



Pre-Budget Submission 2023-2024

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ABOUT US

The National Pharmaceutical Services Association (NPSA) is the peak industry body representing full-line Community Service Obligation (CSO) pharmaceutical wholesalers in Australia.

NPSA Member companies have been supporting Australians for over 100 years and are solely dedicated to health logistics, providing a vital part of Australia's complex health infrastructure. We are the link between the manufacturers of medicines, vaccines and medical products and the community.

We have built and are continually enhancing a world leading, strong and agile system specifically to cater for Australia's medicine and medical product supply chain needs. Collectively we have invested more than \$750 million over the last decade alone, in state-of-the-art storage and distribution facilities, transport and a highly trained workforce nationally.

With eyes across the whole medicine supply chain in Australia the NPSA is uniquely placed to support all tiers of government to deliver health services to the community via the Pharmaceutical Benefits Scheme (PBS), National Diabetes Services Scheme (NDSS) and National Immunisation Program (NIP), improving access to healthcare for patients no matter where they live.

WHAT WE DO

SUPPORTING THE PBS AND OUR HEALTH SYSTEM EVERY DAY

The NPSA members deliver more than 371 million medicines to enable 5,600 community pharmacies to dispense 303 million PBS prescriptions annually, supporting equitable access to healthcare. Including non-PBS medicines and other healthcare products, NPSA members currently fulfil orders for more than 2 million units per day into community pharmacies.

These deliveries are achieved almost always within 24 hours of receiving an order, to anywhere in Australia, including rural and remote communities in every state and territory.

Additionally, we support our health system by delivering all medical devices under the NDSS.

The NPSA members underpin the National Return of Unwanted Medicines Program (NatRUM) ensuring safety and quality use of medicines.

Our members support government in times of crisis through their capability to adapt and meet the challenges of a growing number of extreme weather events. They have maintained medicine access to affected communities through bushfires and floods, power outages, storms and roadblocks.

Having visibility throughout the supply chain, NPSA is a vital source of information on medicine stock holdings and shortages across the industry and provides regular support to Government. NPSA members also manage medicine recalls and reporting to suppliers and Government.

COVID RESPONSE

During the height of the COVID-19 pandemic, our members managed unprecedented surges in demand, recording historic milestones in health logistics - distributing more than 70 million PBS medicines during March and early April 2020 representing an 80% uplift on normal PBS volumes.

NPSA members stepped into an industry leadership position, assisting government and supply chain stakeholders to actively manage medicine shortages, ensuring equitable access to critical medicines.

At very short notice our members managed supply issues and the complex and highly pressured distribution of Rapid Antigen Tests (RATS) and the newly approved COVID anti-viral medicines.

This was all on the back of seamlessly managing seasonal private market Flu Vax procurement, ordering, storage and distribution into community pharmacy during the height of the pandemic with virtually no product loss or spoilage.



INTRODUCTION

The NPSA welcomes the opportunity to provide this pre-Budget submission to the Treasurer. As Australia faces many challenges domestically and globally, community access to medicines has been the one service that has remained uninterrupted thanks to the innovation and commitment of our members to deliver 24-hour access to PBS medicines wherever and whatever the circumstances.

Our members' network underpins the National Medicines Policy which aims to improve health outcomes for all Australians however, the capacity to deliver this quality and reliability of service is being put at risk.

We take this opportunity to provide recommendations for consideration in relevant Government programs, operations and funding models. These recommendations have been developed partly from the learnings from the last three years which highlighted the essential need to ensure a reliable and sustainable medicine supply chain - a service our members provide both to the community and Government that is often taken for granted but in times of crisis is fundamental to our country's response.

On that basis the NPSA is seeking support for the following policy and program reforms as part of the 2023-24 Budget process:

Recommendation 1:	Improve Australia's Emergency Management response
Recommendation 2:	Continue making medicines affordable for all
Recommendation 3:	Improve Health Regulations to ensure medicines are accessible and safer for all
Recommendation 4:	Improve affordability and uptake of COVID-19 vaccines by moving their access and supply the National Immunisation Program
Recommendation 5:	Collaborate with industry to avoid funding a very expensive and highly duplicative National Medicines Traceability Framework
Recommendation 6:	Honour Government funding commitments under the Seventh Community Pharmacy Agreement



Recommendation 1:

Improve Australia's Emergency Management response by:

1. Establishing a Health Logistics Supply Chain Advisory Group within the National Emergency Management Agency (NEMA)
2. Strengthening investment and support in the Pharmaceutical Benefits Scheme (PBS) Community Service Obligation (CSO) for 24-hour delivery of medicines nationwide
3. Embedding the capacity of the CSO suppliers in the administration and delivery of the National Medical Stockpile
4. Establishing a permanent Medicines and Devices Supply Chain Shortages Advisory Group within the Department of Health and Aged care (DOHA)

Australia is working hard to manage natural and critical disasters and their impacts on the community but the prevalence of these events remains high. Therefore, it is important that Government, business and community planning focuses on the actions we take when these events occur.

The NPSA members have consistently provided 24 hour access to medicines for the Australian community through floods, droughts, bushfires, and pandemic crises. This is possible through the continued investment in our infrastructure, including some \$750M over the last five years, to deliver the PBS's Community Service Obligation. Our disaster recovery and crisis management experience is continually utilised to support Government in delivering healthcare during good times and bad. We want to offer that knowledge and experience alongside other logistics experts to improve Australia's critical response capacity.

The NPSA is calling on the NEMA to establish a permanent and regular advisory group with the health logistics sector, in particular the medicine supply chain including NPSA as a key member of this advisory group, to provide a unified response in times of crisis management. This would allow Government to capture lessons learned from the ongoing responses by our members to floods, bushfire and pandemic to further public policy development and support public and private future investment in response capability.

Recognising the foresight and value of the Government's investment in the capacity of Australia's medicine supply chain to ensure timely access to medicines consistent with the [National Medicines Policy](#), the NPSA is calling upon the Government to ***maintain and expand the PBS CSO to ensure the Government's strong record on access to medicines in times of crisis and irrespective of location.*** Over 300 million medicines are accessed annually within 24 hours under this arrangement.

Recognising the positive impact, the CSO has had on Australia's preparedness for disaster and crisis responses, the NPSA calls on the Government to ***reassess the management of the National Medical Stockpile and how it can be integrated into the well-established logistics chain for medicines and devices in Australia.*** The opportunity to refresh stock, reduce expiration without use and leverage an already efficient supply chain network across Australia's primary and acute care health system, as well as local government, aged care and defence force locations, represents a prime opportunity for efficiency and better service and support.

And with the increasing risks associated with medicine supply shortages and management in Australia, the NPSA is calling on the ***DOHA to establish a permanent advisory group with the medicines and devices supply chain including NPSA as key member to proactively manage the risks associated with shortages of supply of imported and relied upon healthcare.*** Since COVID-19, NPSA members have helped ensure equity of access to medicines in short supply and have proactively forewarned of trends in use of medicines that put patient access at risk. It is no longer adequate to rely on ad-hoc advice from the sector, the health system needs to formalise its partnerships with its service providers to be proactive in the management of future and current medicine and device shortages.



Recommendation 2:

Continue making medicines affordable for all

1. Reviewing the s100 and s85 arrangements for accessing medicines on the PBS to ensure they are accessible for patients and affordable to supply under those arrangements

The NPSA notes the Government is currently reviewing the Health Technology Assessment that underpins access to medicines on the PBS. Increasingly, medicines previously available under s100 in the acute care setting need to be made available under s85 in the primary care setting, via community pharmacy.

Whilst s100 listings are cheaper for Government, they are a burden to the community for ease of access where a condition is stable and chronic. Previous moves to improve access to these medicines via community pharmacy has been done without the Government paying for the appropriate supply chain service: dispensing fees, wholesale mark-up fees and the assurances and protections of the PBS CSO.

The NPSA is calling on the Government as part of this HTA review to not only put patient access first as part of its review process, but ensure that in improving patient access it remunerates the full supply chain appropriately. Access is more than just the medicine



Recommendation 3:

Improve health regulations to keep medicines accessible and safer for all

1. Registering vaping devices used for smoking cessation as a therapeutic good and held to the same standards as other prescribed smoking cessation therapies currently supported and supplied through community pharmacy to ensure access, safety and reduction in black-market supplies

The NPSA supports the work underway by the TGA to review the supply, use and potential diversion of nicotine vaping products (NVP) in Australia.

Successive Governments have supported access to NVPs as a healthcare product – that is, for the potential to support smoking cessation or reduce the adverse health impacts of nicotine through the traditional delivery mechanism of a cigarette, and to improve controls of importation of NVPs for other uses.

Based on this healthcare objective, the NPSA supports the registration of NVPs as therapeutic goods, requiring them to meet and comply with regulatory standards and to improve control of the products imported and circulated in Australia.

The NPSA has managed the supply of other nicotine replacement therapies (NRT) via community pharmacy as both a prescribed and on the shelf product. Making these products a registered good would capture these products under the same standards of supply and distribution as well as the same standards of demonstrated clinical efficacy and safety as per other NRT products used in Australia to help manage nicotine addiction.

This approach would reduce some of the administrative burden of the current arrangements seeking to minimise diversion and support the costs of increased border controls proposed on the import and onshore management of these products – striking the balance of access for healthcare, with protection against the increasing risks associated with uptake of NVPs in young children and adolescents.¹

¹ Therapeutic Goods Administration, [‘Proposed Reforms to the regulation of nicotine vaping products, consultation paper’](#), Canberra November 2022, accessed 20 January 2023



Recommendation 4:

Improve affordability and uptake of COVID-19 vaccines by moving their access and supply to the National Immunisation Program

1. Australia's NIP is a highly efficient and effective model for determining access, encouraging uptake and ensuring supply of approved vaccines.
2. The duplication in costs and effort to separately supply the COVID-19 vaccine needs to stop, freeing up those costs for investment in other programs

The Halton Review of '[COVID 19 Vaccine and Treatment Purchasing and Procurement in September 2022](#)' recommended that: "Vaccine distribution arrangements should be reviewed in order to test value for money and reduce wastage while ensuring timely access".

This is based on the following observations from that report:

- The need to mitigate the effects of COVID-19 is likely to remain. However, policy settings have not been updated to take account of already widespread COVID-19 infections and associated high levels of hybrid immunity, the possibility of future waves and variants, and developments in vaccine and therapeutic science and manufacturing.
- A portfolio approach and potentially redundancy will be needed to ensure access. This context continues to present real challenges in decision-making in respect of procurement of, eligibility for, and distribution of both vaccines and treatments. Supply chain issues remain with potential shocks or spikes in demand hard to estimate.
- Pre-pandemic structures and processes were not fit for purpose in an emergency context. With the likelihood of continuing waves of COVID-19 and the need for ongoing, integrated advice, new advisory structures and mandates will be required. It is timely to consider the role and nature of existing structures and processes; and
- Utilise existing and established distribution channels (primary care including general practice and pharmacies, and states and territories) and maintain capacity to ensure distribution of vaccines can be scaled up rapidly in the event of a need for high levels of vaccination for a new more virulent variant.

COVID-19 treatments were quickly moved from the National Medical Stockpile to the PBS with access through community pharmacy. Delays in moving the COVID-19 vaccines to the NIP will continue to cost the Government in duplication and complexity of supply chain arrangements, and costs in patient uptake with the need for the community to accept the vaccine as part of the standard NIP arrangements in Australia based on the best clinical advice of the [Australian Technical Advisory Group on Immunisation's](#) (ATAGI) advice.

Australia's NIP has a demonstrated capacity to deliver across multiple sites, multiple jurisdictions and to support ordering and stock management that helps de-risk the processes for the Commonwealth and the states and territories.

NPSA is calling on Government to work with the existing medicine distribution network who have capacity and capability to tool up and manage the requirements for all COVID vaccines – frozen or cold chain.

Placing the COVID-19 vaccines on the same operational and supply chain platform as other vaccines on the NIP, with an appropriate contingency for scale-up in terms of crisis, would be consistent with the management and support of the current access to the annual flu shot in Australia – both in the public and private access systems.



Recommendation 5

Collaborate with industry to avoid funding a very expensive and highly duplicative National Medicines Traceability Framework

1. Device listings, acute care, and aged care has never been higher. No money should be unnecessarily diverted from these priorities.
2. Australia has a very low rate of counterfeit medicine due to the existing controls and tracking within the medicines supply chain.
3. Medicine recalls and on shore shortages are capably being managed by the current supply chain with no cost impost on Government.
4. Adoption of track and trace from manufacture to dispensing has proven to be an extremely expensive and often unsuccessful change overseas, leading to delays in access to medicines for patients, particularly where it impacts on the supply chain between the manufacturer to receipt by the pharmacy.
5. The priority should be to make use of existing infrastructure based on the assessment of the risk points in the supply chain which are deemed to be extremely low and waste no more of the Government's finite health resources on this program.

The Government through the Therapeutic Goods Administration (TGA) in partnership with the Technology Assessment and Access Division (TAAD) in the Department of Health and Aged Care (DOHA) has been consulting on the introduction of a national track and trace framework for over three years. This extended timeframe reflects the complexity and risk and costs for Government and the supply chain.

The consultation commenced shortly after the Government was unable to implement its 2018-19 Budget measure to [‘improve payment administration’](#) of special price arrangements on the PBS.²³

Consultation during this time has consistently elicited evidence that Australia currently manages the areas of “risk” with competency and at minimal risk to the patient – and as importantly NO additional cost to Government. There is no problem to solve for patient safety. This reflects the already rigorous systems and security in place within the entire supply chain for the control of medicines into Australia, and their movement around Australia to the point of dispensing.

Proposing this new standard for use throughout the supply chain will not only compromise timely access to medicines, but it will also set aside the last five to ten years of infrastructure investment that underpins that access. The current Government standard for service delivery is 24-hour access for a patient to almost any medicine regardless of where they live. This is based on a payment regime that has consistently devalued the cost of supply of each medicine over the past ten years. It has made no allowance for inflation, higher numbers of high care drugs being transported and increasing volumes of medicines – now over 310M annually.

The cost of implementing this proposed framework is too high for Government, too high for consumers and too high for the sector when there are so many other shortfalls in investment in the health system at this time.

The Government should put the track and trace project on hold and based on the risk assessment for counterfeit and diverted medicines supply versus the risk assessment of access to practitioners and diagnostics, focus its attentions and additional resourcing in this area alongside appropriate funding of the wholesale mark-up and Community Service Obligation, to ensure the continued quality of access and control the sector has been providing for the last decade.

² Australian Government, [‘Budget Measures, Budget Paper No.2 2018-19’](#), 8 May 2018 page 112

³ Australian Government, [‘Budget Measure, Budget Paper No.2 2020-21’](#), 6 October 2020, page 99



Recommendation 6:

Honour Government funding commitments under the Seventh Community Pharmacy Agreement

1. Urgent correction of the floor price calculation for multiple pack low value items in the Legislative Instrument which is inconsistent with the Government's policy commitments in the seventh community pharmacy agreement.
2. Urgent correction of the current Wholesale Mark Up calculations that are being undertaken inconsistently with the relevant Legislative Instruments
3. Return of funds not provided as a result of agreement with the medicines sectors

As part of the 7CPA the former Government, with Labor's support, recognised the considerable work wholesalers do to ensure 24-hour access to medicines Australia-wide. This came after our largely unseen work supporting the response to the fires of 2019-20, the floods of 2020 and the COVID medicines access crisis of 2020. We continue that work today as floods continue to devastate parts of Australia and interrupt their critical supply chains.

During the 2019/2020 7CPA negotiation process Government acknowledged that the medicine distribution network required stability and investment. In recognition the 7CPA included the introduction of the floor price WMU recognising that over 82% of PBS items distributed by wholesalers are priced at less than \$15 and that a calculation based on a percentage of the value of the medicine no longer reflected the true cost of distributing that medicine.

The introduction of this floor price WMU was partially offset by the NPSA's offer to lower the ceiling price WMU reflecting an expected net additional investment of \$82M over the life of the Agreement. It was a genuine attempt to risk share the cost of distributing medicines around a country as large as Australia and yet with a population one third of the UK.

However, the Government has applied an incorrect formula resulting in copious medicines attracting an even lower WMU than they had before the floor price was introduced. It is in contradiction with the principles committed to in the 7CPA and is in direct contrast to the increasing costs of all supply chains in Australia from fuel to food.

The Government must honour the commitment in the 7CPA to a genuine floor price WMU for all low cost medicines to continue to make them viable to distribute to pharmacies.

This latest WMU error builds on the ongoing mistakes since 2014.

Calculations of the WMU on hundreds of PBS items have been inconsistent with the Legislative Instrument legislating the basis of the calculation since the CSO Deeds were introduced. **These errors in law are resulting in underpayments on average of around \$27million annually.**

The Government must also compensate for the further losses being incurred by the medicine supply chain as a result of the price cut agreements negotiated with the medicine suppliers and without consultation with the supply chain.



With some 1000 items reducing on 1 April 2023, the % value of their WMU will automatically reduce. Further losses to the agreed value of the 7CPA for wholesaling are expected based on the new application of price disclosure discounts to molecules not discounting based on the government's capacity to transfer the percentage discounting on medicines price less than \$4.50 to any other F2 medicine. Noting current generic supply contracts often offer a guaranteed discount or rebate to purchasing pharmacies over the breadth of the portfolio, this impact is going to be considerable for our members.

At the time of the 7CPA such a magnitude of price cuts was not discussed or disclosed to the NPSA who negotiated in good faith a new set of arrangements to keep the medicine supply chain viable in Australia.

All up, NPSA members are already facing a shortfall of around \$90M over the life of the Agreement as a direct result of the floor price WMU error, the catch-up price reductions and the ongoing risks of price disclosure.

This is before the historical annual losses of around \$27million are considered.

The Government must correct the errors and stop the underpayments immediately and compensate the companies who have been underpaid as a result of these errors.

The Government must also look at reforms to compensate for the further erosion of the payments for supply as a result of the medicines agreements and their failure to recognise once again the true cost of supply.

CONCLUSION

In conclusion the NPSA is committed to partnering with Government to share knowledge and expertise in health logistics. We have recommended specific areas where our contribution to planning and action will positively impact many areas of risk and ongoing challenge both environmentally and economically for our country.

We have also recommended that opportunity to re-design the vaccine supply chain in conjunction with the NPSA members investing in upscaling capability as required. The NPSA is confident that Government will deliver significant savings that can be redeployed to other health portfolio areas of need.

This willingness of NPSA to collaborate on building a more effective and efficient health system is offered with the backdrop of an ongoing dispute with the Department of Health over errors in wholesale margin calculations and medicine agreement impacts which must be considered in the context of this budget – prior funding agreements must be honoured and in good faith the NPSA seeks these matters to be addressed and resolved.

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