Review of Pharmacy Remuneration and Regulation
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Pharmacy Review (MDP 900)
Department of Health
GPO Box 9848
Canberra ACT 2601

via email: pharmacy.review@health.gov.au

Dear Professor King,

RE: REVIEW OF PHARMACY REMUNERATION AND REGULATION INTERIM REPORT

Thank you for providing Pfizer Australia with the opportunity to make a submission to the *Review of Pharmacy Remuneration and Regulation* Interim Report.

Pfizer Australia is one of Australia's leading providers of prescription medicines and consumer health products. We manufacture and deliver medicines and vaccines that millions of Australians use every day to live longer, healthier and more productive lives. We are proud of the active role we play in Australia's health system and the wider contribution we make as an innovator, employer and manufacturer.

Pfizer Australia is currently the only major pharmaceutical manufacturer in the country that currently uses a *direct* distribution model ("Pfizer Direct)" to sell prescription medicines into community pharmacies. Thirteen percent of all Pharmaceutical Benefits Scheme (PBS) medicines distributed to community pharmacies across the country go through Pfizer Direct. This experience provides us with a unique perspective on pharmaceutical wholesaling, logistics and distribution arrangements in the Australian context.

Pfizer Australia supports the Review Panel's strategic vision for an integrated and sustainable community pharmacy sector, which is adaptive to the inevitable changes in health care given Australia's ageing population, rapid advances in technology and ongoing PBS reform. Our submission (Attachment 1) provides feedback on a selection of the Review Panel's 'Options for Reform'.

Pfizer Australia is a member of Medicines Australia (MA), the peak body representing innovative pharmaceutical companies in Australia, and the Australian Self Medication Industry (ASMI), the peak body representing companies involved in the manufacture and distribution of consumer healthcare products in Australia. Pfizer Australia was involved in the preparation of MA's and ASMI's more extensive submissions to this Review. We support the principles upon which both submissions are based and encourage the Review Panel to carefully consider the analysis and recommendations provided within each.

Thank you again for the opportunity to contribute to this Review. Pfizer Australia is available to provide further information to the Review Panel, as required.

Yours sincerely,

Melissa McGregor

ATTACHMENT 1

Submission to the *Review of Pharmacy Remuneration and Regulation's Interim Report*

Option No.	Option for Reform Details / Commentary	Pfizer Australia's Response
Chapter 2: Consumer Access and Experience		
Option 2-6: Consumer Medicines Information	A Consumer Medicines Information (CMI) leaflet should be offered and made available to consumers with all prescriptions dispensed in accordance with Pharmaceutical Society of Australia (PSA) guidelines. The PSA guidelines and the distribution of CMIs to consumers need to be audited and enforced to ensure compliance. Pharmacists and the pharmacy industry should continue to work on the improvement of CMIs and the use of technology to make medicines information more available to consumers.	Pfizer Australia believes that CMIs play an important role in empowering patients by promoting health literacy. We support the current guidelines which state the CMI should be made available to consumers at the point of dispensation by the pharmacist. We agree with the Panel's comments that technology can improve the accessibility of medicine information. Pfizer Australia, for example, has a mobile application ("Pfizer Meds") where consumers can access the CMI for any prescribed Pfizer product and we include CMIs on our corporate website.
Option 2-8: Electronic Medications Record	The electronic personal medications record should cover all Australians and ensure appropriate access by, and links between, community pharmacy, hospitals and all doctors. This record should also include a vaccines register.	Pfizer Australia supports appropriate communication, including through electronic medication records, to support a holistic patient care model provided through pharmacies, hospitals and surgeries. To this end, we support the Review Panel's position that an electronic personal medications record (including the Australian Immunisation Register) should be established. We also agree with the Review Panel's recommendation that such a record should form part of the national My Health Record system.
Chapter 3: The Role of Community Pharmacy in Medicine Supply		
Option 3-2: Complementary Medicines – Supply from Pharmacies	Community pharmacists are encouraged to: • display complementary medicines for sale in a separate area where customers can easily access a pharmacist for appropriate advice on their selection and use • provide appropriate information to consumers on the extent of, or limitations to, the TGA role in the approval of complementary medicines. This could be achieved through the provision of appropriate signage (in the area in which these products are sold) that clearly references	Pfizer Australia wholly supports the need for continual education to improve health literacy of consumers. However, in line with the position set out by the Australian Self-Medication Industry (ASMI) in its response to this Option for Reform: • We are concerned with the implication that complementary medicines as a class have limited efficacy, and • We do not agree that pharmacy layout and simplistic (and potentially misleading) signage are an appropriate means

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	any limitations on the medical efficacy of these products noted by the TGA.	of achieving improved health literacy. We strongly urge the Review Panel to re-consider this Option for Reform in light of the arguments and evidence provided in ASMI's detailed submission.
Option 3-3: Placement of Schedule 2 and 3 Medicines within a Pharmacy	Access to Pharmacy Only (Schedule 2) and Pharmacist Only (Schedule 3) medicines should be clearly separated from complementary medicines within a pharmacy. Options to achieve this might include: • ensuring that all Pharmacy Only and Pharmacist Only medicines only be accessible from 'behind the counter' in a community pharmacy so that a consumer must always seek assistance or advice in obtaining these medicines • requiring that complementary medicines are not displayed 'behind the counter' in a community pharmacy.	Pfizer Australia does not support this Option for Reform. S3 and S2 medicines have different risk profiles and different scheduling factors. S2 medicines treat conditions that can be managed by the consumer without the need for medical intervention. S2 medicines are therefore suitable for self-selection, with support from the pharmacist *if required*. We strongly urge the Review Panel to re-consider this Option for Reform in light of the arguments and evidence provided in ASMI's detailed submission.
Option 3-4: Sale of Homeopathic Products	Homeopathy and homeopathic products should not be sold in PBS-approved pharmacies. This requirement should be referenced and enforced through relevant policies, standards and guidelines issued by professional pharmacy bodies.	Pfizer Australia's response to this proposal is guided by our responsibilities as a research-based pharmaceutical company. Our commitment is to evidence-based developments in public health and, in this context, to pharmaceutical interventions that have proven therapeutic effectiveness. Pfizer Australia supports the Panel's recommendation that homeopathic products should not be sold in PBS-approved pharmacies, unless supported by evidence.
Chapter 5: The Regulation of Pharmacy for Medicine Supply		
Option 5-9: Harmonising Pharmacy Legislation	As early as practicable, the Australian Government, through the Australian Health Minister's Advisory Council, should seek to harmonise all state, territory and federal pharmacy regulations to simplify the monitoring of pharmacy regulation in Australia for the safety of the public. In the long term, a single pharmacy regulator could be considered. As an interim measure, state and territory registering bodies need to coordinate with the Australian Health Practitioner Regulation Agency to ensure that pharmacy	Pfizer Australia agrees that the community pharmacy sector is subject to a complex array of regulations across jurisdictions and that this creates unnecessary red tape in the supply chain. We wholly support the option to harmonize pharmacy regulations across the various jurisdictions. Differing (and onerous) requirements across states/territories with respect to the dispensing of controlled drugs is a case in point. Pfizer Australia has close to 4,500 accounts that require *Renewal of*

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	regulations are being adequately monitored for best practice of pharmacy and the safety of the public.	*Premises License* documentation each year. In addition to this, we need to obtain and verify premises details every time there is a change in ownership (of which there are approximately 30 to 60 each month). The verification process is difficult to streamline because the jurisdictions all have different structures. Pfizer Australia and our distribution partner have had to invest in an additional one and half full time employees (1.5 FTE) just to process these verifications. We also urge government to consider a wholesale review of the various state-based regulations to ensure they are still fit-for-purpose. In our experience, a number of regulations are antiquated and create unnecessary red tape for distributors. For example, in New South Wales the regulation[1] requires that: "107 Mode of delivery (5) A person who supplies a drug of addiction must not deliver a drug of addiction by carrier otherwise than under an arrangement under which the carrier undertakes: (a) to obtain a receipt, dated and signed, from the person to whom the drug is delivered, and (b) to deliver the receipt to the supplier." In practice, this means that for S8 medicines a pharmacist must sign and return the original receipt. Pfizer Australia processes approximately 100 S8 orders per day. Thirty percent of pharmacists do not send back the signed, original receipt within the requested timeframe. In any one week, this can mean we are chasing up to 150 different customers – an unnecessary administrative burden. To put this in perspective, we have one full time colleague solely dedicated to following up S8 receipts with customers. This administrative burden could be eased if sponsors were allowed to accept, for example:

[1] NSW Poisons and Therapeutic Goods Regulation 2008, Part 4, 107 (5), page 49

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		• A signature upon receipt of S8 medicines, as is the protocol for other medications, or • An e-copy and/or faxed copy of the receipt. Likewise, in New South Wales all new pharmacies are required to provide us with physical copies of their AHPRA registration details, premises license, etc. prior to us being able to send them S8 products. In other jurisdictions (e.g. Victoria), suppliers can simply obtain the pharmacy license information online and no physical copy is required.
Chapter 6: The Distribution of Medicines to Community Pharmacy		
Option 6-1: Community Service Obligation Removal, Retention Or Replacement	**6-1. ALTERNATIVE 1**: The government should remove the Community Service Obligation (CSO), and suppliers of PBS-listed medicines should be placed under an obligation to ensure delivery to any community pharmacy in Australia within a specified period of time (generally 24 hours), with standard terms of trade offered to the pharmacy (such as four weeks for payment) using one or more of a specified panel of wholesalers as follows: a. an initial Panel of around five wholesalers would be approved. It is expected that these will include the existing CSO Distributors b. the relevant terms of trade and other supply conditions may vary between medicines. For example, for high-cost medicines or medicines that have cold-chain supply requirements, the supply conditions may differ from those for low-cost medicines to ensure that there is not an unreasonable risk or cost placed on either community pharmacy or consumers c. a cap should be placed on the amount that a community pharmacy contributes to the cost of a medicine. This cap should be in the range of $700 to $1000.	Pfizer Australia supports competition and efficiency in pharmaceutical distribution arrangements. As we outlined in detail in our first written submission to this Review in response to the Discussion Paper, the Pfizer Direct model has proven to be a successful alternative to the traditional wholesaler model, and demonstrates there are efficiencies to be gained for taxpayers and pharmacists, as well as improvements in patient access. We believe the CSO system should reflect these learnings by embracing a mixed model system. That is, • We would not support a system which requires all PBS medicines to be available through the CSO in its current form (i.e. the prohibition of direct supply). • At the same time, we would not support moving to a requirement to have all manufacturers to supply direct to pharmacy. Some manufacturers may not have the economies of scale to support supplying directly to pharmacies (e.g. manufacturers of speciality medicines and limited product lines). These requirements would not be consistent with supporting a

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	6-1. ALTERNATIVE 2: The government should retain the current CSO arrangements but ensure that all service standards, such as the 24-hour rule, are uniformly implemented. **6-1. ALTERNATIVE 3:** The government should conduct a separate review of the CSO to ensure current arrangements demonstrate value for money. A review would also present an opportunity to potentially streamline existing or remove unnecessary regulation. Such a review would require the full cooperation of the CSO Distributors, which would provide financial data and other relevant information to government.	viable medicines industry in Australia, contravening a key value of Australia's National Medicines Policy. In order to uphold the objectives of the CSO at each step of the supply chain, we would propose that the new, mixed model system should consider the following changes: • Encouraging transparency of supply chain costs to encourage innovation and efficiencies • Adopting a remuneration model that more accurately reflects actual supply chain costs • Opening the CSO funding to non-wholesaling distributors as well as traditional wholesalers to encourage competition and to ensure government support that supports equitable access flows to all pharmacists and patients, regardless of the distributor • Developing consistent service level benchmarks across the board, which ensure the focus remains on equitable and timely patient access at every stage of the supply chain.
Option 6-2: Supply Of High-Cost Medicines	In line with Option 6-1, patients should be able to receive high-cost medicines from the community pharmacy of their choice. A cap should be placed on the amount that a community pharmacy contributes to the cost of a medicine. This cap should be in the range of $700 to $1000 so that all PBS-approved community pharmacies can supply all PBS medicines required by the public.	Pfizer Australia acknowledges the challenges faced by community pharmacy when managing high-cost medicines. Our position on this Option for Reform would depend on how the proposed cap would work in practice, i.e. • Which stakeholder would be responsible for funding the 'gap'? • Which stakeholder would be responsible for claiming the 'gap' (e.g. wholesalers or manufactures)? • What process would the relevant stakeholder have to follow in order to claim the 'gap'? • Would the 'gap' be claimed when the pharmacist receives the stock or when the stock is dispensed?

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		• Would the cap create a perverse incentive for pharmacies to over-stock high cost medicines? Any revised model should be pragmatic, fair and not place undue financial or process burden on stakeholders.
Chapter 7: Future Community Pharmacy Agreements		
Section 7-1: The CPA Process	Even if the parties directly participating in the CPA process did not change, the need for broad and clear consultation remains. At a minimum, future consultations should include the CHF, PSA, the NACCHO, Primary Healthcare Networks and others, including the Rural Health Alliance, the AMA, GBMA, NPS MedicineWise, the RACGP, organisations representing various disease cohorts/populations and manufacturers of medicines et cetera. These consultations should be organised by the Australian Government and attended by the aforementioned representative organisations.	Pfizer Australia notes and wholly supports the Panel's commentary that future CPA consultations should include a broad range of affected stakeholders. Innovative pharmaceutical companies should be represented by Medicines Australia. We would also argue that manufacturers that operate a direct distribution model to sell prescription medicines into community pharmacies, such as Pfizer Australia, should also be included in the consultations. Thirteen percent of all PBS medicines distributed to community pharmacies across the country go through Pfizer Direct. This experience provides us with a unique perspective on pharmaceutical wholesaling, logistics and distribution arrangements in the Australian context.
Chapter 10: Further Issues		
Option 10-5: General Medicine – Listing Arrangements	When an 'original' (or 'branded') medicine comes off patent then the government should hold a tender for the listing of generic versions of the medicine. The government should limit the number of generic versions of a particular medicine to be listed to a relatively small number that is still sufficient to allow for patient choice (e.g. four generics and the original brand of the medicine). The chosen generics should be those best able to meet the distribution and other conditions required by the government at the least cost to the PBS.	Pfizer Australia strongly opposes this recommendation. First, the Review Panel has not provided a robust case for change. The Panel suggests that having a number of generic competitors "potentially raises inventory and related stock-ordering and stock-holding costs", but provides no evidence that this is actually an issue in the current market. Second, procurement mechanisms such as tendering may: • Restrict patient and physician choice • Increase the risk of supply disruptions • Increase the impact of supply disruptions by reducing the

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		number of alternative suppliers able to step in to supply the market, particularly at short notice. In line with the arguments presented in Medicines Australia's submission, Pfizer Australia supports the current formulary architecture of the PBS and does not support a broad based tendering model for PBS medicines.