MEDICINES Australia

Review of Pharmacy Remuneration and Regulation
Discussion Paper

23 September, 2016

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Introduction

Medicines Australia welcomes the *Review of Pharmacy Remuneration and Regulation* Discussion Paper.

Medicines Australia is the peak industry body representing the research-based innovative pharmaceutical industry in Australia. Our members research and develop, manufacture and supply medicines and vaccines to the Australian community. Our members represent over 80 per cent of the Australian prescription medicines market by value.

Pharmacists play a crucial role in the delivery of health and health care outcomes in Australia; like innovative medicines manufacturers, they are part of the broader pharmaceutical supply chain. Currently, remuneration of the pharmaceutical supply chain makes up a significant share of Australian Government, and consumer/patient, pharmaceutical costs. Reforms that are likely to impact on the operations of the supply chain, including manufacturers, will require further consultation with the sector to avoid unnecessary or unintended consequences.

Central to Australia's world-leading health care system is universal medicines access underpinned by the National Medicines Policy (NMP) and the Pharmaceutical Benefits Scheme (PBS). Therefore, it is imperative that reforms to pharmacy regulation and remuneration must align with the objectives of the National Medicines Policy (NMP); and be consistent with tenets of the Pharmaceutical Benefits Scheme (PBS).

Medicines Australia has drawn upon themes presented in the Paper to make general recommendations. Specific questions are discussed by exception.

Recommendations:

Medicines Australia recommends (in relation to pharmacists) that remuneration:

1. should accurately reflect the value added; the complexity of the engagement and/or service; and the patient benefit
2. should reflect the cost and cost effectiveness of dispensing activities and services
3. should be appropriately targeted and standardised
4. should be transparent; and
5. emerging issues relating to different mark-ups and inconsistent fees should be examined and resolved.

This submission is designed to provide a broad overview of the views of our members. However, in addition, Medicines Australia anticipates that individual members will make separate submissions to the Panel to draw further upon the themes and highlight areas where they identify specific impact at company-level.

We acknowledge that the release of the Paper follows extensive consultation with key stakeholders including Medicines Australia. We look forward to further consultation on the issues raised in the Paper and to work collaboratively with the Panel, the Australian Government, the Department of Health and key stakeholders, as the Review continues and the report is finalised.

Fundamental Principles for the Review

The successful ongoing achievement of health outcomes for all Australians depends fundamentally on universal medicines access underpinned by:

- The National Medicines Policy[1], including a competitive, efficient and viable pharmacy sector;
- A stable and predictable PBS policy environment that appropriately values innovative therapies;
- Health Care Professionals at the interface of patient health care support, including community and hospital pharmacists;
- Appropriate sector agreements that foster the above.

Medicines Australia supports the role that pharmacists play in the delivery of health and health care outcomes in Australia including, appropriate levels of remuneration and transparency in remuneration arrangements.

We particularly note that discrepancies in remuneration and benefit arrangements under Section 100 (S100), Section 85 (S85) and Section 94 (S94) of the PBS and handling of these between pharmacy settings are increasingly of concern, especially in relation to high-cost medicines (further detailed in Q24 below).

Overview of Themes

The National Medicines Policy and sector agreements

Australia's NMP is a "cooperative endeavour"[2] which aims to bring about better health outcomes for all Australians. It relies upon the existence and sustainability of the broader pharmaceutical supply chain (including the medicines industry, wholesalers, and pharmacists).

We note that Community Pharmacy Agreements (CPAs) have been in place in Australia for many years. Successive CPAs have provided predictability and stability for Government, community pharmacy and consumers. Similarly, a previous agreement with the innovator medicines industry via the landmark 2010 Memorandum of Understanding (MOU) generated savings to the Australian Government and a period of relative predictability and stability for the medicines industry, Government and consumers. Medicines Australia broadly supports agreements in and across the sector where such agreements are transparent, consistent with the objectives of the NMP, and promote predictability and stability.

The Pharmaceutical Benefits Scheme (PBS)

Access to innovative pharmaceutical products, including vaccines, via the PBS has been a major contributor to the health outcomes of all Australians for over 50 years[3].

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[1] The National Medicines Policy (NMP) is available at www.health.gov.au/nationalmedicinespolicy. Its four core objectives are:

- Timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- Medicines meeting appropriate standards of quality, safety and efficacy;
- Quality use of medicines (QUM); and
- Maintaining a responsible and viable medicines industry

[2] Australian Government Department of Health. 1999. National Medicines Policy, available: http://www.health.gov.au/nationalmedicinespolicy

[3] The Australian Institute of Health and Welfare (2013) estimates that the number of premature deaths before the age of 75 fell by over a third between 1997 and 2012. Furthermore, recent research by Lichtenberg (2015) of Colombia University attributes 60% of the decline in premature mortality in Australia over this period to the listing of innovative medicines on the PBS. Deaths from heart disease and other circulatory diseases has fallen more than five-fold since the late 1960s and deaths from AIDS from 764 in 1994 to 75 in 2013. Cancer survival has also

The PBS is widely recognised as one of the best publicly-funded medicines systems in the world. It provides Australians with timely, reliable and affordable access to medicines, irrespective of where they live and consistent with the objectives of the NMP. One of the major strengths of the PBS is that it is a national program, ensuring a consistent approach to evaluation, pricing, and distribution of medicines, regardless of geographic location.

In Australia, the use of medicines is the most common health intervention to combat illness, disease and promote good health and wellness. Of the more than 137.3 million General Practice Medicare-claimed visits in 2014-15, medicines were prescribed 86% of the time[4].

Expenditure on the PBS is proven sustainable, with only modest growth, at levels below inflation over recent years, and at a consistent level of around 0.6% of GDP[5].

The sustainability of the PBS is the result of successive reforms and the introduction of enduring mechanisms, many of which were struck in collaboration with the innovative medicines industry. These measures include *price disclosure*, which enables market pricing for off-patent medicines. In addition, risk sharing arrangements and rebate agreements between medicines sponsors and the Australian Government (particularly for high-cost medicines) are working to deliver a financially stable PBS.

Location and Ownership

Medicines Australia supports our publicly subsidised, universal healthcare system and believes that continuity of supply for medicines including access to pharmacies, particularly in rural and regional areas, is key. As such, pharmacy ownership and location rules should encourage competition where it can be supported by the local community.

Measures that would lessen competition in the community pharmacy setting, could detract from the objectives of the NMP, creating unintended consequences for the supply chain and should be approached with caution.

Pharmacy Remuneration for Dispensing

As the discussion paper indicates, pharmacy remuneration for dispensing, and remuneration for wholesaler distribution, is a significant proportion of the Government-reported expenditure on *Pharmaceutical Benefits Paid*.

Medicines Australia concurs with the finding in the Paper that “the proportion of PBS expenditure that goes to community pharmacy represents almost 30% of total expenditure on the PBS, even without including pharmacy programs and the wholesalers Community Service Obligation (CSO) payments”[6].

This analysis aligns with our own research showing that, of $12 billion in expenditure in 2013-14 (including Commonwealth and consumer contributions), pharmacy was the beneficiary of 36% ($4.3 billion), wholesalers 6% ($0.7 billion) and manufacturers 59% ($7.1 billion), excluding rebates paid through other agreements (such as for high-cost drugs).

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improved substantially in recent years, with 5 year cancer survival increasing from 49% in 1986 to 62% in 2007. Lichtenberg (2015) estimated that innovative medicines contributed 40% of this survival gain.

[4] General Practice Activity in Australia 2014-15, Family Medicine Research Centre, University of Sydney, page 37

[5] Medicines Australia 2016. Submission to the 2016-17 Federal Budget. Available: https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/02/20160205-MA-2016-draft-budget-submission-Final.pdf. Figures are calculated from Australian Bureau of Statistics and Australian Government Department of Health PBS figures.

[6] Review of Pharmacy Remuneration and Regulation Discussion Paper, p20

Therefore, in assessing appropriate levels of remuneration for dispensing, Medicines Australia recommends that remuneration should:

- reflect the value added; the complexity of the engagement and/or service; and the patient benefit
- include consideration of the cost-effectiveness of dispensing activities and services
- be appropriately targeted and standardised
- should be transparent wherever possible and
- Fees and mark-ups should be equitable across the different settings in which medicines are dispensed.

Wholesaling, Logistics and Distribution Arrangements

Medicines Australia supports competition and efficiency in the wholesale supply arrangements, and supports the Panel exploring further efficiencies in the current system. However, it does not support or advocate monopoly wholesale supply arrangements, or mandating the transfer of wholesale supply to manufacturers.

System reforms, for example expansion of S100 to community pharmacy, have been essential in helping to modernise the system. However, some reforms have been piecemeal or incomplete. In the case of S100 mark-ups, we recommend the Panel consider aligning the mark-ups to ensure equity of remuneration in each respective setting (or incorporating a fair wholesale distribution fee into the ex-manufacturer price paid by the Government for affected medicines).

This would provide medicines manufacturers with a straightforward model for compensation for the expansion of Section 100 to community pharmacy. Further work would be required to calculate a fair wholesaler mark-up taking into account the variability of distribution costs to different destinations across the country.

Accountability and Regulation

Compounding (particularly chemotherapy drugs)

- Medicines Australia has previously worked with the Therapeutic Goods Administration on the regulatory standards for compounding of sterile injectable(s). We support appropriate levels of regulatory assessment and monitoring in this regard to ensure premises are appropriately assessed and licensed to Good Manufacturing Practice (GMP) standards, particularly where compounding is conducted on a large scale.
- Under the 6CPA, the Australian Government provided $372 million for chemotherapy compounding and a two-tier fee structure based on the TGA licensing level.
- Medicines Australia understands that there may be anecdotal evidence to suggest that some pharmacies are cross-subsidising their compounding practices from their dispensing revenue. Such a practice is not supported by Medicines Australia and should be further examined.
- Medicines Australia is also concerned by reports that there are large-scale compounding of unapproved products that are largely unregulated.
- Medicines Australia would be happy to work with the Australian Government to review and evaluate the impact and suitability of the current regulations and other arrangements for compounding, including chemotherapy compounding and funding.

Consumer Experience

- Patients are at the centre of Australia's health care system and pharmacists play a critical role in educating and providing medicines information to them.
- With regard to prescription medicines, the role of the pharmacist should complement and enhance (and not compete with or supersede) the information and/or advice provided by health care practitioners, general practice doctors (GPs), nurses and other allied health professionals, hospitals, specialists, health consumer organisations (HCOs) and patient groups etc.
- It should be clear to consumers where and how to access medicines information when they need it and in a format that is understood. It is also important that there is confidence that the information being provided is accurate, relevant to their particular need(s) and up-to-date.
- Medicines sponsors are required to ensure that patient information (meeting the requirements for patient information under the Therapeutic Goods Regulations) is provided, in a manner that will enable the information to be given to a person when the goods are administered or otherwise dispensed[7]. Manufacturers cannot supply information to patients directly[8].
- Medicines Australia recently hosted a multi-level stakeholder meeting with representatives from across the pharmaceutical sector supply chain on provision of CMI.
- Participants noted that patients have differing needs and differing levels of health literacy and behaviours and that any reforms in this area need to accommodate this, as well as the implications of the digital age.
- Manufacturers would support exploring efficiencies that could be gained by moving to fully electronic CMI's and PI's or other tools to provide relevant, accurate and up to date information to those who need it.
- Medicines Australia is keen to work with the Department of Health, the TGA and relevant stakeholders to determine the most appropriate *source of truth* for consumer medicines information.

Conclusion

Medicines Australia commends the Review and its aim to provide "recommendations to support future Government decisions on the remuneration and regulation of community pharmacy (including wholesalers) in subsequent Community Pharmacy Agreements"[9].

Medicines Australia further supports "achieving arrangements which are transparently cost-effective for Government and consumers, financially sustainable, considerate of current and future expectations for the community pharmacy sector, and effective in delivering quality health outcomes and promoting access and quality use of medicines, in the context of Australia's NMP and the broader Australian health sector"[10]

Medicines Australia looks forward to further consultation with the Panel and thanks the Panel for considering this submission.

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[7] Therapeutic Goods Regulation 1990 viewed at https://www.legislation.gov.au/Details/F2016C00801
[8] Prescription Medicines manufacturers are prohibited from communicating directly with consumers (this is often referred to as 'direct to consumer' (DTC), and as such are bound by the requirements under the Therapeutic Goods Act (TG Act) and the Medicines Australia Code of Conduct
[9] Review of Pharmacy Remuneration and Regulation Discussion Paper p8
[10] Ibid p9

Responses to Specific Questions

Questions on Pharmacy Remuneration for Dispensing

In the following section, Medicines Australia responds to specific questions from the discussion paper where they have particular impact or interaction with manufacturers within the supply chain but is not an exhaustive examination of all factors that may affect sponsors of medicines. Medicines Australia will be happy to meet with the Panel to provide further detail or clarity if required.

Question 8. Is it appropriate that the Government continues to negotiate formal remuneration agreements with the Guild on behalf of, or to the exclusion of, other parties involved in the production, distribution and dispensing of medicines? If so, why? If not, why not, and which other parties should be involved? Is there currently an appropriate partnership with these other parties, including consumers?

- At present, there is a lack of transparency and clarity about each of the components of the 6CPA, yet it has a direct impact on supply and price and therefore directly affects the medicines industry.
- Agreements affecting the broader pharmaceutical supply chain should be explained to stakeholders, and wherever possible, they should be consulted with directly affected stakeholders.
- Future negotiations (such as for a 7CPA) should therefore include Medicines Australia.

Question 13. Is this requirement *[for paper prescription]* a significant impediment to online ordering and remote dispensing? If so, should this impediment be removed? In this scenario, what compensating arrangements would need to be implemented to ensure that there is appropriate oversight and control over dispensing and patient choice of pharmacy?

- We support appropriate take-up and use of new technology where it helps deliver more effective and efficient health outcomes. This includes alternatives to paper-based scripts.

Question 16. Should dispensing fee remuneration more closely reflect the level of effort in each individual encounter through having tiered rates according to the complexity of the encounter? For example, should dispensing fees paid to pharmacists differ between initial and repeat scripts?

- Overall, we consider that there would be considerable difficulty associated with the administration of tiered rates of remuneration if they are based on such things as the “complexity of the encounter” or the level of “effort” afforded to the dispensing of an initial versus repeat prescription; as it cannot be assumed that a repeat prescription is less complex. For example, dispensing a repeat prescription may bring added complexity where counselling is required on the patient’s initial response, contraindications or switching.
- However, the value-add, complexity of the interaction and patient benefit are important considerations when determining the appropriate and cost-effective remuneration for dispensing and services

Question 21. Is the Premium Free Dispensing Incentive achieving its intended purpose of increasing the uptake of generic medicines? Are there better ways to achieve this?

- We note that there are numerous considerations taken into account in determining the 'selection' of a medicine. Brand price premiums are a market-based mechanism allowing scope for patient choice in healthcare. Where patients are willing to pay a brand price premium, this choice should be appropriately accommodated.

Question 22. Should the timeframes for payment settlements for very high cost medicines be lengthened throughout the supply chain and mandated by Government?

- The timeframes for payment settlements for high-cost and very high-cost medicines should not be mandated by Government and/or lengthened throughout the supply chain.
- It is true that recent PBS listings of high cost drugs via S85 have raised issues associated with trading terms and supply arrangements for manufacturers, pharmacy and wholesalers. This has placed some pressure on the community pharmacy (and distribution) model. However, it was the flexibility in the current system that enabled affected parties to address these issues appropriately and in a timely manner.
- The current levels of flexibility in determining timeframes for payment, on a case-by-case, confidential and commercial basis, should be retained.
- We would further note that any reforms to the current arrangements need to be very closely examined to ensure they do not infringe Competition and Consumer Laws.

Question 24: Given that very high cost drugs are likely to become more common to the PBS, should this remuneration structure for hospitals change to more closely reflect the remuneration structure of community pharmacy?

- There are a number of concerns that manufacturers have raised with regard to the structure for remuneration and mark-ups dependant on the setting, (dispensing and wholesaling) that have led to notable unintended consequences for manufacturers and potential inequity for patients. These are detailed below. Medicines Australia would be happy to discuss these issues in more detail with the Panel should this be required

    i. There is a disparity in benefits paid by the Australian Government between medicines dispensed via hospital (S94) and community pharmacy; specifically that these costs are significantly greater for S94 dispensing than S90 for high priced medicines. In addition, current mark-ups at the wholesaler and pharmacy level are unclear under S85 and S94 public and private hospital pharmacies. It is unclear how and why different benefit entitlements are allocated and who receives them.

    ii. We understand that in some states the hospital pharmacies are the recipients of the 11.1 per cent mark-ups, not the wholesaler. This mark-up is not clearly identified as a 'wholesaler' mark-up in the relevant publicly available documentation. Our members may therefore be paying much higher *rebates* to the Australian Government than they need to with significant unintended consequences for local operating manufacturers.

iii. The dual listing of high-cost medicines under S100 and S85 has the potential to lead to inefficiencies in the healthcare system, due to misalignment in the mark-ups between hospital and community pharmacy when dispensed under S85. This can amount to several thousands of dollars for some high-cost medicines.

iv. Medicines Australia considers that it would be fair and equitable to ensure that remuneration, mark-ups, and distribution fees are consistent with the NMP and PBS principles. Fees should be consistent regardless of whether they are prescribed as a S85, S94 or S100 benefit.

v. The principle role of the pharmacist is one of dispensing and providing education and advice associated with medicines and their use. S94 pharmacy remuneration fee could be fixed or capped (such as occurs for community pharmacies) to ensure efficiency in the system and promote PBS sustainability

vi. The level of mark-ups is also unclear under the new S100 Community Access Program. The Program removes the requirement for patients and prescribers to be affiliated with a hospital setting. Whilst this gives patients the choice of where to access their medicines, the pricing mechanism for mark-ups in this setting is not as clear as for S85, creating uncertainties in what to charge and what to claim.

vii. The existence of S100 community access and S100 private access is becoming a bigger issue of concern (with some 34 per cent of S100 benefits now provided through community pharmacy.[11] This has created flow-on administration and funding issues, given S100 medicines are not afforded the same wholesaler mark-ups as Section 85 benefits (S85).

viii. The existence of S100s in community pharmacy means that there is no provision for the wholesaler fee, with the result that Medicines Australia companies are sometimes having to rebate the pharmacy or the wholesaler.

Question 30. Would it be preferable when a medicine is dispensed if advice given to consumers is remunerated separately; for example, through a MBS payment? Would this be likely to increase the value consumers place on this advice?

AND

Question 31. If an MBS payment for professional pharmacy advice was introduced, what level of service should be provided? Should the level of payment be linked to the complexity of particular medicines? Should it be linked to particular patient groups with higher health needs?

- All potential avenues of remuneration should be explored by the Panel, provided those avenues are consistent with the NMP and the PBS and the impact and unintended consequences are well understood and consulted upon.

Question 40. What pharmacy services should be fully or partially Government funded and what is best left to market or jurisdiction demands?

- Community pharmacy is not precluded from providing services to patients if there is an absence of subsidies. Some pharmacies have already differentiated their business model(s) to accommodate other non-subsidised services. Medicines Australia supports models that can respond to demand as long as

[11] Ibid p14

the impact and unintended consequences are well understood and consulted on.

Questions on Wholesaling, Logistics & Distribution Arrangements

Question 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?

- The NMP ensures that all Australians, regardless of where they live or their incomes, have timely access to the medicines they need, when they need them, at a cost that individuals and the community can afford.
- Medicines Australia does not believe that a *one size fits all* approach to medicines distribution networks would be efficient. Medicines Australia notes that medicines supply has been successfully achieved through various forms, including through direct-from-manufacturer supply arrangements.
- Where direct supply is possible, this represents an efficient, complementary arrangement to support access to medicines and allows businesses to remain flexible in response to the environment. However, direct-from-manufacturer supply arrangements cannot be implemented by all manufacturers, particularly manufacturers with specialty medicines, limited product lines, or small volume medicines.
- Direct-from-manufacturer supply arrangements should remain a complementary and case-by-case offering, rather than a mandated alternative to specialised wholesale business models.

Question 84. Is a percentage mark-up paid by the pharmacist an appropriate way to compensate wholesalers? Would an alternative compensation arrangement be preferred? If so, please provide details of preferred arrangements.

- Medicines Australia supports exploration of alternate models to the percentage mark-up paid by pharmacist for supply. In particular, with the falling prices of medicines through price disclosure, a fixed mark-up could be considered (as applies to high cost medicines, and as per the Administration, Handling and Infrastructure (AHI) fee pharmacists receive under the 6CPA) for CSO Distributors rather than a percentage mark-up.
- Equity principles must be observed so patients pay the same and have timely, continued access to medicines through pharmacies, wherever they are located. This is best achieved through regulation of supply arrangements with agreed fees or mark-ups.

Question 86: Should the onus for the delivery of medicines to community pharmacy around Australia in a timely fashion be imposed on the manufacturers as part of their listing requirements on the PBS?

- This questions intrinsically relates to the payment and reimbursement of manufacturers for the molecules that have been approved for listing on the PBS, and conditions of listing. Therefore, Medicines Australia suggests that it would increase regulation and increase inefficiency to make individual manufacturers responsible for the distribution of medicines as part of their PBS listing requirements. While sponsors could be funded to distribute out of the existing wholesale mark-ups, the oligopoly power of a small number of full-service wholesalers would be expected to lead to fees/charges exceeding the currently

regulated margin - with consequences for the viability of many lower-margin products.

- Further, as stated above, a one-size-fits-all approach cannot be applied to this issue. By way of example, Pfizer Direct is currently exploring initiatives to streamline ordering processes based on demand.
- The CSO funding pool recognises the high costs of distribution in rural and remote locations which are not adequately covered by wholesaler mark-ups. It would not be feasible to distribute a CSO-like pool across all sponsors and, without such funding, distribution to every pharmacy within Australia is likely to become unviable.

Question 89: The Panel notes that state and territory governments already tender for the supply of medicines to public hospitals, should the Commonwealth and state and territory governments work together for a single tendering model for relevant public hospitals and community pharmacy in the relevant state? If so, should it be for all medicines or specific medicines (e.g. biosimilar or generic medicines)?

- Medicines Australia supports the current architecture of the PBS, particularly the split in formularies F1 and F2, as they respect the different position of single brand (predominantly on-patent) innovator medicines compared to multi-brand, commoditised molecules.12
- The current PBS is working well and has contributed significantly to Australia's world-leading health care system and health outcomes. Medicines Australia does not support a broad-based single tendering model for PBS medicines as it would contravene the NMP and would have a negative impact on patient health outcomes.
- Policies leading to single or sole supply arrangements, which may arise in markets that tender for supply, introduces significant risks and potential for unintended consequences to the continuous supply of medicines for patients.
- Medicines Australia consider that the New Zealand experience demonstrates many downsides of single tender models and that these outweigh short-term cost-containment benefits.

[12] Department of Health, Formulary Allocations. See http://www.pbs.gov.au/info/industry/pricing/pbs-items/formulary-allocations