiency in Health: Productivity Commission Research Paper. [online] Productivity Commission, p. 51. Available at: <https://www.pc.gov.au/research/completed/efficiency-health/efficiency-health.pdf> [Accessed 12 Sep. 2023].

197 Productivity Commission (2015). Efficiency in Health: Productivity Commission Research Paper. [online] Productivity Commission, p. 55. Available at: <https://www.pc.gov.au/research/completed/efficiency-health/efficiency-health.pdf> [Accessed 12 Sep. 2023].

198 The Pharmacy Guild of Australia (2011). Pharmacy Guild submission in response to The Productivity Commission- Issues Paper: The Economic Structure and Performance of the Australian Retail Industry. [online] Productivity Commission, p. 3. Available at: <https://www.pc.gov.au/inquiries/completed/retail-industry/submissions/sub072.pdf> [Accessed 11 Sep. 2023].

199 See Ilardo, M.L. and Speciale, A. (2020). The Community Pharmacist: Perceived Barriers and Patient-Centered Care Communication. *International Journal of Environmental Research and Public Health*, [online] 17(2), pp. 2-3. doi:<https://doi.org/10.3390/ijerph17020536>.

### 2.3.3 Remote Kiosks

**Figure 4: Example of Medavail's SpotRx Pharmacy, A Self-Service Pharmacy Kiosk Available in The United States Which Was Recently Purchased by CVS Pharmacy<sup>200</sup>**



#### 2.3.3.1 INNOVATION DESCRIPTION

##### What is the innovation and how does it work?<sup>201</sup>

- **Innovation overview:** Remote kiosks are automated, self-service machines or terminals designed to dispense prescription medications and provide related pharmaceutical services. These kiosks are typically placed in healthcare settings, including clinics and hospitals, although in principle may located in any number of other accessible locations. Remote kiosks involve a technology-driven approach to dispensing that allows prescription medications to be dispensed to patients without the need for them to physically visit a traditional pharmacy.
- **How it works:** The operation of remote medication kiosks combines automated systems and advanced technology to provide patients with a convenient and accurate means of obtaining their prescribed medications:
  - **Prescription transmission:** The process begins when a prescription is electronically transmitted to a remote medication kiosk, often through secure healthcare networks.
  - **Professional review:** Upon receipt of the prescription, trained healthcare professionals carefully review it for accuracy and safety. This ensures that the right medication and dosage are being dispensed.
  - **Automated dispensing:** Inside the kiosk, there is an automated dispensing system that precisely measures and dispenses the prescribed medication. This automated system guarantees accuracy in dosage, minimising the risk of human error.

200 Pennic, J. (2023). M&A: CVS Pharmacy Acquires MedAvail's Pharmacy Assets. [online] hitconsultant.net. Available at: <https://hitconsultant.net/2023/01/26/cvs-pharmacy-acquires-medavails-pharmacy-assets/> [Accessed 7 Sep. 2023].

201 Goundrey-Smith, S. (2013). Pharmacy Automation. In: Information Technology in Pharmacy: An Integrated Approach. Springer Link, pp.95–119.

- **Labelling and packaging:** Following dispensing, the medication is securely labelled and packaged within the kiosk. This packaging is designed to maintain the integrity and safety of the medication until it reaches the patient.
- **Accessibility:** Patients can easily access their medications from the remote kiosk using a unique identifier or code provided to the patient.
- **Pharmacist oversight:** Remote medication kiosks often have a pharmacist available, typically virtually but also on-site, to oversee the dispensing process by the automated machine. This ensures an additional layer of safety and provides patients with the opportunity to ask any questions they may have about their medications.

### What benefits and/ or improvements does the innovation bring to vulnerable cohorts?<sup>202</sup>

- **Access:** Remote kiosks greatly improve medication access for vulnerable populations, including those with limited mobility or those residing in remote areas. These kiosks may be placed strategically in various locations, ensuring that vulnerable cohorts can more easily access essential medications. This may be especially important in locations where access to pharmacists is limited due to labour shortages or remoteness.
- **Convenience:** The convenience offered by remote kiosks, including 24/7 availability and reduced wait times, is particularly valuable for vulnerable individuals, making it easier for them to manage their health conditions individually or for carers on their behalf.
- **Adherence:** Remote kiosks often include features that support medication adherence, such as reminders and access to pharmacists, which are crucial for vulnerable patients, especially those with chronic illnesses, in maintaining their health and well-being. In fact, one recent study found that patient use of a kiosk in a hospital lead to lower prescription abandonment rates and comparable pickup and consultant experiences to those at the standard pharmacy counter.<sup>203</sup>

### How has government enabled this innovation?

- **Regulation:** In Ontario, Canada, the Government has enabled the use of remote kiosks by accrediting and approving their use. Specifically, the Ontario Rural and Northern Health Care Panel in 2011 advocated the use of developing telepharmacy technology and automated, pharmacist-controlled prescription medication remote dispensing units to meet the pharmacy needs of rural areas. To enable this innovation, the kiosks, created by MedCentre, were accredited under Ontario's guidelines to deal with the constraints of cost, time and a lack of supporting infrastructure.<sup>204</sup>
- **Funding:** In Scotland, the Government has enabled robotic pharmacy kiosks through funding initiatives. In particular, the Scottish Government partly funded a project in

202 Singer, J.A. (2022). Bring Drug Dispensing into the Modern Age with Vending Machines. [online] Cato.org. Available at: <https://www.cato.org/blog/bring-drug-dispensing-modern-age-vending-machines>.

203 Hirsch, J.D., San Agustin, K., Barnes, C., Agarwal, A., Allen, K., Rivera, S., Laufer, D., Maria, R., Lake, S. and Daniels, C.E. (2021). Impact of a contactless prescription pickup kiosk on prescription abandonment, patient experience, and pharmacist consultations. *Journal of the American Pharmacists Association*, 61(2), pp.151-157.e1. doi:<https://doi.org/10.1016/j.japh.2020.10.011>.

204 Goodridge, D. and Marciniuk, D. (2016). Rural and remote care. *Chronic Respiratory Disease*, [online] 13(2), p.198. doi: <https://doi.org/10.1177/1479972316633414>.

Aberdeenshire to trial a kiosk which enabled users to speak remotely to a pharmacist via webcam and securely access either dispensed or recommended OTC medicines near to their home. This initiative formed part of a greater ambition to support the access of pharmacy services by people living in remote and rural areas across Scotland.<sup>205</sup>

- **Adoption:** In the United States, the Defence Health Agency (DHA) has enabled the use of ScriptCenter automated pharmacy kiosks and locker systems for prescription pick-up in specific military hospitals and clinics. In 2021, a plan was executed to place 80 ScriptCenter units in 69 stateside military hospitals and clinics in 2021. These units offer after-hours prescription pick-up, reducing congestion in pharmacy areas, shortening wait times, and increasing accessibility for same-day prescription needs. The ScriptCenters' enrolment process is simple, requiring a one-time registration involving military ID card scanning, a password and pin, and takes less than two minutes.<sup>206</sup>

### What are the associated risks with this innovation and how could they be mitigated?<sup>207</sup>

- **Technical failures:** Technology like remote kiosks can experience technical failures or system disruptions, potentially impeding patient access to medications. Developing comprehensive technical support and contingency plans can maintain a seamless prescription dispensing process.
- **Supply chain risks:** Remote kiosks present risks related to the sourcing of medications and the logistics required for their timely and secure delivery, which can impact patient access to vital treatments. This risk may be mitigated through robust supplier diversification strategies, such as engaging multiple suppliers to reduce dependency on a single source, and optimised logistics planning.
- **Medication errors:** Automated processes for medication dispensing can make errors, such as dispensing the wrong medication or incorrect dosages. To mitigate this risk, automated verification systems, including barcode scanning technology, can be used. Additionally, having remote pharmacists available for oversight and consultation can serve as a safety net to prevent and rectify errors.
- **Security concerns:** Security vulnerabilities, such as hacking and data breaches, can jeopardise patient information and privacy. Mitigating this risk could involve implementing security measures, including advanced encryption protocols and regular security audits.
- **Missed interactions:** The absence of in-person pharmacist interactions can lead to missed opportunities for patient consultations and guidance. To mitigate this risk, virtual pharmacist consultations via video conferencing or chat services can be integrated

205 Wemyss, E. (2015). Robotic 'pharmacy kiosk' offers revolution in medicine access in rural areas | News | The University of Aberdeen. [online] [www.abdn.ac.uk](https://www.abdn.ac.uk/news/7976/). Available at: <https://www.abdn.ac.uk/news/7976/> [Accessed 7 Sep. 2023].

206 TRICARE News (2021). ScriptCenter Kiosks Offer Easy Prescription Pick Up. [online] TRICARE Newsroom. Available at: <https://newsroom.tricare.mil/News/TRICARE-News/Article/2594809/scriptcenter-kiosks-offer-easy-prescription-pick-up> [Accessed 7 Sep. 2023]. See also Sullivan, C. (2022). Barksdale opens new ScriptCenter Kiosk. [online] Air Force Global Strike Command AFSTRAT-AIR. Available at: <https://www.afgsc.af.mil/News/Article-Display/Article/3164390/barksdale-opens-new-scriptcenter-kiosk/> [Accessed 7 Sep. 2023].

207 See generally Letafat-nejad, M., Ebrahimi, P., Maleki, M. and Aryankhesal, A. (2020). Utilization of integrated health kiosks: A systematic review. *Medical Journal of the Islamic Republic of Iran*, [online] 34, pp.8–11. doi:<https://doi.org/10.34171/mjiri.34.114>.

directly into the kiosk interface. Clear user instructions can be provided for accessing these services, ensuring that patients can seek professional guidance when necessary.

### 2.3.3.2 SPECIFIC INNOVATION CASE STUDY

#### MedAvail's SpotRx Pharmacy and Cigna Medical Group Partnership<sup>208</sup>

- **Overview:** In 2021, MedAvail's SpotRx Pharmacy, a technology-enabled pharmacy company, partnered with Cigna Medical Group, an operator of multi-speciality health care centres, to introduce an innovative solution that enhances medication access for patients in the Phoenix area. This collaboration integrated self-serve pharmacy kiosks, known as SpotRx pharmacy kiosks, into select Cigna Medical Group clinics. The kiosks offered patients the convenience of virtual consultations with pharmacists, on-site prescription filling, and the option for free home medication delivery. In January 2023, MedAvail agreed to sell to CVS Pharmacy assets related to its SpotRx pharmacies located in Arizona, California, Michigan and Florida.<sup>209</sup>
- **How it works:** SpotRx pharmacies were integrated into Cigna Medical Group clinics to provide a more convenient experience for patients. Here is an explanation of how SpotRx pharmacies work:
  - **Integration with clinics:** SpotRx pharmacies are integrated into Cigna Medical Group clinics. This integration allows patients to access pharmacy services without the need for separate visits to an external pharmacy.
  - **Virtual pharmacist consultations:** Patients can engage in virtual consultations with experienced pharmacists. During these consultations, patients can discuss their medications, clarify any doubts and receive guidance on how to take their prescriptions effectively.
  - **Prescription filling:** Following the virtual consultation, patients have the convenience of filling their prescriptions right within the Cigna Medical Group clinic. This eliminates the need for patients to visit a standalone pharmacy, saving them time and effort.
  - **Follow-up calls:** SpotRx pharmacists provide ongoing support through follow-up care calls. These calls serve to reinforce medication adherence, ensuring that patients are taking their medications as prescribed. This proactive approach helps to enhance the overall health outcomes of patients.
  - **Refill reminders:** Patients on chronic medications receive refill reminders from local SpotRx pharmacists. This ensures that patients never run out of essential medications, promoting continuity of care and reducing the risk of medication interruptions.

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208 Paul, C. (2021). MedAvail's SpotRx Pharmacy and Cigna Medical Group Partner to Help Improve Medication Access in Phoenix. [online] [www.businesswire.com](https://www.businesswire.com/news/home/20210209005230/en/MedAvail%E2%80%99s-SpotRx-Pharmacy-and-Cigna-Medical-Group-Partner-to-Help-Improve-Medication-Access-in-Phoenix). Available at: <https://www.businesswire.com/news/home/20210209005230/en/MedAvail%E2%80%99s-SpotRx-Pharmacy-and-Cigna-Medical-Group-Partner-to-Help-Improve-Medication-Access-in-Phoenix> [Accessed 7 Sep. 2023].

209 Yi, J.-Y. (2023). MedAvail announces Sale of Pharmacy Assets to CVS Pharmacy | MedAvail. [online] MedAvail. Available at: <https://investors.medavail.com/news-releases/news-release-details/medavail-announces-sale-pharmacy-assets-cvs-pharmacy> [Accessed 7 Sep. 2023].

### 2.3.3.3 APPLICABILITY TO AUSTRALIA

#### What is the typical/ current approach in Australia?

- **Low Adoption:** There is no information on the extent to which remote kiosks are used in Australia. Nevertheless, calls for their greater use, as detailed in the following paragraph, imply that uptake is low.
- **Subject of Debate:** The use of remote kiosks has been the subject of debate for some time in Australia. In the late 1990s, 'drug vending machines' were proposed as a solution to support rural and regional communities.<sup>210</sup> More recently, the *Review of Pharmacy Remuneration and Regulation Final Report* recommended that the Australian Government should, among other things, "trial the use of machine dispensing in a small number of relevant secure locations in communities that are not currently served by a community pharmacy."<sup>211</sup> Moreover, in 2021 the Australian Medical Association published a discussion paper, 'The Future of Dispensing', in which it recommended that dispensing machines should be incorporated into general practices.<sup>212</sup>

#### What considerations affect whether this can be adopted/ scaled in Australia?

- **Technology infrastructure:** Remote kiosks rely heavily on advanced technology, including dependable internet connectivity, to operate effectively.
- **Supply chain resilience:** Establishing a reliable supply chain ensuring consistent availability of medicines can support and maintain an uninterrupted service.
- **Existing regulations and guidelines:** Facilitating the adoption and scaling of remote kiosks may require government to review existing regulation e.g., the requirement that medicines be dispensed by pharmacists and medications be provided to patients outside of pharmacies in only a limited number of cases, including pharmacy unavailability, Aboriginal Health Services and in emergencies via the "doctor's bag".<sup>213</sup>

210 Meredith, H. (1999). Drug vending machines proposed for bush. [online] Australian Financial Review. Available at: <https://www.afr.com/policy/health-and-education/drug-vending-machines-proposed-for-bush-19990611-k8te6> [Accessed 7 Sep. 2023].

211 King, S., Watson, J. and Scott, B. (2018). Review of pharmacy remuneration and regulation: final report. [online] Analysis & Policy Observatory, pp.53–54. Available at: <https://apo.org.au/node/143826> [Accessed 7 Sep. 2023].

212 Australian Medical Association (2021). The future of dispensing – ensuring Australians have affordable and accessible medicines into the future. [online] AMA, p.12. Available at: <https://www.ama.com.au/sites/default/files/2021-10/Future%20of%20Dispensing%20Discussion%20Paper.pdf> [Accessed 7 Sep. 2023].

213 Lim, D., Emery, J.D., Lewis, J. and Sunderland, V.B. (2011). Australian dispensing doctors' prescribing: quantitative and qualitative analysis. *Medical Journal of Australia*, 195(4), p. 174. doi:<https://doi.org/10.5694/j.1326-5377.2011.tb03272.x>; Department of Health (2017). PBS Pharmaceuticals in Hospitals Review Final Report. [online] The Pharmaceutical Benefits Scheme, p.100. Available at: <https://www.pbs.gov.au/info/reviews/pbs-pharmaceuticals-in-hospitals-review> [Accessed 7 Sep. 2023]; RACGP (2018). RACGP - Criterion GP5.3 – Doctor's bag. [online] Racgp.org.au. Available at: <https://www.racgp.org.au/running-a-practice/practice-standards/standards-5th-edition/standards-for-general-practices-5th-ed/general-practice-standards/gp-standard-5/criterion-gp5-3-doctor-s-bag>.

### 2.3.4 Smart Lockers

**Figure 5: The g-PharmaCollect, Developed by Glintt, Located Outside a Community Pharmacy in Portugal<sup>214</sup>**



#### 2.3.4.1 INNOVATION DESCRIPTION

##### What is the innovation and how does it work?<sup>215</sup>

- **Innovation overview:** Smart lockers, specifically prescription collection lockers, are automated storage systems designed to facilitate the secure dispensing of medications to patients using a 'Click and Collect' approach. These lockers incorporate a computer system that manages the lockers themselves and patient access, allowing for convenient and faster medication distribution.
- **How it works:** Though the mechanism may differ depending on the type of locker, smart lockers broadly work via:
  - **Prescription filling:** Once a prescription is prepared and the medication is ready for pickup, it is securely placed inside a designated compartment within the smart locker.
  - **Patient notification:** Patients are promptly notified through their mobile devices or desktops when their medication is available for collection. This notification serves as an alert that their prescription is ready.

214 Gama, L. (2023). Pharmacy Smart Lockers: The Future of Medication Dispensing. [online] Bloq.it. Available at: <https://bloq.it/future-of-pharmacies-with-pharmacy-smart-lockers/> [Accessed 7 Sep. 2023].

215 Smart locker technology is not limited to pharmaceuticals and prescription pickups. Its uses extend across various sectors with applications ranging from food, retail, and e-commerce to university campuses, where it offers efficient parcel delivery solutions. See, for example, Gundu, T. (2020). Smart Locker System Acceptance for Rural Last-Mile Delivery. [online] IEEE Xplore. doi: <https://doi.org/10.1109/IMITEC50163.2020.9334107>.

- **Locker pick-up:** When patients arrive at the location where the smart lockers are installed, there are alternative methods to access the locker containing their medications depending on the locker set up. These access methods include:
  - **Unique code:** Patients may enter a unique code assigned to them, granting access to the designated locker compartment.
  - **Customer credentials:** Some systems require patients to provide their credentials, such as a username and password.
  - **QR codes:** QR codes scanned via a mobile app or device can also be used to unlock the locker.
  - **Tracking numbers:** In certain setups, patients may enter a specific tracking number associated with their prescription.

### What benefits and/ or improvements does the innovation bring to vulnerable cohorts?<sup>216</sup>

- **Convenience:** Smart lockers address mobility challenges commonly faced by people with disabilities or the elderly by allowing swift medication collection without queuing at pharmacies. Additionally, they enable 24/7 out-of-hours medication access and collection, promoting convenience and increased patient satisfaction, particularly for those working long hours on low incomes who cannot easily get time off work. In aged care facilities, smart lockers may streamline distribution, easing staff workload and ensuring timely medication delivery to residents.
- **Accessibility:** For those with social phobias, anxieties and mental health issues, the option to collect medications from smart lockers alleviates the stress associated with in-person interactions at pharmacies, providing a discreet and anxiety-free solution.
- **Safety:** For individuals who are immunocompromised, avoiding crowded public spaces like pharmacies is crucial to their health, and smart lockers offer a safe and convenient alternative for medication retrieval, reducing exposure risks and ensuring their healthcare needs are met with minimal health risks, stress or discomfort.

### How has government enabled this innovation?

- **Limited government involvement:** Government enablement of the innovation of pharmaceutical smart lockers has been somewhat limited to date. Most of the innovation in this field has been driven by commercial initiatives, often on a small-scale basis and through trial implementations.<sup>217</sup>

<sup>216</sup> Yeo, Y.-L., Chang, C.-T., Chew, C.-C. and Rama, S. (2021). Contactless medicine lockers in outpatient pharmacy: A safe dispensing system during the COVID-19 pandemic. *Research in Social and Administrative Pharmacy*, 17(5), pp.1021–1023. doi: <https://doi.org/10.1016/j.sapharm.2020.11.011>.

<sup>217</sup> See, for example Turner, C. and Penkett, E. (2019). Co-op set to disrupt the pharmacy market. [online] Co-operative.coop. Available at: <https://www.co-operative.coop/media/news-releases/co-op-set-to-disrupt-the-pharmacy-market> [Accessed 7 Sep. 2023]. See also Luís, A.F.S., Martins, G.M.C., Caldeira, J.M.L.P. and Soares, V.N.G.J. (2022). Smart Lockers: Approaches, Challenges and Opportunities. *International Journal of Engineering and Advanced Technology*, 11(3), pp.141–149. doi: <https://doi.org/10.35940/ijeat.c3374.0211322>.

## What are the associated risks with this innovation and how could they be mitigated?<sup>218</sup>

- **Security risks:** A significant risk is the potential for unauthorised access to medication. To mitigate this risk, robust authentication and encryption measures can be implemented. This includes requiring patients to use secure login credentials or two-factor authentication and using strong encryption protocols to protect data during transmission and storage.
- **Dispensing errors:** There is a risk of dispensing errors, where patients receive the wrong medication from the smart locker. To mitigate this, robust inventory management and quality control processes could be in place. Implementing barcode scanning or RFID technology for accurate medication tracking can also help prevent errors.
- **Technical failures:** Technical failures such as system glitches or malfunctions could disrupt medication access. To address this, regular maintenance and system monitoring can be conducted to identify and address issues promptly. Additionally, backup access methods, such as manual overrides or staff assistance, can be available in case of technical failures.
- **Patient education:** Patients may not fully understand how to use the smart lockers, leading to confusion or misuse. Effective patient education and clear instructions, both in written and visual formats, can be provided to ensure patients can confidently and correctly access their medications.

### 2.3.4.2 SPECIFIC INNOVATION CASE STUDY

#### Smart Lockers in Portugal – Bloq.it and Glintt Partnership

- **Overview:** In 2021, Bloq.it, a Portuguese start up, in collaboration with technology supplier Glintt, introduced Smart Lockers to streamline the process of purchasing and collecting medicines in Portugal. The initiative, known as g-PharmaCollect, uses contactless smart lockers installed in participating pharmacies to offer a swift and autonomous experience. This service aims to eliminate the need for time-consuming queues, providing customers with a hassle-free experience that takes less than 10 seconds. It is available in four Portuguese pharmacies located in Braga, Barreiro, Loures, and Matosinhos.<sup>219</sup>
- **How it works:<sup>220</sup>**
  - **Advance orders:** Patients can order the products they need from a pharmacy in advance, eliminating the need to go to the pharmacy and wait in line to get their items. Currently, prescription medications are not available through this service, but there are plans to make them available in the future.
  - **Mobile notification:** Once the ordered products are ready for collection, patients receive a message on their mobile phone. This message also contains an authentication code.

<sup>218</sup> See generally Fielder, D., U. John Tanik, Cristiane Chaves Gattaz, Tanik, M.M. and Fuad Gattaz Sobrinho (2017). Mobile healthcare delivery: A dynamic environment where healthcare, mobile technology, engineering, and individual lifestyles converge. *IEEE*, pp.1–7. doi:<https://doi.org/10.1109/secon.2017.7925358>.

<sup>219</sup> Amado, I. (2021). Comprar e recolher medicamentos de um cacifo inteligente? Bloq.it e Glintt criam solução inovadora – Executive Digest. [online] Executive Digest. Available at: <https://executivedigest.sapo.pt/noticias/comprar-e-recolher-medicamentos-de-um-cacifo-inteligente-bloq-it-e-glintt-criam-solucao-inovadora/> [Accessed 7 Sep. 2023].

<sup>220</sup> Gama, L. (2023). Pharmacy Smart Lockers: The Future of Medication Dispensing. [online] Bloq.it. Available at: <https://bloq.it/future-of-pharmacies-with-pharmacy-smart-lockers/> [Accessed 7 Sep. 2023].

- **Collection:** With the authentication code, patients can go to the pharmacy and easily collect their products. There is no need to wait in queues, and it is a secure process.

#### 2.3.4.3 APPLICABILITY TO AUSTRALIA

##### What is the typical/ current approach in Australia?

- **Low smart locker adoption:** The extent to which lockers are used in Australia is unclear. My Parcel Locker, a leading specialist provider of electronic parcel lockers in Australia, has a medical locker project in Sir Charles Gairdner Hospital (Nedlands, Western Australia).<sup>221</sup> Beyond this, information on the use of lockers is limited.

##### What considerations affect whether this can be adopted/ scaled in Australia?

- **Public education** would be required to familiarise patients with smart lockers, their benefits and to teach how to use them.
- **The accessibility** of remote lockers, particularly in their ability to be installed in remote and regional areas,<sup>222</sup> means that the technology may be an appropriate tool to support remote or regional communities in Australia access pharmaceutical services. In this respect, parcel lockers have emerged as a reliable alternative to reduce the problems of home delivery services and support the receipt of goods in low-accessibility and low areas.<sup>223</sup> This related innovation-area additionally highlights the potential of remote lockers to similarly improve access to healthcare services in remote and regional areas.
- **Existing regulations and guidelines:** Facilitating the adoption and scaling of smart lockers may require government to review existing regulation e.g., the requirement that medicines be dispensed by pharmacists and medications be provided to patients outside of pharmacies in only a limited number of cases, including pharmacy unavailability, Aboriginal Health Services and in emergencies via the “doctor’s bag”.<sup>224</sup>

221 My Parcel Locker (n.d.). Medical. [online] My Parcel Locker. Available at: <https://myparcellocker.com/industries/medical/> [Accessed 7 Sep. 2023].

222 See, e.g., Blignaut, C. (2020). Large-scale rollout of smart lockers fast-tracked during coronavirus to ensure safe collection of chronic medication · MedPharm Publications. [online] MedPharm Publications. Available at: <https://medpharm.co.za/home-featured/large-scale-rollout-of-smart-lockers-fast-tracked-during-coronavirus-to-ensure-safe-collection-of-chronic-medication/> [Accessed 12 Sep. 2023].

223 Di Gangi, M., Polimeni, A. and Belcore, O.M. (2023). Freight Distribution in Small Islands: Integration between Naval Services and Parcel Lockers. Sustainability, [online] 15(9), p.7535. doi:<https://doi.org/10.3390/su15097535>.

224 Lim, D., Emery, J.D., Lewis, J. and Sunderland, V.B. (2011). Australian dispensing doctors' prescribing: quantitative and qualitative analysis. Medical Journal of Australia, 195(4), p. 174. doi:<https://doi.org/10.5694/j.1326-5377.2011.tb03272.x>; Department of Health (2017). PBS Pharmaceuticals in Hospitals Review Final Report. [online] The Pharmaceutical Benefits Scheme, p.100. Available at: <https://www.pbs.gov.au/info/reviews/pbs-pharmaceuticals-in-hospitals-review> [Accessed 7 Sep. 2023]; RACGP (2018). RACGP - Criterion GP5.3 – Doctor’s bag. [online] Racgp.org.au. Available at: <https://www.racgp.org.au/running-a-practice/practice-standards/standards-5th-edition/standards-for-general-practices-5th-ed/general-practice-standards/gp-standard-5/criterion-gp5-3-doctor-s-bag>.

### 2.3.5 Drone Delivery

**Figure 6: Drone manufactured to deliver medication to rural residents in Goondiwindi, Queensland<sup>225</sup>**



#### 2.3.5.1 INNOVATION DESCRIPTION

##### What is the innovation and how does it work?

- **Innovation overview:** Instead of in-person visits to collect medication, the delivery of pharmaceuticals by drone involves the use of unmanned aerial vehicles, commonly referred to as drones, to transport medications and pharmaceutical products directly to patients' home addresses, or between pharmacies. The innovation is particularly effective in remote geographies.<sup>226</sup>
- **How it works:** The mechanics of drone pharmaceutical delivery follows an established process:<sup>227</sup>
  - **Validation:** The process starts with a patient's prescription, which is received and validated by a pharmacy.
  - **Preparation:** The prescribed medication is prepared in secure packaging to maintain its integrity during transport.
  - **Dispatch:** The medication is loaded into a compartment within a delivery drone.
  - **Navigation:** The drone's GPS system is programmed with the coordinates of the delivery location.
  - **Delivery:** The drone lands at a pre-designated drop-off point. Access to the medication compartment may require authentication, such as a secure code or biometric verification, ensuring only authorised individuals can retrieve the medication.
  - **Monitoring:** Throughout the entire journey, both the pharmacy and the patient can track delivery in real-time, enhancing security and allowing for an immediate response in case of any anomalies.

225 LGAQ (2022). Drones deliver medication to rural residents in Goondiwindi. [online] LGAQ. Available at: <https://www.lgaq.asn.au/news/article/1281/drones-deliver-medication-to-rural-residents-in-goondiwindi> [Accessed 6 Sep. 2023].

226 Lin, C.A., Shah, K., Mauntel, L.C.C. and Shah, S.A. (2018). Drone delivery of medications: Review of the landscape and legal considerations. *American Journal of Health-System Pharmacy*, 75(3), pp.153–158. doi:<https://doi.org/10.2146/ajhp170196>.

227 Johnson, A.M., Cunningham, C.J., Arnold, E., Rosamond, W.D. and Zègre-Hemsey, J.K. (2021). Impact of Using Drones in Emergency Medicine: What Does the Future Hold? *Open Access Emergency Medicine*, Volume 13, pp.487–498. doi:<https://doi.org/10.2147/oaem.s247020>.

- **Return:** After successful delivery, the drone returns to base, ready for its next delivery.

### What benefits and/ or improvements does the innovation bring to vulnerable cohorts?<sup>228</sup>

- **Availability:** Drone-enabled pharmaceutical delivery ensures the rapid availability to medications and medical supplies and reduces wait times. This may be advantageous for people with disabilities, the elderly, and those in aged care who may have limited mobility or face challenges in traveling to pharmacies. Quick deliveries help them receive essential medications promptly, ensuring their health needs are met without unnecessary delays.
- **Access:** Drones can navigate difficult terrain, remote areas and regions with limited infrastructure. This may benefit vulnerable cohorts residing in remote or hard-to-reach locations by ensuring access to vital medical supplies and medications without the obstacles of challenging terrain or inadequate transportation options.
- **Adherence:** Drones can deliver medications to remote areas on schedule, improving patient adherence to treatment plans, which is particularly important for those managing chronic conditions. Moreover, vulnerable cohorts often rely on regular medication routines. Drone delivery ensures consistent and timely supply, aiding them in adhering to prescribed treatments and maintaining their overall health and well-being.

### How has government enabled this innovation?

- **Funding:** UK Research and Innovation (UKRI) has advanced drone delivery in Scotland through funding initiatives, e.g., the "Care and Equity – Healthcare Logistics UAS Scotland (CAELUS)" consortium, comprising NHS Scotland, airports, air traffic control and the University of Strathclyde. UKRI funding aims to establish a national drone network enhancing medical supply transport across Scotland, enabled by strategic landing stations at NHS sites, a comprehensive digital delivery network model and integration with air traffic control rules.<sup>229</sup>
- **Regulations:** In the US, the Government has enabled drone pharmaceutical delivery by gradually revising regulations. Specifically, the Federal Aviation Administration (FAA) initially imposed restrictive provisions on drone operations. However, over the past five years, the FAA has shown a willingness to relax some of these provisions, including by permitting autonomous drone operations while retaining remote pilot control.<sup>230</sup>

228 Hii, M.S.Y., Courtney, P. and Royall, P.G. (2019). An Evaluation of the Delivery of Medicines Using Drones. *Drones*, 3(3), p.52. doi:<https://doi.org/10.3390/drones3030052>.

229 Corporate Communications (2022). Next phase of project to develop UK's first medical delivery drone network launches | University of Strathclyde. [online] [www.strath.ac.uk](http://www.strath.ac.uk). Available at: <https://www.strath.ac.uk/whystrathclyde/news/2022/nextphaseofprojecttodevelopuksfirstmedicaldeliverydronenetworklaunches/>.

230 Ricci, J. (2022). No Drone Zones: Assessing the FAA's Role in Implementing Geofencing and the Future of Drone Regulations in the United States. *University of Illinois Journal of Law, Technology and Policy*, p. 161.

## What are the associated risks with this innovation and how could they be mitigated?<sup>231</sup>

- **Medication security:** The risk of unauthorised access to medications is a potential risk. To mitigate this, robust cybersecurity and strict access controls can protect the integrity of delivered medications.
- **Drone collision:** Congestion around depo sites can lead to accidents or failed deliveries. Mitigation includes airspace management (e.g., designated drone flight corridors, altitude restrictions and traffic management systems to prioritise medication delivery routes, monitoring and managing deviant drone behaviour, geofencing and signal jamming to prevent incursions into restricted areas), research into an Internet-of-Drones (infrastructure designed to provide control and access over the internet between users and drones).<sup>232</sup>
- **Technical failures:** Drone malfunctions or technical glitches in flight could result in accidents or failed deliveries. Adoption of the latest drone technology, regular maintenance and stringent quality control measures can reduce the risk of technical failures.

### 2.3.5.2 SPECIFIC INNOVATION CASE STUDY

#### Michigan Medicine and Zipline Partnership to Deliver Prescriptions<sup>233</sup>

#### Figure 7: Example drone developed by Zipline, capable of completing a 16-kilometre flight in about 10 minutes<sup>234</sup>



- **Overview:** In 2024, Michigan Medicine, the University of Michigan's academic medical centre, and Zipline, a company that designs, manufactures, and operates delivery drones, will introduce an autonomous drone-based home delivery service for prescription medicines to Washtenaw County residents.

<sup>231</sup> Emimi, M., Khaleel, M. and Alkrash, A. (2023) "The Current Opportunities and Challenges in Drone Technology", International Journal of Electrical Engineering and Sustainability (IJEES), 1(3), pp. 74–89 (esp. pp. 85-86). Available at: <https://ijeess.org/index.php/ijeess/article/view/47> [Accessed 14 Sep. 2023].

<sup>232</sup> Merkert, R. and Bushell, J. (2020). Managing the drone revolution: A systematic literature review into the current use of airborne drones and future strategic directions for their effective control. Journal of Air Transport Management, 89, p.101929. doi:<https://doi.org/10.1016/j.jairtraman.2020.101929>.

<sup>233</sup> Masson, M. (2023). Michigan Medicine to deploy Zipline's drone service for delivery of patient prescriptions | Michigan Medicine. [online] [www.michiganmedicine.org](https://www.michiganmedicine.org). Available at: <https://www.michiganmedicine.org/news-release/michigan-medicine-deploy-ziplines-drone-service-delivery-patient-prescriptions> [Accessed 6 Sep. 2023].

<sup>234</sup> Bonifacic, I. (2023). Next-generation Zipline P2 Zip drone comes with an adorable 'droid' sidekick. [online] Engadget. Available at: <https://www.engadget.com/next-generation-zipline-p2-zip-drone-comes-with-an-adorable-droid-sidekick-183238257.html> [Accessed 6 Sep. 2023].

- **How it works:** Michigan Medicine and Zipline's home drone delivery service ensures the safe and timely delivery of pharmaceutical products and medications in the following way:
  - **Loading:** Pharmaceutical products and medication are loaded into the autonomous electric drone. These medications are carefully packaged to maintain their integrity during transport.
  - **Planning:** Zipline's system plans the most efficient route for the drone to reach the patient's location.
  - **Flying:** The drone takes off autonomously from a number of docks stationed across the region. They can fly, almost silently, during the day or night and in various weather conditions, ensuring that patients receive their medications when needed.
  - **Tracking:** Patients and healthcare teams can track the drone's progress in real-time using the Zipline app or website. This provides peace of mind to patients waiting for their essential medications.
  - **Delivery:** The drone reaches the designated delivery location, which can be as small as a patio table, with ultraprecise accuracy to ensure that the pharmaceutical products are delivered intact and ready for use.
  - **Receipt:** The patient receives the pharmaceutical products and can immediately use the medications, following any instructions contained within the delivery package, to continue their treatment regimen.

### 2.3.5.3 APPLICABILITY TO AUSTRALIA

#### What is the typical/ current approach in Australia?

- **Nascent Drone Delivery:** In Australia, the delivery of pharmaceuticals by drones is still emerging. Currently, two drone delivery services are approved in Australia by the Civil Aviation Safety Authority (CASA). One is Wing Aviation Pty Ltd, which delivers supplies on-demand to customers who live in a 10 km radius from a base station, including over-the-counter pharmaceuticals, in North Canberra (ACT) and Logan (QLD). The other is Swoop Aero, which delivers medical supplies and equipment within a 60 km radius of the local airport in Goondiwindi (QLD).<sup>235</sup>
- **Trial Programmes:** In 2022, the Goondiwindi Region in Queensland became the first Australian community to trial medication deliveries to remote residents using autonomous drones. Supported by a partnership between Terry White Chemmart Goondiwindi, the Goondiwindi Regional Council, Swoop Aero and wholesaler Symbion (with funding from EBOS Group), this project involved the launch of pilot flights covering a 40 km radius from the Goondiwindi Aerodrome, aiming to bridge the gap in healthcare access for remote regions.<sup>236</sup>

<sup>235</sup> Wiedemann, M., Vij, A. and Banerjee, R., (2023). Validating the benefits of increased drone uptake for Australia: geographic, demographic and social insights. p.38.

<sup>236</sup> Goondiwindi Regional Council (2022). Goondiwindi Region is first regional place in Australia to deliver rural medications by drone. [online] Goondiwindi Regional Council. Available at: <https://www.grc.qld.gov.au/news/article/486/goondiwindi-region-is-first-regional-place-in-australia-to-deliver-rural-medications-by-drone> [Accessed 6 Sep. 2023].

### What considerations affect whether this can be adopted/ scaled in Australia?<sup>237</sup>

- **Technology advancement** may be required to facilitate safe and efficient large-scale drone operations. This includes enhanced battery life, obstacle detection and autonomous navigation.
- **Regulation** is potentially an enabler for the successful scaling of pharmaceutical drone delivery. The Civil Aviation Safety Authority (CASA) in Australia has exhibited a proactive stance by approving initial drone delivery services, approving two services to operate in North Canberra (ACT) and Logan (QLD), and Goondiwindi (QLD), respectively. Developing a regulatory framework that accommodates and promotes drone deliveries nationwide could enable its adoption, including by enforcing safety standards, establishing designated air corridors, implementing privacy and security protocols and encouraging the use of new technologies.
- **Infrastructure development** can facilitate the operation of large-scale drone networks. This involves establishing physical infrastructure, such as dedicated drone ports, charging stations, landing zones and air traffic management systems.
- **Stakeholder engagement** can support delivery drone use. Government bodies like CASA and health authorities must collaborate to establish regulations that balance safety, innovation, and the public interest. Industry players, including those from the aviation and pharmaceutical sectors, should partner with manufacturers and technology providers to drive advancements and adoption. Engaging the public through informative campaigns and open dialogues is crucial to building acceptance and trust for drone deliveries.

THIS DOCUMENT HAS BEEN RELEASED UNDER THE FREEDOM OF INFORMATION ACT BY THE DEPARTMENT OF HEALTH AND AGING

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<sup>237</sup> Wiedemann, M., Vij, A., Banerjee, R., O'Connor, A., Soetanto, D., Ardeshiri, A., V, A., Wittwer, G. and Sheard, N. (2023). *Validating the benefits of increased drone uptake for Australia: Geographic, demographic and social insights*. [online] Drones, pp.250–272. Available at: <https://www.drones.gov.au/sites/default/files/documents/validating-the-benefits-of-increased-drone-uptake-for-australia-final-report.pdf> [Accessed 14 Sep. 2023].

## 2.3.6 Physician Dispensing

**Figure 8: Physician Selecting Medication to Dispense to A Patient<sup>238</sup>**



### 2.3.6.1 INNOVATION DESCRIPTION

#### What is the innovation and how does it work?<sup>239</sup>

- **Innovation overview:** Physician dispensing refers to the practice of doctors directly supplying medicines to patients. In this model, physicians not only diagnose and prescribe treatments but also distribute the prescription medicine to patients at the same time, eliminating the need for patients to visit a separate pharmacy to fill their prescriptions.
- **How it works:** Though the process may vary between countries, physician dispensing generally adheres to the following pattern:
  - **Diagnosis and prescription:** The doctor assesses the patient's condition, diagnoses the issue and prescribes the necessary medicine.
  - **Patient education:** The doctor informs the patient about how to take the medicine, including potential side effects and any specific instructions.
  - **On-site dispensing:** Instead of giving the patient a prescription, the doctor provides the medicine directly to the patient, typically from their on-site stock or through automated dispensing systems. For repeat prescriptions, the patient can pick up the medication or have it delivered depending on the services available.
  - **Billing and Payment:** The cost of the medications and any related service fees is usually included in the patient's overall medical bill.

<sup>238</sup> Phipps, D., Ashour, A., Riste, L., Lewis, P. and Phipps, Ashcroft, D. (2020). Understanding dispensing errors and risk. [online] The Pharmaceutical Journal. Available at: <https://pharmaceutical-journal.com/article/ld/understanding-dispensing-errors-and-risk>.

<sup>239</sup> Grissinger, M. (2015). Good Intentions, Uncertain Outcomes: Physician Dispensing in Offices and Clinics. *Pharmacy and Therapeutics*, [online] 40(10), pp.620-25. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4606851/#:~:text=Opponents%20of%20physician%20dispensing%20cite> [Accessed 7 Sep. 2023].

## What benefits and/ or improvements does the innovation bring to vulnerable cohorts?

- **Benefits:** Direct dispensing by physicians can bring several potential benefits and improvements to vulnerable cohorts:<sup>240</sup>
  - **Adherence:** Promotes adherence to prescribed medication regimens by eliminating potential for patients not to get round to filling their prescriptions. This is valuable for the elderly or those with disabilities, as they may face difficulties in ensuring prescriptions are dispensed.
  - **Convenience:** Eliminates the need for patients, particularly those who may have mobility challenges or limited access to transportation, to make additional trips to a pharmacy. This means that individuals with disabilities, elderly patients and those residing in aged care facilities can access their prescribed medications without the added burden of travel, which can be particularly taxing for them.
  - **Cost:** Results in lower drug and overall treatment costs, as higher generic rates and reduced quantities have shown to result from physician dispensing. For individuals with disabilities, the elderly, and those in aged care facilities, cost-effective healthcare solutions are paramount. Direct physician dispensing contributes to this by reducing the financial burden associated with medication and treatment.

## What are the associated risks with this innovation and how could they be mitigated?

- Direct dispensing is not uncontroversial (e.g., there has been tension between dispensing doctor practices and community pharmacies concerning the quality and type of service that each provides) and there are several risks associated with the innovation:<sup>241</sup>
  - **Medication errors:** Mistakes in prescribing, such as selecting the wrong medication or incorrect dosing, may occur more frequently due to the absence of oversight provided by pharmacists double-checking the prescription. Such errors could lead to patient harm, adverse reactions or treatment inefficacy. This can be mitigated by implementing safety checks, such as electronic prescription systems and decision support software, into the prescribing process. Ongoing training and education on safe medication practices may also reduce the likelihood of medication errors.
  - **Overprescribing:** Physicians may be more inclined to prescribe medications when they also dispense them, potentially leading to overprescribing and a conflict of interest, in that their financial interests influence their prescribing decisions. For instance, the OECD has observed in relation to Switzerland that “perverse incentives remain in pharmaceutical distribution”.<sup>242</sup> Specifically, they noted that: “As efforts are made to re-orient pharmacy practice towards a focus on quality of care, policies in some cantons to allow doctors to dispense drugs continue to work against this – and create perverse incentives for over-prescription. While this is sometimes justified in terms of supporting health care in remote areas of Switzerland, it is likely the dispensing doctors make it more difficult for pharmacists

<sup>240</sup> Weiss, M.C., Grey, E., Harris, M. and Rodham, K. (2015). Dispensing doctor practices and community pharmacies: exploring the quality of pharmaceutical services. *Primary Health Care Research & Development*, 17(01), pp.42–55. doi:<https://doi.org/10.1017/s1463423615000092>.

<sup>241</sup> Grissinger, M. (2015). Good Intentions, Uncertain Outcomes: Physician Dispensing in Offices and Clinics. *Pharmacy and Therapeutics*, [online] 40(10), pp.620–695. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4606851/#:~:text=Opponents%20of%20physician%20dispensing%20cite> [Accessed 7 Sep. 2023].

<sup>242</sup> Ibid 134.

to develop a sustainable business model to serve remote areas.”<sup>243</sup> This may be mitigated by promoting clear prescribing guidelines and protocols that maintain patient-centred care and discourage overprescribing, encouraging physicians to conduct comprehensive medication reviews for patients with multiple medications and mandating continuing education on appropriate prescribing practices. Moreover, reducing the financial incentives for doctors to overprescribe, such as by limiting their compensation to indirect means (e.g., through increased patient traffic) may mitigate such risks.<sup>244</sup> Relatedly the AMA has said (written in the context of appropriate financial incentives for placing automated dispensing machines in GP practices): “The collocation of pathology collection centres in general practice could serve as a model for contractual arrangements which would ensure that no financial incentive was gained from prescribing. Under this model, a flat rate would be paid to the general practice for having a dispensing machine on site. Doctors or practices would not receive payments based on individual scripts.”<sup>245</sup>

- **Supply issues:** Physicians lack the resources and infrastructure needed to ensure a consistent and reliable supply of medications, unlike pharmacies which are well-equipped in managing medication inventories and have established supply chains. To mitigate this risk, physicians can explore collaborations with pharmaceutical wholesalers. They could also implement automated inventory management systems to help monitor medication stock levels, ensuring that necessary medications are consistently available to patients.

### How has government enabled this innovation?

#### ■ **Regulation:** Physician dispensing regulations differ between countries:

- **Switzerland:** In Switzerland, changes to regulations governing medication dispensing have expanded dispensing rights for general practitioners to most Swiss regions. Historically physician dispensing was limited to rural areas.<sup>246</sup>
- **United Kingdom:** In the UK, pharmaceutical services can be provided from community pharmacies as well as by dispensing doctor practices, without a pharmacy, in rural areas. Approximately 7% of all prescription items are dispensed by doctors.<sup>247</sup>
- **United States:** Physician dispensing is permitted in most states. However, it is often restricted to addressing immediate patient needs. Certain states mandate that physicians who dispense medications must hold licenses from or be registered with the Board of Pharmacy or acquire special permits for this practice.<sup>248</sup> The American Medical Association Code of Ethics emphasises that physicians can

243 Ibid 134.

244 See Kaiser, B. and Schmid, C. (2014). Does Physician Dispensing Increase Drug Expenditures? Empirical Evidence from Switzerland. *Health Economics*, 25(1), pp.71–90. doi:<https://doi.org/10.1002/hec.3124>.

245 Australian Medical Association (2021). The future of dispensing – ensuring Australians have affordable and accessible medicines into the future. [online] AMA, p.12. Available at: <https://www.ama.com.au/sites/default/files/2021-10/Future%20of%20Dispensing%20Discussion%20Paper.pdf> [Accessed 7 Sep. 2023].

246 Junod, V., Baud, C.-A., Schmitt-Koopmann, C., Devaud, J.-C., Bonnard, M., Pautex, S., Broers, B. and Simon, O. (2023). Why are we still using counterfoil prescription pads? | *Swiss Medical Weekly*. [online] smw.ch. Available at: <https://smw.ch/index.php/smw/announcement/view/60#:~:text=In%20most%20of%20the%20Swiss> [Accessed 7 Sep. 2023].

247 Dispens (n.d.). About Dispensing Practice. [online] DDA - Dispensing Doctors' Association. Available at: <https://www.dispensingdoctor.org/dispensing-practice/> [Accessed 7 Sep. 2023].

248 Grissinger, M. (2015). Good Intentions, Uncertain Outcomes: Physician Dispensing in Offices and Clinics. *Pharmacy and Therapeutics*, [online] 40(10), p. 620. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4606851/#:~:text=Opponents%20of%20physician%20dispensing%20cite> [Accessed 7 Sep. 2023].

dispense drugs within their office practices provided that such dispensing primarily benefits the patients.<sup>249</sup>

### 2.3.6.2 SPECIFIC INNOVATION CASE STUDY

#### Physician Dispensing in Switzerland

- **Overview:** In Switzerland, approximately 25% of pharmaceutical sales by value are attributed to self-dispensing doctors, while the remaining drug revenue is divided between pharmacies (approximately 50%) and hospitals (approximately 25%).
- **How it works:**<sup>250</sup>
  - **Dispensing:** In regions (called cantons) where physicians are permitted to dispense drugs, patients have two options for obtaining prescription medications. They can visit pharmacies with a valid prescription from a physician, or they can directly acquire prescription drugs from the physician's practice.
  - **Financials:** Both pharmacists and dispensing physicians generate profit from drug sales through mark-ups which are established by national regulation. Specifically, federal regulations determine the ex-factory prices and retail prices of all drugs covered by mandatory health care. The pharmaceuticals sold by a dispensing physician are priced at the retail cost plus a 2.5% value-added tax (VAT). This pricing structure allows the physician to achieve a gross profit margin equal to the gap between the retail price and the factory price.<sup>251</sup> Moreover, there is an additional basis for revenue which differs between pharmacists and physicians:<sup>252</sup>
    - **Pharmacist dispensing:** Pharmacist-dispensing accrues a lump-sum consultation fee, which depends on the quantity of drugs dispensed.
    - **Physician dispensing:** Physician-dispensing does not accrue a fee in itself. Instead, physicians charge for consultations, determined by a time-based, fee-for-service tariff.
  - **Special Licences:** In addition to the different ways in which pharmacists and physicians may generate income, the OECD has also noted that special licenses are required in 13 cantons (out of 26): “Only independent physicians with a special license accorded by cantons are allowed to dispense medication, in principle these are intended to be doctors operating in rural areas or in cantons with a relatively low number of pharmacies.”<sup>253</sup>

### 2.3.6.3 APPLICABILITY TO AUSTRALIA

#### What is the typical/ current approach in Australia?

- In Australia, medicines are dispensed by pharmacists, and medications are provided to patients outside of pharmacies in only a limited number of cases:

<sup>249</sup> The Code Says: The AMA Code of Medical Ethics' Opinions on the Sale and Dispensing of Health-Related Products. (2010). pp.925–7.

<sup>250</sup> Rachamin, Y., Meier, R., Valeri, F., Rosemann, T. and Muheim, L. (2021). Physician-dispensing as a determinant of clinical and process measurements in patients at increased cardiovascular risk: A cross-sectional study in Swiss general practice. *Health Policy*, 125(10), p. 1306. doi: <https://doi.org/10.1016/j.healthpol.2021.07.014>.

<sup>251</sup> Kaiser, B. and Schmid, C. (2014). Does Physician Dispensing Increase Drug Expenditures? Empirical Evidence from Switzerland. *Health Economics*, 25(1), p. 74. doi:<https://doi.org/10.1002/hec.3124>.

<sup>252</sup> Rachamin, Y., Meier, R., Valeri, F., Rosemann, T. and Muheim, L. (2021). Physician-dispensing as a determinant of clinical and process measurements in patients at increased cardiovascular risk: A cross-sectional study in Swiss general practice. *Health Policy*, 125(10), p. 1306. doi: <https://doi.org/10.1016/j.healthpol.2021.07.014>.

<sup>253</sup> OECD (2011). OECD Reviews of Health Systems: Switzerland 2011. [online] OECD Reviews of Health Systems, OECD, p.49. doi:<https://doi.org/10.1787/9789264120914-en>.

- **Pharmacy unavailability:** General practitioners are permitted to prescribe and dispense pharmaceuticals subsidised by the PBS only where there is no reasonable pharmacy coverage.<sup>254</sup> In practice, this applies to some 80 sites in rural and remote Australia.<sup>255</sup>
- **Aboriginal Health Services:** Under the Remote Area Aboriginal Health Services (RAAHS) Programme, Aboriginal Health Services in remote locations are permitted to supply medicines, without the need for a pharmacist to dispense.<sup>256</sup>
- **Doctor's bag:** In emergency situations, doctors can supply a limited quantity of medicines to patients via a "doctor's bag," providing these medications at no cost and including usage instructions.<sup>257</sup>

#### What considerations affect whether this can be adopted/ scaled in Australia?<sup>258</sup>

- **Physician training** could be an enabler in guaranteeing the competency and expertise of physicians involved in dispensing medicines. Mandatory and standardised specialised training and learning programmes can ensure that doctors remain up to date with the latest advancements, best practices in medication management and patient safety protocols.
- **Stakeholder engagement** involving medical associations, pharmacy organisations, patient advocacy groups, and regulatory bodies can foster consensus and collaboration in the implementation of physician dispensing.

254 Lim, D., Emery, J.D., Lewis, J. and Sunderland, V.B. (2011). Australian dispensing doctors' prescribing: quantitative and qualitative analysis. *Medical Journal of Australia*, 195(4), p. 174. doi:<https://doi.org/10.5694/j.1326-5377.2011.tb03272.x>.

255 Ibid 172.

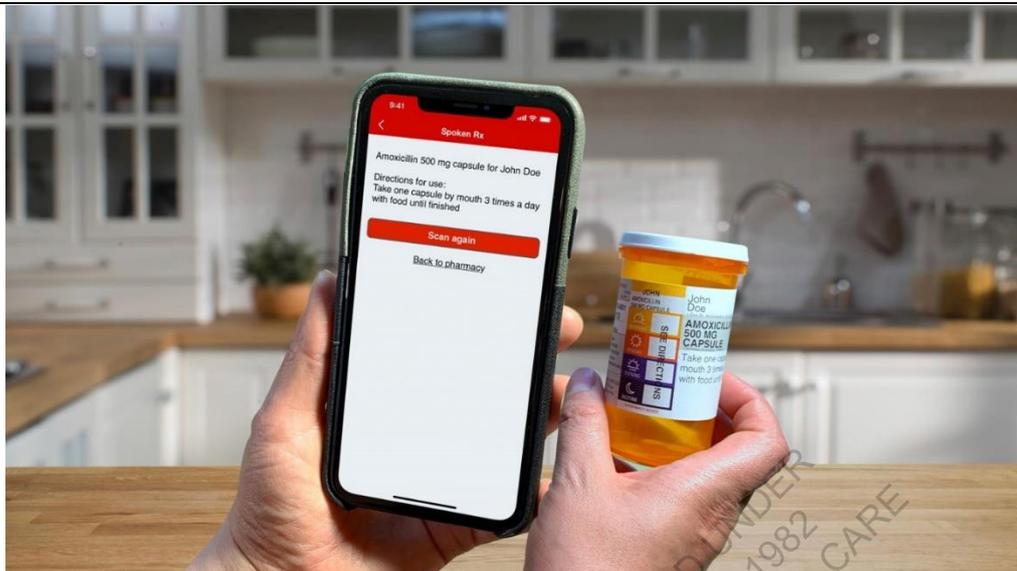
256 Department of Health (2017). PBS Pharmaceuticals in Hospitals Review Final Report. [online] The Pharmaceutical Benefits Scheme, p.100. Available at: <https://www.pbs.gov.au/info/reviews/pbs-pharmaceuticals-in-hospitals-review> [Accessed 7 Sep. 2023].

257 RACGP (2018). RACGP - Criterion GP5.3 – Doctor's bag. [online] [Racgp.org.au](https://www.racgp.org.au). Available at: <https://www.racgp.org.au/running-a-practice/practice-standards/standards-5th-edition/standards-for-general-practices-5th-ed/general-practice-standards/gp-standard-5/criterion-gp5-3-doctor-s-bag>; Health, A.G.D. of (n.d.). Pharmaceutical Benefits Scheme (PBS) | Prescriber Bag Supplies. [online] [www.pbs.gov.au](https://www.pbs.gov.au). Available at: <https://www.pbs.gov.au/browse/doctorsbag>.

258 See generally Lober, C.W., Behlmer, S.D., Penneys, N.S., Shupack, J.L. and Thiers, B.H. (1988). Physician drug dispensing. *Journal of The American Academy of Dermatology*, 19(5), pp.915–919. doi:[https://doi.org/10.1016/s0190-9622\(88\)70251-0](https://doi.org/10.1016/s0190-9622(88)70251-0).

## 2.3.7 Accessible Packaging

**Figure 9: CVS Pharmacy's Spoken Rx, The First In-App Prescription Reader to Be Developed by A National Retail Pharmacy<sup>259</sup>**



### 2.3.7.1 INNOVATION DESCRIPTION

#### What is the innovation and how does it work?

- **Innovation overview:** Accessible pharmaceutical packaging aims to make it easy for people, particularly vulnerable patients, to access and use pharmaceutical products safely and efficiently. This is a relatively recent phenomenon due to increased awareness of inclusivity, technological advancements, and a growing understanding of diverse healthcare needs, resulting in user-friendly packaging solutions emerging in recent years.<sup>260</sup>
- **How it works:** Accessible packaging features include:<sup>261</sup>
  - **Enhancing medication information access:**
    - **QR codes:** QR codes on the packaging that, when scanned with a smartphone or tablet, provide access to comprehensive medication information.
    - **Braille labels:** Braille script to medication labels, enabling visually impaired individuals to identify their medications independently by touch.
    - **Multi-language instructions:** Medication instructions in multiple languages to accommodate users from diverse linguistic backgrounds.
    - **Large PILs:** Provides comprehensive medication information in large-print Print Information Leaflets (PILs) for easy reading.

259 Blanchette, M. (2021). Spoken Rx 'Talking' Prescription Labels Now Available in All CVS Pharmacy Locations. [online] www.cvshealth.com. Available at: <https://www.cvshealth.com/news/innovation/spoken-rx-talking-prescription-labels-now-available-in-all-cvs.html> [Accessed 7 Sep. 2023].

260 Lorenzini, G. (2018). Toward Inclusive Pharmaceutical Packaging: An Innovation and Design Process Perspective. Lund University, [online] p.10. Available at: <https://portal.research.lu.se/en/publications/toward-inclusive-pharmaceutical-packaging-an-innovation-and-design> [Accessed 7 Sep. 2023].

261 Hughes, R., Carr, M., Walsh, M. and Hughes, A.C. author R. (2009). Improving patient safety: reducing medication errors through use of acceptable, accessible medicines packaging. [online] The Pharmaceutical Journal. Available at: <https://pharmaceutical-journal.com/article/research/improving-patient-safety-reducing-medication-errors-through-use-of-acceptable-accessible-medicines-packaging>.

- **Assisting with medical identification:**
  - **Tactile markings:** Raised or textured markings on the packaging to help individuals with tactile impairments distinguish between different medications through touch.
  - **Colour-coding:** Assigns consistent colours to medication categories, aiding quick identification.
- **Facilitating medication management:**
  - **Large, high-contrast text:** Information on the packaging in larger fonts and high-contrast colours for improved readability.
  - **Easy-to-open caps:** Caps with user-friendly features like ergonomic shapes or surfaces to facilitate easy opening for individuals with limited dexterity.
  - **Pill organisers/DAA:** Multi-compartment organisers, often with days of the week or dosing times labelled, to simplify medication management and ensure correct dosing. Similarly, Dose Administration Aids (DAAs) are devices which divide medications into individual doses and arranged into a dose schedule throughout the day.

### What benefits and/ or improvements does the innovation bring to vulnerable cohorts?<sup>262</sup>

- **Safety:** Ensures improved patient safety by reducing the risk of medication errors, ensuring correct dosing and providing critical information required to administer medication individually and as carers. This is especially beneficial to vulnerable populations, such as the elderly, visually impaired individuals, those with limited dexterity and non-native speakers, who are at a higher risk of medication-related errors and complications.
- **Independence:** Empowers people with disabilities and the elderly to open and use products on their own, reducing their reliance on others for everyday tasks and promoting self-sufficiency and dignity.
- **Literacy:** Enhances health literacy and ensures a clear understanding of medication by providing diverse individuals with easy access to information, facilitating identification and simplifying the management of their medications. This is especially beneficial to individuals with varying degrees of visual, tactile or cognitive impairments, as well as those from diverse linguistic backgrounds, promoting equitable access to essential medication information and usage.

### How has government enabled this innovation?

- Government regulations and standards have enabled accessible packaging.<sup>263</sup> For instance, in relation to Braille packaging:
  - **United Kingdom:** All medicines must have the name of the medicine displayed in Braille on the labelling.<sup>264</sup> Likewise, it has been mandatory since 2005 for Patient

<sup>262</sup> Lorenzini, G. (2018). Toward Inclusive Pharmaceutical Packaging: An Innovation and Design Process Perspective. Lund University, [online]. Available at: <https://portal.research.lu.se/en/publications/toward-inclusive-pharmaceutical-packaging-an-innovation-and-desig> [Accessed 7 Sep. 2023].

<sup>263</sup> In New Zealand, Arthritis New Zealand and Packaging New Zealand have worked in collaboration to promote accessibility guidelines for packaging, albeit related to food packaging: Fain, B., Arthritis New Zealand and Packaging New Zealand (2022). Food Packaging Design Accessibility Guidelines. [online] Arthritis New Zealand. Available at: [https://www.arthritis.org.nz/wp-content/uploads/2019/02/PAC\\_ArthritisGuidelines.pdf](https://www.arthritis.org.nz/wp-content/uploads/2019/02/PAC_ArthritisGuidelines.pdf) [Accessed 12 Sep. 2023].

<sup>264</sup> Medicines and Healthcare products Regulatory Agency (2014). Medicines: packaging, labelling and patient information leaflets. [online] GOV.UK. Available at: <https://www.gov.uk/guidance/medicines-packaging-labelling-and-patient-information-leaflets#braille-on-labelling-and-in-pils>.

Information Leaflets (PILs) to be available for blind and partially sighted patients.<sup>265</sup>

- **European Union:** Since 2005, all pharmaceutical packaging is required to carry Braille labelling. Specifically, the name of the product must be expressed in braille format on the packaging and PILs should be made available on request in appropriate formats.<sup>266</sup>
- **Canada and the USA:** In 2009, the International Association of Diecutting and Diemaking (IADD) introduced a new standard known as "Can-Am Braille." Closely mirroring the European Braille Standard, this standard serves as a broad directive for incorporating braille on pharmaceutical packaging within Canada and the United States. However, it is not mandatory North America.<sup>267</sup>

### What are the associated risks with this innovation and how could they be mitigated?

- **Accidental opening:** Accessible packaging designed for ease of use may also be prone to accidental opening, leading to potential misuse or exposure to children. To mitigate this risk, packaging could incorporate child-resistant features and comply with the child-resistant packaging requirements for medicines (e.g., TGO 95) while remaining user-friendly for those with disabilities.<sup>268</sup>

#### 2.3.7.2 SPECIFIC INNOVATION CASE STUDIES

##### CVS Pharmacy – Spoken Rx<sup>269</sup>

- **Overview:** Spoken Rx is an innovative in-app prescription reader introduced by CVS Pharmacy, a national retail pharmacy with nearly 10,000 locations across the United States. Developed in partnership with the American Council of the Blind, this audio prescription label solution is designed to assist individuals with visual impairments and those who cannot read standard print labels. It is available at no additional cost to patients and can be accessed through the CVS Pharmacy App, compatible with Voiceover for iOS, Siri, or Google Assistant on smartphones.
- **How it works:** Spoken Rx operates through a combination of technology and accessible design. It works in the following way:<sup>270</sup>
  - **RFID:** Each prescription container has a special RFID label affixed to the bottom.

<sup>265</sup> Medicines and Healthcare products Regulatory Agency (2014). Patient information leaflets for blind and partially-sighted patients. [online] GOV.UK. Available at: <https://www.gov.uk/government/publications/patient-information-leaflets-for-blind-and-partially-sighted-patients>.

<sup>266</sup> www.pharmabraille.com. (n.d.). Introduction to Pharmaceutical Braille – PharmaBraille. [online] Available at: <https://www.pharmabraille.com/pharmaceutical-braille/introduction-to-pharmaceutical-braille/>.

<sup>267</sup> Lim, B. (2020). The Current State of Braille on Packaging in Canada and Whether it Should Change. [online] p.6. Available at: <https://www.torontomu.ca/content/dam/gcm/images/Community/Thesis/2020/LIM-BRAILLE.pdf> [Accessed 1 May 2023]. See also Botta, M. (2017). Braille in Pharma: Differing Views in the U.S. and Europe. [online] Pharmaceutical Processing World. Available at: <https://www.pharmaceuticalprocessingworld.com/braille-in-pharma-differing-views-in-the-u-s-and-europe/>.

<sup>268</sup> Therapeutics Goods Australia (TGA) (2022). Child-resistant packaging requirements for medicines - Guidance on TGO 95. [online] Therapeutic Goods Administration (TGA). Available at: <https://www.tga.gov.au/resources/resource/guidance/child-resistant-packaging-requirements-medicines-guidance-tgo-95>.

<sup>269</sup> CVS Health (2021). *Spoken Rx 'Talking' Prescription Labels Now Available in All CVS Pharmacy Locations*. [online] www.cvshealth.com. Available at: <https://www.cvshealth.com/news/innovation/spoken-rx-talking-prescription-labels-now-available-in-all-cvs.html> [Accessed 14 Sep. 2023].

<sup>270</sup> CVS Health (2023). *Video tutorials showcase Spoken Rx, audible prescription solution by CVS Pharmacy*. [online] www.cvshealth.com. Available at: <https://www.cvshealth.com/news/pharmacy/spoken-rx-and-hadley-videos.html> [Accessed 14 Sep. 2023].

- **App:** Patients need to have the CVS Pharmacy App installed on their smartphones. This app is compatible with Voiceover for iOS and can be used with Siri or Google Assistant for Android devices.
- **Scanning:** To access the information on the prescription label, patients simply scan the RFID label using the Spoken Rx tab within the CVS Pharmacy App.
- **Playback:** Once the label is scanned, the app will read aloud important prescription details either in English or Spanish. This includes information like the patient's name, the name of the medication, and dosage instructions.
- **Accessibility:** For patients who may not have a smartphone, CVS Pharmacy offers a standalone speaker device that can also read the Spoken Rx labels.

**Figure 12: SimpleDose simplifies prescription medication by sorting, packing and delivery medications to patients' doors in easy-to-use sachets 271**



### SimpleDose – Online DAA Alternative to Webster-paks<sup>272</sup>

- **Overview:** SimpleDose, an Australian medication delivery service, is an innovative Dose Administration Aid service which offers a patient-friendly approach to medication management and markets itself as an alternative to Webster-paks. Relevantly, SimpleDose offers pre-packaged, labelled doses which are packaged based on the time of day the medication should be taken, simplifying medication management and reducing the risk of missed doses. It combines Webster-paks' convenience with online ordering, offering an efficient solution for patients taking multiple medications at varying times.
- **How it works:** SimpleDose offers convenient DAA services through a relatively simple online delivery process which works as follows:
  - **Transfer and set up:** SimpleDose assists in transferring prescriptions and setting up the service. They coordinate with doctors and the Pharmaceutical Benefits Scheme (PBS) to dispense prescriptions.

<sup>271</sup> SimpleDose (n.d.). How it Works. [online] SimpleDose. Available at: <https:simpledose.com.au/how-it-works/> [Accessed 12 Sep. 2023].

<sup>272</sup> SimpleDose (n.d.). *SimpleDose - Medication. Sorted.* [online] SimpleDose. Available at: <https://simpledose.com.au/> [Accessed 14 Sep. 2023].

- **Packaging:** Medication is packaged based on the time of day it should be taken. Each dose is contained in an easy-to-use, tear off sachet which is made of perforated plastic. This avoids the challenges sometimes associated with pushing medication out of blister packs. The precise way in which SimpleDose adheres to regulations regarding packaging is unclear. However, as SimpleDose operates as an online pharmacy, the assumption is that it is permissible for them to package medicines as typical pharmacists do.<sup>273</sup>
- **Delivery:** Every month, patients receive the required medication by home delivery which is available nationwide. Patients can also directly communicate with a SimpleDose pharmacist through their online pharmacy from 9am to 8pm AEST, 7 days a week. SimpleDose ensures timely deliveries by scheduling automatic repeats before patients run out of medication.
- **Doctor communication:** SimpleDose maintains open lines of communication with patients' doctors. They send patients a monthly medication list with detailed dose instructions, including images to help identify each pill. They also notify patients of any new prescriptions required and arrange assistance for emergency scripts if necessary.
- **Safety and monitoring:** A registered pharmacist checks every dose sachet for accuracy at multiple points in the process, every month. They also review patients' complete medication lists from their GPs whenever there is a change to identify and address any potential interactions. This ensures patients' medication management is both convenient and safe.

### 2.3.7.3 APPLICABILITY TO AUSTRALIA

#### What is the typical/ current approach in Australia?

- In Australia, the accessibility and inclusivity of packaging and labels is regulated through a combination of legislated mandatory requirements as well as recommendations and best practice:
  - **Mandatory requirements:** In 2016, the TGA introduced two new standards, referred to as TGO 91 and TGO 92, to make labels of prescription and non-prescription medicines clearer and safer to use.<sup>274</sup>
  - **National standards:** In July 2021, the Australian Commission on Safety and Quality in Health Care established a National Standard for Labelling Dispensed Medicines, providing guidance to ensure that all consumers can safely and effectively take their medications.<sup>275</sup> These include standards for dispensed medicine labels, such as using explicit and clear dosing instructions, and supporting strategies like using a standard sans serif font.<sup>276</sup>
- **Recommendations rather than mandatory:** At present, several features which promote accessibility are classified as recommendations and best practice, rather than as mandatory requirements, including colour contrast to ensure legibility of text, the use

<sup>273</sup> Ibid

<sup>274</sup> Therapeutics Goods Australia (TGA) (2022b). Medicine labels: Guidance on TGO 91 and TGO 92. [online] Therapeutic Goods Administration (TGA). Available at: <https://www.tga.gov.au/resources/resource/guidance/medicine-labels-guidance-tgo-91-and-tgo-92>.

<sup>275</sup> Pharmaceutical Society of Australia Ltd. (2022). Medicine Safety: Disability Care - Safer Medicines Use in People with Disability. [online] pp.48-9. Available at: <https://www.psa.org.au/advocacy/working-for-our-profession/medicine-safety/disability-care/> [Accessed 7 Sep. 2023].

<sup>276</sup> Australian Commission on Safety and Quality in Health Care (2021). National Standard for Labelling Dispensed Medicines. [online] Australian Commission on Safety and Quality in Health Care, pp.30, 45. Available at: <https://www.safetyandquality.gov.au/publications-and-resources/resource-library/national-standard-labelling-dispensed-medicines> [Accessed 7 Sep. 2023].

of braille and other languages, and QR codes.<sup>277</sup> To date, adoption and implementation of such guidelines has been limited.<sup>278</sup>

- Some Australian services and products exist:
  - **Our Pills Talk:** Our Pills Talk, a smartphone app, enables pharmacists to generate personalised QR barcodes on prescription labels and medication, enabling patients to scan them, which translates prescription information into speech, helps verify medication accuracy, sets reminders and stores comprehensive medication information, enhancing medication management and safety for patients. This QR code is not only affixed to medication but also printed on repeat prescription forms, supporting anyone who has difficulty reading labels (e.g., those who are visually impaired, dyslexic, autistic, the elderly, ESL (English-as-a-Second Language) patients and Aboriginal and Torres Strait Islander peoples).<sup>279</sup>
  - **Webster Packs:** Webster packs are multi-dose medication packs that help individuals take the right dose of their medications at the right time. They are one of the leading DAAs in Australia and are widely used, including in the residential Aged Care sector.<sup>280</sup> Webster packs are available in different varieties as well as to distinguish between different types of medications or dosage schedules. Additionally, Webstercare offers low vision packs and cytotoxic support products. They also have multi-lingual packs available in 21 different languages, with the days of the week and dosage times listed in the customer's native language. In 2020, Webstercare launched the first-ever Parkinson's 6 dose Webster-pak.<sup>281</sup>

#### What considerations affect whether this can be adopted/ scaled in Australia?

- **Affordability:** The affordability of accessible packaging solutions is a factor which may influence their adoption. If they are cost-effective or financial incentives are otherwise provided, pharmaceutical companies are more likely to invest in and adopt them, making them accessible to a wider population.
- **Consumer Education:** Elevating awareness and providing comprehensive education to patients and healthcare providers regarding the advantages of accessible packaging can play a pivotal role in stimulating demand and fostering widespread adoption.<sup>282</sup>
- **Stakeholder Collaboration:** Collaboration between pharmaceutical companies, government agencies and advocacy groups can streamline resources, regulatory support and consumer input to develop and promote accessible packaging solutions, ensuring they meet the needs of individuals with disabilities and gain wider adoption in Australia.

277 Therapeutics Goods Australia (TGA) (2022b). Medicine labels: Guidance on TGO 91 and TGO 92. [online] Therapeutic Goods Administration (TGA). Available at: <https://www.tga.gov.au/resources/resource/guidance/medicine-labels-guidance-tgo-91-and-tgo-92>.

278 Pharmaceutical Society of Australia Ltd. (2022). Medicine Safety: Disability Care - Safer Medicines Use in People with Disability. [online] p. 48. Available at: <https://www.psa.org.au/advocacy/working-for-our-profession/medicine-safety/disability-care/> [Accessed 7 Sep. 2023].

279 Ourpillstalk.com.au. (2018). Our Pills Talk | Our Pills Talk. [online] Available at: <https://ourpillstalk.com.au/> [Accessed 11 Sep. 2023].

280 Stevens, E. (2022). One Important Routine to Maintain During the Holiday Period. [online] Webstercare. Available at: <https://www.webstercare.com.au/one-important-routine-to-maintain-during-the-holiday-period/> [Accessed 12 Sep. 2023].

281 Webstercare (2020). Webster-pak® Community | Webstercare Medication Management. [online] Webstercare. Available at: <https://www.webstercare.com.au/product/webster-pak-community/> [Accessed 12 Sep. 2023].

282 See, e.g., Wunderman Thompson. (2022). Degree Inclusive. [online] Available at: <https://www.wundermanthompson.com/work/degree-inclusive>.

## 2.3.8 Smart Packaging

**Figure 10: Röchling Medical's Connect-E-Cap Records Fill Level, Provides Next Dose Reminders, Reads Out Information and Transmits Data to Doctors<sup>283</sup>**



### 2.3.8.1 INNOVATION DESCRIPTION

#### What is the innovation and how does it work?

- **Innovation overview:** Smart pharmaceutical packaging integrates advanced technologies such as sensors, electronics, indicators, and interactive elements into packaging.<sup>284</sup>
- **How it works:** There are three main types of smart packaging in pharmaceuticals and each works slightly differently:
  - **Active packaging** refers to incorporating technology that responds to factors like light, oxygen, and moisture to protect molecules and provide an alert if medication is spoiled, enhancing quality and shelf life.
  - **Intelligent packaging** involves the integration of indicators and sensors within or on the packaging to provide real-time information about the condition and use of the medicine, including dose tracking, medication reminders, and refill alerts.
  - **Connected packaging** integrates technologies like QR codes or RFID tags, enabling interaction between the packaging and external devices, like smartphones, to enhance patient experience and provide in-depth information about the product.<sup>285</sup>

<sup>283</sup> Röchling (n.d.). Connect-e-Cap | Röchling EN. [online] [www.roechling.com](http://www.roechling.com). Available at:

<https://www.roechling.com/medical/pharma/pharmaceutical-primary-packaging/connect-e-cap> [Accessed 7 Sep. 2023].

<sup>284</sup> Schaefer, D. and Cheung, W.M. (2018). Smart Packaging: Opportunities and Challenges. *Procedia CIRP*, 72, pp.1022–1027. doi: <https://doi.org/10.1016/j.procir.2018.03.240>.

<sup>285</sup> Rydzkowski, T., Wróblewska-Krepsztul, J., Thakur, V.K. and Królikowski, T. (2022). Current trends of intelligent, smart packagings in new medical applications. *Procedia Computer Science*, [online] 207, pp.1271–1282. doi:<https://doi.org/10.1016/j.procs.2022.09.183>.

## What benefits and/ or improvements does the innovation bring to vulnerable cohorts?<sup>286</sup>

- **Adherence:** Smart packaging can incorporate electronic reminders and notifications to help individuals remember to take their medications on time. This feature is especially valuable for vulnerable populations, such as the elderly and those with disabilities, who may encounter challenges with memory or managing complex medication regimens. It may also offer an additional way for carers to ensure their patients are adhering to their medication schedules, including through notification.
- **Safety:** Smart packaging can ensure accurate dosing by dispensing the right amount of medication each time, reducing the risk of over- or under-dosing, eliminating human error, tailoring dosing regimens and reducing overall health risks. This is crucial for people managing polypharmacy as well as people with disabilities who have unique and precise health needs that often demand strict medication management.
- **Literacy:** Smart packaging can display medication instructions and vital information on a built-in screen, making it easier for individuals with limited health literacy to understand how to take their medications correctly.

## How has government enabled this innovation?

- **Limited enablement:** To date, governments have played a relatively minor role in driving innovation in pharmaceutical smart packaging. The UK, Canadian and New Zealand Governments have not created any specific regulations specifically governing pharmaceutical smart packaging.
- **Industry advancements:** Instead, the impetus for smart pharmaceutical packaging innovation has emerged from the industry itself and is a result, in large part, of numerous technological advancements, including breakthroughs in materials science, automation, data analytics, and connectivity solutions.<sup>287</sup>

## What are the associated risks with this innovation and how could they be mitigated?

- **Data privacy:** Smart pharmaceutical packaging may involve collecting and transmitting sensitive patient data, potentially leading to privacy breaches if not adequately protected. To mitigate this risk, pharmaceutical companies can implement encryption, secure data transmission protocols and conduct regular security audits and updates.
- **Technical malfunctions:** Electronic components in smart packaging can fail or malfunction, leading to inaccurate medication information or missed dosages. To mitigate this risk, rigorous quality control and testing of electronic components can be used.
- **Technology overdependence:** Patients may become overly reliant on smart packaging to manage their medications, which can be problematic if the technology fails or if patients neglect other aspects of their healthcare. To mitigate this risk, pharmaceutical companies can encourage patients to view smart packaging as an aid rather than a replacement for responsible medication management. This may include

<sup>286</sup> Bender, B., Chrystyn, H. and Vrijens, B. (2017). Smart Pharmaceuticals. In: C. Thuemmler and C. Bai, eds., Health 4.0: How Virtualization and Big Data are Revolutionizing Healthcare. Springer, pp.61–90.

<sup>287</sup> For an overview of 28 innovations in pill boxes, see, e.g., McQuarrie, L. (2014). 28 Inventive Pill Boxes. [online] TrendHunter.com. Available at: <https://www.trendhunter.com/slideshow/pill-boxes> [Accessed 12 Sep. 2023].

providing educational materials and support to ensure patients understand the importance of their active involvement in their healthcare beyond the technology.

- **Costs:** Developing and implementing smart pharmaceutical packaging can be expensive, potentially increasing the overall cost of medications. To mitigate this risk, regulators and pharmaceutical companies can explore cost-effective solutions while maintaining quality.

### 2.3.8.2 SPECIFIC INNOVATION CASE STUDY

**Figure 11: August Faller's "Medical Prescription" Smart Packaging Syncs with An App Via Bluetooth for Medication Management<sup>288</sup>**



### August Faller Smart Pharmaceutical Packaging Prototypes

- **Overview:** In 2019, August Faller, a German manufacturer and system supplier of pharmaceutical secondary packaging, launched three promising smart packaging prototypes. These showcase the integration of technology and pharmaceutical packaging to enhance patient compliance, medication management, and safety.<sup>289</sup>
- **How it works:** The three products have different features and work in different ways:<sup>290</sup>
  - **Counting device folding carton:** This smart packaging enhances medication adherence by incorporating an e-paper display and user-friendly buttons. Patients can easily confirm their tablet intake and receive low supply alerts, due to its innovative system powered by a microcontroller and battery.
  - **Fill level indicator carton:** Designed for liquid medication, this smart packaging simplifies the dosing process. It features an e-paper display and user-accessible

288 Faller Packaging (n.d.). Smart Packaging Solutions – Faller Packaging. [online] [www.faller-packaging.com](http://www.faller-packaging.com). Available at: <https://www.faller-packaging.com/en/innovations-and-solutions/smart-packaging/smart-packaging-solutions#:~:text=Folding%20Carton%20with%20digital%20connection%20to%20App%20via%20Bluetooth&text=The%20innovative%20packaging%20solution%2C%20which> [Accessed 7 Sep. 2023].

289 Forcinio, H. (2019). Smarter Packaging Comes to the Pharma Market. *Pharmaceutical Technology*, [online] 43(1), pp.52–5452–54. Available at: <https://www.pharmtech.com/view/smarter-packaging-comes-pharma-market>.

290 Faller Packaging (n.d.). Smart Packaging Solutions – Faller Packaging. [online] [www.faller-packaging.com](http://www.faller-packaging.com). Available at: <https://www.faller-packaging.com/en/innovations-and-solutions/smart-packaging/smart-packaging-solutions>.

buttons to check the remaining liquid. Moreover, it includes a clock, LED indicators, and sound signals to provide timely reminders for patients.

- **Medical prescription carton:** Using Bluetooth connectivity, this advanced smart packaging allows doctors and pharmacists to transmit personalised dosage instructions directly to the carton. Patients benefit from timely dosing reminders, LED indicators, sound prompts, and alerts to reorder prescriptions when the supply is low. This seamless communication improves medication adherence and healthcare outcomes.

### 2.3.8.3 APPLICABILITY TO AUSTRALIA

#### What is the typical/ current approach in Australia?

- **Limited smart packaging adoption:** In Australia, information on the degree of adoption of smart packaging for medication is limited. Instead, such packaging typically follows traditional forms, such as blister packs and standard pill bottles, with limited integration of advanced technologies or interactive features.

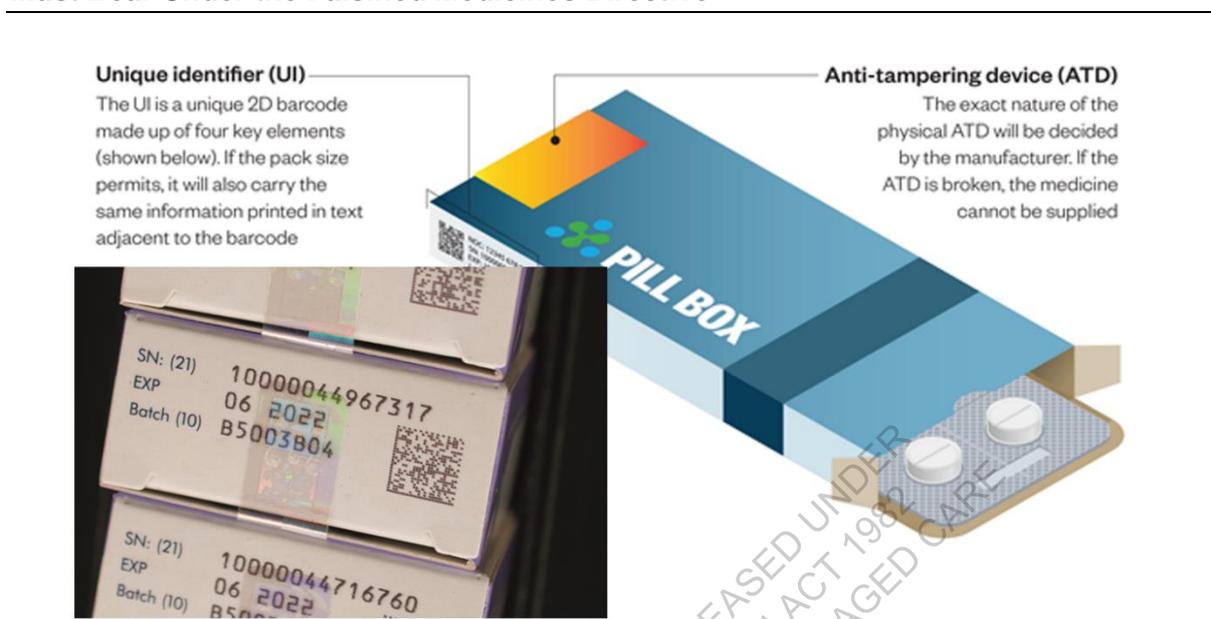
#### What considerations affect whether this can be adopted/ scaled in Australia?

- **Increased production and distribution costs** associated with smart pharmaceutical packaging can influence its widespread adoption. The pharmaceutical industry in Australia, like many others, operates within a competitive marketplace where cost-efficiency is an important consideration. Assessing whether the benefits of enhanced safety and monitoring capabilities justify the potential increase in medication prices for consumers and across the sector is likely an important consideration. Furthermore, not all medications are equally susceptible to tampering or degradation during transit and storage. Therefore, a nuanced approach to smart packaging adoption may be required, considering the specific needs and risk profiles of different pharmaceutical products.<sup>291</sup>
- **Patient education** can play a role in the successful adoption of smart pharmaceutical packaging. Ensuring that patients, including vulnerable cohorts and older populations are well-informed about the benefits and usage of these technologies can facilitate their acceptance and effective utilisation.

<sup>291</sup> See, e.g., Madhusudan, P., Chellukuri, N. and Shivakumar, N. (2018). Smart packaging of food for the 21st century – A review with futuristic trends, their feasibility and economics. *Materials Today: Proceedings*, [online] 5(10, Part 1), pp.21020, 21022. doi:<https://doi.org/10.1016/j.matpr.2018.06.494>.

### 2.3.9 Anti-Counterfeit Packaging

**Figure 13: Diagram of The Two Mandatory Safety Features Which All New Packs of Prescription Medicines Placed on The Market in Europe from February 2019 Onwards Must Bear Under the Falsified Medicines Directive<sup>292</sup>**



#### 2.3.9.1 INNOVATION DESCRIPTION

##### What is the innovation and how does it work?<sup>293</sup>

- **Innovation overview:** The pharmaceutical industry has a history of employing anti-counterfeit packaging measures. Nevertheless, with the rise in the sophistication of counterfeit operations and the prevalence of online markets, it has become increasingly important to introduce advanced anti-counterfeit technologies in pharmaceutical packaging. These innovations are designed to bolster security and reduce susceptibility to counterfeiting, addressing the evolving challenges posed by counterfeit drugs in today's market.
- **How it works:** Sophisticated anti-counterfeit packaging employs various methods and technologies to ensure the safety and authenticity of pharmaceutical products, including:<sup>294</sup>
  - **RFID and NFC Technology:** Medication packaging incorporates Radio Frequency Identification (RFID) or Near-Field Communication (NFC) tags. Scanning these tags provides real-time information about the medication, including its origin and expiration date, ensuring consumers receive genuine products.
  - **Blockchain Solutions:** Blockchain creates an unalterable ledger of a medication's journey from the manufacturer to the consumer. This tamper-proof record ensures

292 NHS Digital. (2022). Falsified Medicines Directive implementation toolkits. [online] Available at: <https://digital.nhs.uk/services/falsified-medicines-directive-fmd>.

293 Smith, D. (2023). How Packaging & Technology Support Anti-counterfeiting in Pharma. [online] Amcor.com. Available at: <https://www.amcor.com/insights/blogs/tamper-proof-pharma-packaging> [Accessed 7 Sep. 2023].

294:// Marks & Clerk - Megan Rannard (2023). Anti-counterfeit packaging - another line of defence. [online] Lexology. Available at: <http://www.lexology.com/library/detail.aspx?g=1d4a8ef6-ee1a-4a56-b6f1-dd8918b99cc4> [Accessed 7 Sep. 2023].

the integrity of the product and provides transparent traceability, reducing the risk of counterfeit drugs entering the supply chain.<sup>295</sup>

- **Micro-Text:** Tiny, difficult-to-replicate text or patterns are embedded in pharmaceutical packaging. Magnification tools allow pharmacists and consumers to verify the presence of these microscopic features, confirming the product's authenticity.
- **Invisible Signatures:** Invisible or cryptographic signatures are embedded during the packaging process. Using a mobile app, consumers can scan the product to verify its authenticity instantly.

### What benefits and/ or improvements does the innovation bring to vulnerable cohorts?

- **Safety:** Ensure that vulnerable populations receive genuine medications, reducing the risk of harm or adverse health effects from counterfeit or substandard drugs.
- **Adherence:** Authentic medications obtained through anti-counterfeit measures lead to better health outcomes for those with chronic illnesses, as consistent treatment is crucial for their well-being.
- **Cost:** Vulnerable individuals are protected from financial exploitation by ensuring they purchase only genuine, effective medications, avoiding the risks associated with counterfeit drug sellers and products.

### How has government enabled this innovation?

- **Regulation:** Some governments have introduced new packaging regulations aimed at ensuring the authenticity and safety of medications in the market:
  - **Europe:** In 2019, the EU introduced the Falsified Medicines Directive (FMD) to fight medicine falsifications and ensure that medicines are safe.<sup>296</sup> Relevant packaging measures included new obligatory safety and authenticity features, such as a unique identifier and an anti-tampering device – on the outer packaging of designated medicines (see Figure 1 above).<sup>297</sup>
  - **United States:** In 2013, the United implemented the Drug Supply Chain Security Act (DSCSA) to prevent the circulation of counterfeit medications.<sup>298</sup> In order to identify and track prescription drugs when they are dispensed in the USA, the Act outlines how to implement electronic tracing that is compatible at the packaging level. By November 2023, it was held that every stakeholder in the distribution of prescription drugs in America, from manufacturers to dispensers, must have bought into and implemented a system giving electronic traceability of each drug package.<sup>299</sup>

295 See, e.g., Rajora, N. (2023). Pharmaceutical Drug Traceability by Blockchain and IoT in Enterprise Systems. *Universal Journal of Pharmacy and Pharmacology*, [online] pp.11–18. Available at: <https://www.scipublications.com/journal/index.php/ujpp/article/view/749> [Accessed 7 Sep. 2023].

296 European Commission Public Health (2023). Falsified medicines. [online] [health.ec.europa.eu](https://health.ec.europa.eu/medicinal-products/falsified-medicines_en#:~:text=Legal%20framework%20%E2%80%93%20The%20Falsified%20Medicines%20Directive). Available at: [https://health.ec.europa.eu/medicinal-products/falsified-medicines\\_en#:~:text=Legal%20framework%20%E2%80%93%20The%20Falsified%20Medicines%20Directive](https://health.ec.europa.eu/medicinal-products/falsified-medicines_en#:~:text=Legal%20framework%20%E2%80%93%20The%20Falsified%20Medicines%20Directive) [Accessed 7 Sep. 2023].

297 Kent, C. (2020). Fraudulent pharmaceuticals: the legacy of anti-counterfeit packaging. [online] *Pharmaceutical Technology*. Available at: <https://www.pharmaceutical-technology.com/features/anti-counterfeit-packaging-pharma/?cf-view> [Accessed 7 Sep. 2023].

298 Pathak, R., Gaur, V., Himanshu Sankrityayan and Jaideep Gogtay (2023). Tackling Counterfeit Drugs: The Challenges and Possibilities. *Pharmaceutical Medicine*, [online] p.286. doi: <https://doi.org/10.1007/s40290-023-00468-w>.

299 Le, P.C.N.S., Grund, L., Marwa, J., Otts, J., Ojo, W. and Arab, F. (2018). Combating Substandard and Counterfeit Medicines by Securing the Pharmaceutical Supply Chain: INNOVATIONS in Pharmacy, 9(2), p.13. doi: <https://doi.org/10.24926/iip.v9i2.966>.

## What are the associated risks with this innovation and how could they be mitigated?

- **Technology Vulnerabilities:** Despite technological advancements, anti-counterfeiting packaging is not foolproof and can be vulnerable to duplication or hacking. Pharmaceutical companies should continuously invest in research and development to stay ahead of counterfeiters by adopting cutting-edge security measures. Regularly updating and improving these technologies can make it more challenging for counterfeiters to replicate them. Collaboration with technology experts and government agencies may also address emerging threats.
- **Supply Chain Weaknesses:** The pharmaceutical supply chain is complex and involves multiple stakeholders, making it susceptible to breaches. Weak links in the supply chain, such as unauthorised distributors or tampering during transit, can compromise the integrity of pharmaceuticals. To mitigate this risk, companies should establish robust supply chain monitoring systems, conduct thorough due diligence when selecting partners, and implement tamper-evident packaging solutions. Enhanced communication and coordination between all participants in the supply chain can help identify vulnerabilities and strengthen security measures.

### 2.3.9.2 SPECIFIC INNOVATION CASE STUDY

#### Bayer HealthCare – AccessReal patented label<sup>300</sup>

- **Overview:** Bayer, a German multinational pharmaceutical company, adopted AccessReal as a solution to combat grey market issues – that is, when unapproved resellers trade products without the brand owner's consent – and counterfeiting. This innovation introduces a patented clone-proof identification label called ARcode for each product, providing a unique identity with serialisation and encryption protection, which distributors, retailers and consumers can personally authenticate using their smartphones.
- **How it works:** To ensure anti-counterfeiting measures, AccessReal operates in the following way:
  - **ARcode Label:** AccessReal introduces a patented ARcode label for each product in Bayer's portfolio. This label is clone-proof and comes with serialisation and encryption protection, making it extremely difficult for counterfeiters to replicate.
  - **Swift Verification:** When distributors and retailers receive Bayer products, they can swiftly verify their authenticity by scanning the ARcode label. This eliminates the need for labour-intensive manual cut-outs (the process of physically cutting out a portion of packaging for verification purposes). Likewise, end-consumers can personally authenticate Bayer products using their smartphones. This feature provides an additional layer of security and trust, allowing customers to confirm the authenticity of their purchases in real-time.

### 2.3.9.3 APPLICABILITY TO AUSTRALIA

#### What is the typical/ current approach in Australia?

- **Strong Existing Protections:** Australia has relatively strong legislation, governance and customs that control the risks of falsified or substandard drugs. For instance, when counterfeit and illegal medications are identified, the TGA issues advisories and safety

300 GS1 Singapore (2023). Strengthening Pharmaceutical Security: How Bayer Utilised AccessReal to Combat Grey Market Activity and Counterfeiting. [online] [www.gs1.org.sg](https://www.gs1.org.sg). Available at: <https://www.gs1.org.sg/SolutionPartners/Articles/strengthening-pharmaceutical-security-how-bayer-utilised-accessreal-to-combat-grey-market-activity-and-counterfeiting-#:~:text=The%20clone%2Dproof%20identification%20label> [Accessed 7 Sep. 2023].

alerts.<sup>301</sup> Moreover, since 2003 the TGA has regulated the design, selection and use of tamper-evident packaging for therapeutic goods with its Code of Practice. Although the code is not mandatory, it has been established as a condition for membership for some industry associations.<sup>302</sup>

- **Continued Vigilance Required:** Aided by such comprehensive controls, the prevalence of counterfeit medications is low in Australia.<sup>303</sup> Nevertheless, in an era when pharmaceutical products are becoming increasingly globalised and more readily available for purchase online, ensuring its control, regulation and quality assurances are effective could be a consideration important. Above all, this can mean continuously incorporating and allowing new innovations and best practice anti-counterfeiting technologies to stay ahead of evolving threats and to maintain the safety and integrity of the pharmaceutical supply chain.<sup>304</sup>

#### What considerations affect whether this can be adopted/ scaled in Australia?

- Several considerations may affect the adoption and scaling of innovative anti-counterfeit pharmaceutical packaging in Australia. These include:
  - **Patient affordability:** Balancing the effectiveness of the anti-counterfeit packaging solution with the cost and affordability of medication may enable widespread use.
  - **Research and development:** Investing in research and development efforts aimed at discovering innovative sustainable packaging solutions can enhance the extent to which the pharmacy sector adopts the innovation.
  - **Stakeholder engagement:** Educating healthcare professionals, pharmacists, and consumers about the new packaging features and how to use them for medication verification can support successful implementation and trust-building.

301 TGA (2022). Alerts. [online] Therapeutic Goods Administration (TGA). Available at: <https://www.tga.gov.au/resources/resource/guidance/alerts> [Accessed 7 Sep. 2023].

302 TGA (2022b). Code of practice for tamper-evident packaging of therapeutic goods. [online] Therapeutic Goods Administration (TGA). Available at: <https://www.tga.gov.au/resources/resource/guidance/code-practice-tamper-evident-packaging-therapeutic-goods> [Accessed 7 Sep. 2023].

303 Hensey, C.C. and Gwee, A. (2016). Counterfeit drugs: an Australian perspective. *Medical Journal of Australia*, [online] 204(9), pp.344–344. doi: <https://doi.org/10.5694/mja16.00105>.

304 Ibid.

### 2.3.10 Sustainable Packaging

**Figure 14: Amgen Redesigned Its Neulasta® Onpro® Kit, Resulting In 32% Less Paperboard, 68% Less Plastic, 50% Reduction in Carton Closure Material Usage, And 33% More Kits on A Pallet<sup>305</sup>**



#### 2.3.10.1 INNOVATION DESCRIPTION

##### What is the innovation and how does it work?<sup>306</sup>

- **Innovation overview:** Sustainable pharmaceutical packaging minimises the environmental impact of pharmaceutical products throughout their lifecycle. It seeks to balance the critical functions of pharmaceutical packaging with environmental and social considerations.
- **How it works:**
  - **Material selection:** Choosing eco-friendly materials, such as recyclable or biodegradable plastics like polyethylene terephthalate or high-density polyethylene, plant-based packaging made of corn, maize, bagasse, sugarcane, bamboo, mushroom or seaweed, and pulp packaging.<sup>307</sup>
  - **Reducing packaging:** Optimising packaging design to use only necessary materials and reducing excess packaging.
  - **Energy efficiency:** Sourcing materials locally or optimising transportation routes to reduce greenhouse gas emissions associated with manufacturing and transportation.
  - **Safe disposal:** Disposing or recycling of packaging safely and properly, including by building public awareness about how to dispose of medications.

<sup>305</sup> Amgen (n.d.). A Smaller Environmental Footprint for Neulasta® Onpro® Kit. [online] Amgen, Inc. Available at: <https://www.amgen.com/responsibility/healthy-planet/environmental-sustainability/case-studies/neulasta-packaging-footprint-reduction#:~:text=The%20packaging%20now%20uses%2032> [Accessed 7 Sep. 2023].

<sup>306</sup> Milanese, M., Runfola, A. and Guercini, S. (2020). Pharmaceutical industry riding the wave of sustainability: Review and opportunities for future research. *Journal of Cleaner Production*, [online] 261, p.7. doi:<https://doi.org/10.1016/j.jclepro.2020.121204>.

<sup>307</sup> Karim-Nejad, L. and Pangilinan, K. (2022). How Should Responsibility for Proper Medication Disposal Be Shared? *AMA Journal of Ethics*, [online] 24(10), pp.971–979. doi:<https://doi.org/10.1001/amajethics.2022.971>.

## What benefits and/ or improvements does the innovation bring to vulnerable cohorts?

- The benefits of sustainable packaging to vulnerable cohorts are not as direct as with other innovations. However, there is one improvement which indirectly supports such groups:
  - **Cost:** Sustainable packaging solutions can sometimes be more cost-effective. For low-income individuals and communities, this can translate into savings on the products they purchase, as well as reduced waste disposal costs.<sup>308</sup>
- **Relevance to other innovations in this report:** More broadly, sustainable packaging can be incorporated into the innovations outlined in this report in various ways to reduce the use of plastics and other non-biodegradable materials, minimise waste and promote environmental sustainability:
  - **Online pharmacies:** Online pharmacies can incorporate sustainable packaging by using materials that are recyclable or biodegradable. For example, OptumRx has introduced fully sustainable medication packaging for medication home delivery made from 100% renewable cotton which is biodegradable, compostable, reusable and recyclable to replace polystyrene or foam.<sup>309</sup>
  - **Drone delivery:** Drone delivery presents some challenges when it comes to sustainable packaging, as the packaging needs to be lightweight and durable enough to withstand the rigours of transportation. However, sustainable packaging options do exist, such as biodegradable foam or paper-based materials. For example, Dronehop, a food, grocery and medical drone delivery service in the UAE, uses biodegradable packaging to allow consumers to shop with minimal harm for the environment.<sup>310</sup>
  - **Medication synchronisation:** Medication synchronisation can adopt sustainable packaging by using materials that are easy to open and close, and that can be reused or recycled. For example, Metsäboard, a European paperboard mills company, developed the Metsäboard Pro FBB Bright, a lightweight board which reduces material usage and results in cost savings, for Medicine-On-Time to use as part of its provision of medication synchronisation solutions in a sustainable manner.<sup>311</sup>
  - **Smart lockers:** Sustainable packaging could be incorporated into smart lockers by using materials that are recyclable or biodegradable, and by encouraging patients to recycle their packaging after use. For example, while there are currently no specific examples of sustainable packaging being incorporated into smart pharmaceutical lockers, SwipBox, a Danish developer of parcel locker solutions, has announced its ambition to develop a solution where consumers receive their orders in reusable, chip-labelled boxes. Once they have collected their goods, they can simply return the box to the locker, where it will be automatically returned to the

308 Nordin, N. and Selke, S. (2010). Social aspect of sustainable packaging. *Packaging Technology and Science*, 23(6), pp.317–326. doi:<https://doi.org/10.1002/pts.899>.

309 Statham, J. (2018). OptumRx Introduces 100% Sustainable Packaging for Medication Home Delivery. [online] [www.businesswire.com](http://www.businesswire.com). Available at: <https://www.businesswire.com/news/home/20180816005071/en/OptumRx-Introduces-100-Sustainable-Packaging-for-Medication-Home-Delivery> [Accessed 11 Sep. 2023].

310 Dronehop (n.d.). How it Works. [online] [www.dronehop.tech](http://www.dronehop.tech). Available at: <https://www.dronehop.tech/how-it-works> [Accessed 11 Sep. 2023].

311 Metsä (2019). Medicine-On-Time Success Story. [online] [www.metsagroup.com](http://www.metsagroup.com). Available at: <https://www.metsagroup.com/metsaboard/news-and-publications/articles/medicine-on-time-success-story/> [Accessed 11 Sep. 2023].

sender or the next company in need of it, reducing waste and promoting sustainability.<sup>312</sup>

- **Remote kiosks:** Remote kiosks could incorporate sustainable packaging by using recyclable or biodegradable materials in the packaging and dispensing process. While there are currently no examples of this practice in the sector, it presents an opportunity for the pharmaceutical industry to reduce waste and promote environmental sustainability.
- **Physician dispensing:** There is potential for the use of reusable or recyclable materials, including in dose administration aids, although there are no examples of sustainability being incorporated into doctors dispensing medications directly to their patients.
- **Smart, accessible and anti-counterfeit packaging:** Sustainable packaging could be incorporated into these processes by using materials that are recyclable or biodegradable, and by designing the packaging to be easily disassembled for recycling. They could likewise be designed to be easily identifiable as recyclable to encourage proper disposal.<sup>313</sup>

### How has government enabled this innovation?

- **Regulation:** Government has facilitated the adoption of sustainable packaging by implementing comprehensive legislative and regulatory reforms, including packaging:
  - **Europe:** In November 2022, the European Commission introduced a draft proposal on packaging and waste.<sup>314</sup> This proposal will replace the existing Packaging and Packaging Waste Directive (PPWD) with a new regulation that directly applies to all Member States and includes all packaging materials placed on the Union market. This impacts pharmaceutical packaging, among other categories, in the following ways:<sup>315</sup>
    - **Symbols:** EU-harmonised sorting and reusability symbols on packaging by 1 January 2028.
    - **QR codes:** Mandatory QR codes which outlines details about packaging reusability and recycling collection points to consumers.
    - **Empty space:** A 40% limit on empty space within packaging.
    - **Recycled content:** All packaging is recyclable and that the plastic parts in packaging contain a minimum percentage of recycled content recovered from post-consumer plastic waste. Some time-limited exemptions to pharmaceutical packaging apply. For instance, packaging directly in contact with medicinal products will be exempt from the recyclability requirements until 1 January 2035.

312 United Nations Development Programme (n.d.). 10,000 sustainable parcel lockers to eliminate cardboard and plastic - Swipbox. [online] UNDP. Available at: <https://www.undp.org/sdg-accelerator/accelerators/sdg-accelerator-denmark/swipbox> [Accessed 11 Sep. 2023].

313 See, e.g., Aquino, R.P., Barile, S., Grasso, A. and Saviano, M. (2018). Envisioning smart and sustainable healthcare: 3D Printing technologies for personalized medication. *Futures*, [online] 103, pp.35–50; doi:<https://doi.org/10.1016/j.futures.2018.03.002>.

314 European Commission (2022). Proposal Packaging and Packaging Waste. [online] [environment.ec.europa.eu](https://environment.ec.europa.eu). Available at: [https://environment.ec.europa.eu/publications/proposal-packaging-and-packaging-waste\\_en](https://environment.ec.europa.eu/publications/proposal-packaging-and-packaging-waste_en).

315 Rudd-Clarke, O.C.-P. and Lundy, A. (2023). Pharma impacted by new EU packaging and packaging waste proposals. [online] Lexology. Available at: <https://www.lexology.com/library/detail.aspx?g=ac550822-f16b-448b-aac8-abe7196baeb3#:~:text=Pharma%20packaging%20exemptions> [Accessed 7 Sep. 2023].

- **New Zealand:** In 2020, The Pharmaceutical Management Agency (Pharmac), signalled its preference 'wherever possible [...] for more environmentally packaging from suppliers and for options that minimise the volume of packaging'.<sup>316</sup>
- **Funding:** Government has also used, albeit to a lesser extent, funding to promote sustainable pharmaceutical packaging solutions:
  - **United Kingdom:** In 2021, UK Research and Innovation (UKRI) invested almost £2 million in 14 projects to address consumer problems with plastic packaging, including the Central Pharma contract Packaging Limited project which aims to create a circular system enabling 100% of medicine blister packs to be recyclable with convenient public drop-off points.<sup>317</sup>
  - **EU:** The European Innovation Council's EIC Accelerator programme supports innovative and high-potential start-ups as well as, small and medium-sized enterprises (SMEs), and recently invested in a company focused on developing smart reusable packaging systems.<sup>318</sup>

### What are the associated risks with this innovation and how could they be mitigated?<sup>319</sup>

- **Procurement:** In the procurement domain, the adoption of sustainable packaging brings several risks. This includes the need to source new materials from new suppliers, which can lead to increased costs and time investments. Moreover, the pharmaceutical industry's reliance on a limited number of sustainable packaging suppliers can result in an imbalance of power, potentially affecting the supply-demand dynamic. To mitigate this risk, measures such as promoting supplier diversity and implementing monitoring and reporting systems can be employed to ensure the successful adoption of sustainable packaging in procurement.
- **Production:** The adoption of new production systems and processes for sustainable materials may extend lead times, resulting in delayed product availability. Investments in new machinery and production process modifications can incur higher costs which may, in turn, the affordability of packaging. This may be mitigated by carefully planning and phasing in the implementation of new production systems and processes, enabling companies to better manage lead times and cost increases while ensuring the affordability of packaging in the long term.

<sup>316</sup> Pharmaceutical Management Agency (Pharmac) (2021). Statement of Intent. [online] Pharmac, p.21. Available at: <https://pharmac.govt.nz/assets/2020-Statement-of-Intent.pdf> [Accessed 7 Sep. 2023].

<sup>317</sup> UKRI (2021). Funding for consumer plastic packaging innovation. [online] www.ukri.org. Available at: <http://ukri.org/news/funding-for-consumer-plastic-packaging-innovation/> [Accessed 7 Sep. 2023].

<sup>318</sup> Packaging Europe (2023). Miwa Technologies receives EU funding to continue scaling up its smart reusable packaging system. [online] Packaging Europe. Available at: <https://packagingeurope.com/news/miwa-technologies-receives-eu-funding-to-continue-scaling-up-its-smart-reusable-packaging-system/9577.article> [Accessed 7 Sep. 2023].

<sup>319</sup> García González, A. (2020). *Exploring The Effects of Plastic-Free Packaging In The Pharmaceutical Industry*. [online] Lund University, pp.40–44. Available at: <https://lup.lub.lu.se/student-papers/search/publication/9022340> [Accessed 15 Sep. 2023].

## 2.3.10.2 SPECIFIC INNOVATION CASE STUDY

**Bormioli Pharmacy – First Compliant Green Plastic Packaging Solution****Figure 15: Bormioli Pharma's Green Plastic Packaging Solutions<sup>320</sup>**

- **Overview:** Bormioli Pharma, an Italian pharmaceutical packaging manufacturer, has committed to bringing sustainability to the pharmaceuticals industry with the first green plastic packaging solution compliant with the European Pharmacopoeia, the source of official quality standards for medicines in Europe. More broadly, in 2022, the company has introduced three eco-friendly packaging ranges, completed three lifecycle assessments for three plastic products, and had 39% sustainable input material in sold products.<sup>321</sup>
- **How It Works:** One notable initiative is Bormioli's innovative green plastic solution, centred around the use of 100% pharmaceutical-grade Recycled Polyethylene Terephthalate (rPET) bottles, which works as follows:
  - **Recycled plastic:** Bormioli uses food-grade 100% recycled Polyethylene Terephthalate which boast the same high-quality performance characteristics as their virgin PET counterparts.
  - **Customised packaging:** This recycled plastic allows Bormioli to create highly customised solutions, and companies can then design containers for medicines and other products using these eco-friendly bottles to suit their needs.

## 2.3.10.3 APPLICABILITY TO AUSTRALIA

**What is the typical/ current approach in Australia?**

- In Australia, some progress has been made to implement and encourage sustainable packaging, including in relation to pharmaceutical packaging:
  - **Proposed regulations:** In June 2023, Australia's Environment Ministers agreed, in an Australian first, to introduce a new regulatory scheme to minimise packaging waste and ensure it is designed for recovery, reuse, recycling, or reprocessing by developing mandatory packaging obligations.<sup>322</sup>
  - **Funding:** In New South Wales, The Western NSW Local Health District (WNSWLHD), funded through the NSW Health Sustainable Futures Innovation

<sup>320</sup> Vankat, C. (2023). Bormioli Pharma to bring sustainability to the pharma industry with the first compliant green plastic packaging solution | Packaging World Insights. [online] Packaging World Insights. Available at: <https://www.packagingworldinsights.com/pharmaceutical/bormioli-pharma-to-bring-sustainability-to-the-pharma-industry-with-the-first-compliant-green-plastic-packaging-solution/> [Accessed 7 Sep. 2023].

<sup>321</sup> Bormioli Pharma (2022). Making Health a Positive Practice: ESG Report 2022. [online] Bormioli Pharma. Available at: <https://www.bormiolipharma.com/en/sustainability> [Accessed 7 Sep. 2023].

<sup>322</sup> Minister for the Environment and Water (2023). Environment Ministers step in to cut packaging waste | Ministers. [online] Dccee.gov.au. Available at: <https://minister.dccee.gov.au/plibersek/media-releases/environment-ministers-step-cut-packaging-waste> [Accessed 7 Sep. 2023].

