Gilead Sciences: Submission to the Review of Pharmacy Remuneration and Regulation

Gilead Sciences (Gilead), as a manufacturer of innovative medicines, supports ensuring Australia’s health care system remains focused on delivering quality health outcomes, promoting access and the quality use of medicines. Given this, Gilead seeks to contribute to the Panel’s understanding of the current system of how innovative medicines are distributed to patients both now and into the future.

Gilead provides responses to the below questions posed by the Panel in the Discussion Paper. To assist readability, we have used the Panel’s numbering and headings and extracted relevant sections from the Paper (see shaded boxes below).

As background, Gilead is the manufacturer of medicines for the treatment of:

- hepatitis B
- hepatitis C (specifically, HARVONI® and SOVALDI®)
- HIV
- chronic lymphocytic leukaemia / follicular lymphoma

Gilead’s medicines HARVONI® and SOVALDI® are available on the PBS for the treatment of chronic hepatitis C in adults through both the PBS General Schedule (‘Section 85’) and the Highly Specialised Drugs (HSD) Program (‘Section 100’) in Australia. The availability of hepatitis C medicines under Section 85 means community pharmacists now play an important role in supplying these medicines to hepatitis patients for the first time. Hospitals in all states, except NSW and ACT, can also dispense section 85 products.

Gilead’s medicines for the treatment of HIV are Section 100 Community access products. Namely, these section 100 products are able to be dispensed within community pharmacy.

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**High Cost Medicines**

New hepatitis C medicines, in particular have presented challenges to current arrangements with significant cash flow issues through the supply chain. For example one hepatitis C medicine, Sovaldi, is $19,367 (plus GST). The mark-up for wholesalers is $69.94 to distribute this drug and the mark-up for pharmacy is $70 plus the dispensing fee.

Additionally, payment timeframes from the wholesalers can be shorter than the reimbursement timeframe from the Commonwealth Department of Human Services back to the pharmacy. It has been put to the Panel that these pressures make pharmacists reluctant to stock these very high cost medicines and this in turn affects patient access.”
22. Should the timeframes for payment settlements for very high cost medicines be lengthened throughout the supply chain and mandated by Government?

Gilead does not believe that payments terms between those entities involved in the supply of medicines to end consumer (being medicine manufacturers, wholesalers and pharmacy) should be mandated by government.

It is important to recognise that medicine manufactures, such as Gilead, typically sell medicines to the wholesalers on certain payment terms and the wholesalers then on sell to pharmacy under their own payment terms. Typically, there is no direct contractual relationship between medicine manufacturers and pharmacists - unless a “direct distribution model” is implemented.

From the date Gilead’s HCV medicines became PBS listed, Gilead has implemented extended payment terms with wholesalers recognising some of the challenges facing some of the other stakeholders involved in making hepatitis C products available to patients. Gilead has offered at least 55-day payment arrangements to all wholesalers. This, in turn, allows wholesalers to offer reasonable payment terms to pharmacists and hospitals across Australia that may be considered to be outside ‘normal’ or ‘standard’ trading terms. We note that the exact payment terms wholesalers offer to their own customers are entirely their own commercial decision. Medicine manufactures mandating certain payment terms from the wholesalers to the wholesaler’s own customers raises competition issues and could negatively impact competition in that space.

Concerns around payment terms for hepatitis C medicines arguably arose because one wholesaler introduced shorter-than-usual payment terms upon the PBS launch of these medicines. This was a commercial decision made by that wholesaler. Given the concerns this raised by the pharmacy sector in light of the Medicare reimbursement payment schedule, that wholesaler ultimately changed their payment terms due to market dynamics and competition. Given this, and despite the cost of Hepatitis C medicines, Gilead anticipates that with appropriate Pharmacy management practices and processes all pharmacies can be in receipt of their Medicare reimbursement before payment to their preferred wholesaler. Reflecting this, Gilead has not received any complaints from pharmacists since that wholesaler changed their payment terms.

To put this in context for the Panel, given Medicare reimburses pharmacists within an average of 9-14 days from receipt of a claim, a typical 30 days-from-end-of-month payment term from a wholesaler will allow a community pharmacist to be in receipt of monies from Medicare anywhere between 2-6 weeks in advance of their payment date with their preferred wholesaler. However, this requires the pharmacist to be timely with their submission of claims to Medicare.

Government mandating certain payment terms in the supply chain also raises competition issues as well as potentially having undesired anti-competitive effects – for example Gilead might not have been able to offer at least 55 day payment terms to wholesalers if the more typical payment term between medicine manufacturers and wholesalers of 30 days was mandated. In addition, mandating longer payment terms could have an undesired effect on medicine manufactures. It is commonly known that most new medicines are subject to some form of confidential risk sharing arrangement with Government. Some of those risk sharing arrangements include repayment of money to Government on certain payment terms. If there is longer payment terms mandated throughout the
supply chain, any extension must flow through to longer payment terms of any rebates etc back to Government. Without this, the ability of medicine manufacturers to manage their long lead times of manufacturing and importing medicines, as well as longer payment terms to wholesalers would be negatively impacted.

Gilead suggests that pharmacists speak to their preferred wholesaler about payment terms for hepatitis C medicines and/or look into what payment terms are offered by the different wholesalers.

23. Are there better ways of achieving patient access to very high cost medicines through community pharmacy that reduce the financial risks to the supply chain and facilitate consumer choice?

Gilead recognises that the availability of high cost drugs to patients via community pharmacy is a recent evolution in our healthcare system and brings many benefits to patients. That evolution also brings challenges in trying to fit within the existing framework for distributing medicines and the existing margins allocated to Section 85 vs. Section 100 products. The Government has long recognised that different medicines may require differentiated supply chain management. For example, the lifesaving drugs program has a different supply chain than Section 85 and Section 100 products.

It is important to recognise that medicine manufactures of Section 100 and Section 85 products, such as Gilead, typically sell medicines to the wholesalers on certain payment terms and the wholesalers then on sell to pharmacy (both retail and hospital) under their own payment terms. Given this (unless a ‘direct distribution model’ is implemented), medicine manufacturers have limited influence with respect to financial risks to the supply chain where a high cost drug has been listed by the Department of Health as being Section 85 product and/or Section 100 product and the respective margins for that product are set under regulation.

As set out in our response to Question 22, Gilead understands that pharmacies are currently managing their financial risk (with respect to payment terms) through good pharmacy management practices, good ordering practices and the management of their own inventory in light of the Medicare repayment schedule.

### High Cost Medicines

*Hepatitis C medicines are dual listed as available under s100 and under s85 (general schedule) of the PBS. This allows patients to access these medicines in hospital as well as the community. However the remuneration structures are quite different and remuneration for community pharmacies dispensing an s100 Highly Specialised Drug (HSD) is less than that for the equivalent s85 general schedule item. In the case of hepatitis C drugs, this means that hospitals are in effect paid an additional mark-up of around $2,000 by the PBS when compared to being dispensed through a community pharmacy.*

Table 4 – Public and private hospital pharmacy mark-ups for section 85 and section 100 medicines
24. Given that very high cost drugs are likely to become more common on the PBS, should this remuneration structure for hospitals change to more closely reflect the remuneration structure of community pharmacy?

Table 4 provides a very easy to understand guide to the existing remuneration structure for medicines throughout the supply chain. Gilead supports changes being made to the existing remuneration structure for:

- Section 100 medicines dispensed by community pharmacy; and
- private and public hospitals, particularly with respect to Section 85 medicines.

**Section 100 medicines dispensed by community pharmacy**

Currently there is no wholesale margin take into account when determining the DPMQ for Section 100 medicines dispensed by community pharmacy. The effect of this is that the medicine manufacturer either pays the wholesaler a fee in lieu of this being paid by the pharmacist and Medicare, and/or the wholesaler levies an additional fee onto the product which the pharmacist cannot recoup from Medicare thereby reducing the pharmacist’s effective margin.

This has the effect that the price of Section 100 products to pharmacists can vary. Typically this variance is greater in high cost medicines, meaning the effective pharmacy mark-up can vary significantly. Likewise, medicine manufacturers also consider this cost when considering the pricing of medicines and forms a disincentive for section 100 medicine manufacturers seeking to have their products made available via community pharmacy.

Given that the Department of Health considers that allowing dispensing of Section 100 medicines via community pharmacy will improve patient access and importantly, patient outcomes, then supply chain participants should be remunerated in the same way as for section 85 medicines. Specifically, Gilead believes that a wholesaler margin needs to be included for Section 100 medicines dispensed by community pharmacy.

**Public and Private Hospitals**
If a hospital dispenses a Section 85 script (which they are eligible to do in all states except NSW and ACT), they can claim an additional 11.1% margin. An uncapped margin does not cause significant issues for lower cost Section 85 medicines dispensed in hospital. However, given the move by the Department to have high cost drugs listed as Section 85 medicines, a cap should be introduced to avoid unintended consequences.

Illustrating the current situation, if a hospital in Victoria dispenses a HCV medicine as a Section 85 prescription, they can claim over $2000 as a margin. Gilead is aware that this margin is not actually being charged by wholesalers. Therefore, when a hospital claims an 11.1% margin, it is not reflective of the hospital’s actual costs of purchasing these medicines.

Gilead believes this current arrangement should change as it currently incentivises hospitals to encourage clinicians to write Section 85 scripts, have these Section 85 scripts dispensed within the hospital and claim a 11.1% margin. Rather, Gilead believes that it would be appropriate for a hospital dispensing a Section 85 medicine to claim up to the same maximum wholesaler margin as what is claimed in a community pharmacy setting.

A hospital’s wholesaler margin when dispensing a Section 85 medicine must be compared to the situation of a hospital dispensing a medicine as a Section 100 script. As set out in Table 4 (reproduced above), if a hospital physician dispenses a medicine as a Section 100 script, the hospital cannot claim any wholesaler margin. For medicines that are both Section 85 and Section 100 listed (such as the hepatitis C medicines) this means that a hospital cannot claim anything as wholesaler fee if they dispense as a Section 100 script but over $2000 with respect to the hepatitis C medicines as a Section 85 script. The deficiencies with this current arrangement are obvious.

These additional costs reduce available PBS funds that could otherwise be used to provide greater access to hepatitis C medicines or other medicines. Furthermore, this funding arrangement does not does not benefit the patient in terms of improved access for medicines given Section 100 dispensing is available to hospitals.

75. Pfizer supply direct and do not provide their medicines for supply through the CSO. Should all PBS medicines be available through the CSO, or is it appropriate for a manufacturer to only supply direct to the pharmacy?

It is appropriate for a medicine manufacturer to choose to supply their products direct into pharmacy as long as the manufacturer ensures that broad accessibility is taken into account. This is particularly important because of the differences in reimbursement between Section 85 and Section 100. As set out above, the lack of a wholesale margin for Section 100 products means that a medicine manufacturer either has to pay the wholesaler for the wholesale margin (or distribution) component of a Section 100 product itself, or appreciate that there will be price variations in its product at pharmacy level given the on-charge of a margin by the wholesaler.

It is important to note that the CSO currently does not cover all PBS listed medicines. Rather, CSO funding is only available with respect to Section 85 listed medicines. – not Section 100 listed medicines (or other medicines such as lifesaving drugs).
76. Should s100 and RPBS items be included in normal wholesale arrangements and in the CSO? If so, why? If not, how do the current arrangements support consumer access to all PBS and RPBS items?

Section 100 and RPBS items should be included in normal wholesale arrangements and in the CSO. This is for the reasons set out above.

86. Should the onus for the delivery of medicines to community pharmacy around Australia in a timely fashion (e.g. 24-hours) be imposed on the manufactures as part of their listing requirements on the PBS?

Medicine manufacturers either: (a) undertake scientific research and develop innovative medicines, or (b) manufacture generic version of innovative medicines. It is not within the core capabilities of medicine manufacturers to be distribution and logistics providers. In Australia this activity is commonly outsourced to supply chain organisations (namely, subject matter experts). By imposing such a requirement, the Australian government would essentially be requiring medicine manufacturers to diversify their businesses into areas that are not considered to be a core competency of the organisation. Even though this could (and would) be outsourced, this would still impose an additional cost and burden on medicine manufacturers that could only be recouped in terms of the prices they are willing to accept for their products.