SHPA NSW Branch Submission on the Draft *Medicines, Poisons and Therapeutic Goods Bill 2022* (NSW) – June 2022

The Society of Hospital Pharmacists of Australia (SHPA) is the national, professional organisation for the 6,100+ Hospital Pharmacists, and their Hospital Pharmacist Intern and Hospital Pharmacy Technician colleagues working across Australia's health system, advocating for their pivotal role improving the safety and quality of medicines use. Embedded in multidisciplinary medical teams and equipped with exceptional medicines management expertise, SHPA members are progressive advocates for clinical excellence, committed to evidence-based practice and passionate about patient care.

SHPA members lead Pharmacy Departments and are in leadership and management positions in hospitals across Australia. SHPA members are also employed in a range of innovative outreach and liaison services in community healthcare settings. SHPA NSW Branch welcomes the opportunity to make a submission to this consultation. For further information or to discuss our submission further, please contact Jerry Yik, Head of Policy and Advocacy, jyik@shpa.org.au.

4. Key provisions of the Draft Medicines, Poisons and Therapeutic Goods Bill 2022

4.1. Objects and Guiding Principle (section 3)

Question 1:

Should any changes be made to the objects and the guiding principle in the Draft MPTG Bill?

SHPA accepts in principle the objectives of the Draft MPTG Bill.

4.2. Adoption of the National Poisons Standard (section 6)

Question 2:

Do you have concerns about NSW automatically adopting the Schedules of the National Poisons Standard?

SHPA does not hold objection to NSW automatic adoption of the Schedules of the National Poisons Standard.

SHPA supports in principle national uniformity under a National Poisons Standard to facilitate and assist with consistency in the operational aspects of medicine management between jurisdictions.

5. Regulation of supply, prescribing and other activities (Chapter 2)

5.1. Wholesale supply (Part 2.2 and 3.2)

Question 3:

(a) Are the controls in relation to wholesale supply appropriate?

SHPA strongly holds that pharmacists from a public policy perspective should remain legislative caretakers and license holders of scheduled substances in administering the Act including wholesale supply provisions.

SHPA notes the proposal to effectively by-pass pharmacy licensing in a number of wholesale supply areas to external pharmacy business administrators and listed entities would effectively deregulate medicines governance.

External business administrators and listed entities are not subject to independent professional standards and liabilities enshrined in national health practitioner laws. These professional laws independently impose and mandate professional and personal obligations and liabilities in managing scheduled substances which are in addition to the requirements under the MPTG bill. These independent mandates provide necessary support to ensure the Bill is appropriately administered and that governance is paramount over any conflicts of interest which may arise and inherent with external administrators of a pharmacy business.

SHPA sees no true barrier in licensing authorized pharmacists or pharmacies for listed entities or external administrators of pharmacy businesses in the wholesale supply and management of scheduled substances, in which entities would still be required to provide effective management and oversight by pharmacists anyway. SHPA raises concerns over not being presented with data to support reasons for the change on any public policy grounds.

SHPA also raises concerns that deregulating oversight to those who are not subject to the same independent professional standards and liabilities as enshrined under national health practitioner laws would compromise the administration of the Act and be in conflict with the Act's purpose to ensure health and safety of the public. SHPA highlights that *issues do arise when pharmacists are not involved* in medicines management, as can be seen from the recent Royal Commission into Aged Care Safety and Quality, the recent Inquiry into Health outcomes and access to health and hospital services in rural, regional and remote New South Wales, and a number of NSW Health inquiries into chemotherapy dosing. SHPA submits that by-passing pharmacy wholesale supply licensing will lead to public policy safety issues including the safety and other costs to society which should be avoided.

SHPA urgently seeks further consultation on this part of the proposal and further opportunity to gain clarification to appropriately address such a significant change in legislation.

Supply between private hospitals, public hospitals and other health service entities.

In practice medicines need to be shared across health services including between private and public facilities. Pharmacy licensing is central to effective governance and administration of the proposed Bill. The transfer of medicines from one hospital pharmacy to another may be required in times of supply chain shortages or unexpected therapeutic demands critical to patient care. These practices assist hospitals to minimise unnecessary medicine wastage, more effectively manage stock levels and enable better responses critical to patient care. This includes between public hospitals, between private and public and from private pharmacies to private hospitals.

The Act should appropriately reflect within a pharmacy's poisons license the ability to undertake such practices which are appropriately governed and highly controlled. This is to avoid the unnecessary separation in stock management to comply with the current wholesale provisions of the Act which do not align with modern-day practice, i.e. private hospital pharmacy entities need to separate wholesale stock to hospitals and other stock held under a poisons license. NSW law is currently inconsistent and out of step with other jurisdictions, is cumbersome and does not adequately reflect current supply chain practices between private pharmacy suppliers contracted to provide pharmacy services to hospitals. The proposed Bill needs to amend wholesaling licensing / pharmacy poisons license to permit the ability supply between these entities.

SHPA welcomes revision and clarity around the transfer between registered hospital authorities be it private or public hospital pharmacies for limited and emergency circumstances. Legislative frameworks should consider the supply of medicines from both public and private hospital pharmacies to outreach and primary care services to better reflect and adapt to current and future models of healthcare delivery and medicine management. This is pertinent in the context of health system pressures and the relationship between hospitals and primary care where pharmacy licensing retains oversight of wholesale supply.

(b) Should external administrators of a pharmacy business be able to wholesale supply in limited cases?

External business administrators are not subject to independent professional standards and liabilities enshrined in national health practitioner laws. These professional laws independently impose and mandate professional and personal obligations and liabilities in managing scheduled substances which are in addition to the requirements under the MPTG bill. These independent mandates provide necessary support to ensure the Bill is appropriately administered

and that governance is paramount over any conflicts of interest inherent with external administrators of a pharmacy business. As per the response in question 3(a), SHPA recommends maintaining pharmacist licensing and oversight on various public policy grounds in order to maintain the object and purpose of the MPTG Bill. There are no effective or practical barriers in which independent pharmacy supply licensing should be removed. There has been no real evidence to support the proposal on why pharmacists or pharmacies would not be able to effectively be engaged in the circumstances that were presented in the discussion paper.

(c) Are the provisions relating to Schedule 7 substances and wholesaling appropriate?

SHPA supports the proposition to introduce a license to supply Schedule 7 substances and prohibit wholesale supply for domestic use.

5.2. Obtaining a wholesale supply of medicines (Parts 2.3 and 3.2)

Question 4:

a) Are the provisions in relation to obtaining a wholesale supply of scheduled substances appropriate?

SHPA strongly holds that pharmacies must remain legislative caretakers in the administration of the Act as outlined in question (3).

SHPA welcomes the change to improve transparency in relation to the supply of wholesale medicines by a person or authorised entity to better reflect actual supply chain mechanisms which exist in highly controlled environments such as hospital facilities, ensure that pharmacy remains central in the management of scheduled substances.

b) Is the list of organisations that would require a license before being able to obtain a wholesale stock scheduled substances appropriate?

SHPA welcomes the list of entities recognized but maintains the need for pharmacy oversight in the wholesale supply of specified scheduled substances or other prescribed therapeutic goods as discussed in questions 3(a) and (b).

SHPA puts forward consideration for areas where service delivery and medicines management may occur beyond public hospitals I.e. outreach services.

c) Are there other entities that should be eligible to apply for an 'obtain license'?

Other entities may include private healthcare services or outreach programs where the primary purpose is the delivery of health care services which involve medicine management, in which they may obtain original supply from a pharmacy to onward supply to a patient.

d) Are there other means by which entities should be able to receive medicines?

SHPA does not currently propose any other means but rather authorised pharmacists should be more actively engaged where future need arises.

5.3. Prescribing and supply (Parts 2.4, 2.5, 3.3, and 3.4)

Question 5:

Do you have any comment on the prescribing and supply provisions under the Draft MPTG Bill?

SHPA believes the bill should incorporate and recognise pharmacists in prescribing and supply provisions. Pharmacists are currently permitted and actively being engaged under emergency orders to supply and prescribe vaccines and schedule 2 and 3 medicines.

The Pharmacy Board of Australia recognizes prescribing of medicines to be within a pharmacists' scope of practice, which could be enabled where appropriate upon the approval of the NSW Health Secretary but must first be included within the proposed bill to have the option in the future to do so, as is the case with other allied health practitioners.

SHPA makes mention of pharmacists' ability to prescribe scheduled 2 and 3 medicines and vaccines under emergency orders which shows how effective and necessary pharmacy is in delivery of care. Further the increasing roles of pharmacists seen with partnered prescribing medication charting in NSW hospitals is consistent with other jurisdictions around the country and form part of required skillsets in the health workforce particularly in light of current pressures and ongoing health workforce shortages. The Bill needs to be able to facilitate the real likelihood of future pharmacist prescribing which would still be regulated by the requirement of Health Minister endorsement and approval under NSW National Health Practitioner laws in line with other allied health professionals enabled to prescribe under the Act.

5.4. Administration 7

Question 7: (This question is presented before question 6.)

a) Are there any issues relating to the controls on administration under the Draft MPTG Bill?

SHPA also sees benefit in acknowledging standards in which authorised persons or facilities would undertake administration of medicines. SHPA notes the difficulties and cross-over which occurs with patients and carers administering medicines within these settings. SHPA suggests including an exclusion provision as part of the definition of administration to address the complexities mentioned as is done in other pieces of legislative drafting.

b) Do you support the Draft MPTG Bill explicitly excluding administration from the definition of

supply?

Although SHPA does not strictly oppose its exclusion from the definition, SHPA sees real benefit in including or at least recognising a definition of administration separate to the definition of supply to properly reflect actual practices which hospitals must regulate for at a local level.

Again, SHPA notes the difficulties mentioned in the consultation and suggests including an exclusion provision to address the complexities mentioned.

5.5. Registration scheme to prescribe or supply for Opioid Treatment Program (Part 3.4)

Question 6:

Is registration scheme sufficient control in the administration, prescribing and supply of methadone or buprenorphine under the OTP?

SHPA does not note any objection to the proposed registration scheme and welcomes the streamlining of processes.

6. Dealing with public health risks and responding to serious safety risks

6.1. Responding to public health risks (Part 7.4)

6.2. Responding to serious safety risks (Part 7.4)

Question 8:

(a) Are the new powers relating to public health risk authorisation orders appropriate?

SHPA does not note objection.

(b) Are supply prohibition orders, which enable the Secretary to restrict supply of substances pending evaluation of their risk, appropriate?

SHPA supports in principle both the powers for public health risk authorisation and prohibitions to restrict supply of substances pending appropriate evaluation but seeks to address that in the first instance, pharmacy remains the primary point of call in an emergency as has been seen in recent floods and fire emergencies to be the most robust system of ensure public safety.

7. Investigation, penalties, enforcement, and compliance (Chapters 5 and 6)

Question 9:

Do you support the introduction of PIN offences and Compliance Notices as additional enforcement tools?

SHPA in principle supports the introduction of PIN offences and compliance notices to better enforce legislative requirements with commensurate response.

7.1 Authorised officer powers

Question 10:

Are the proposed powers of authorised officers appropriate?

SHPA limits its response in the support of the proposed powers which appear wide in scope and beyond what may be considered necessary without particulars around safeguarding the balance of other inherent public rights.

There is a lack of specificity in which the powers may be exercised and has the potential for wider than necessary interpretation. It is hard to ascertain why current criminal laws do not adequately enable a similar outcome.

8. Drug Misuse and Trafficking Act 1985 interaction (Schedule 4 of Draft MPTG Bill)

8.1. Moving offences to the Drugs Misuse and Trafficking Act 1985 and new offences relating to "prohibited scheduled substances"

Question 11:

Are there concerns about including offence in the DMTA in relation to prohibited scheduled substances?

SHPA limits the support for including DMTA offences being applied in relation to prohibited scheduled medicines as not necessarily commensurate in all circumstances in which an offence would be deemed and should not be left for sole interpretation by the courts. There appears to be grey areas not well articulated within the Draft Bill. Suggest permitting provisions which allow for honest inadvertent breaches to be deemed an offence.

8.2. Drug Misuse and Trafficking Authorities (Part 3.5)

Question 12:

Are there any circumstances when a DMT authority is required for a purpose other than medical or scientific research, or for analytical, teaching or training purpose?

SHPA foresees there may be appropriate circumstances not able to exhaustively be articulated in which DMT may be required, such as those which may not be included under wholesale supply and similar.

9. Regulatory Advisory Committee and Clinical Advisory Committee (Part 7.1)

9.1. Regulatory Advisory Committee

9.2. Clinical Advisory Committee

Question 13:

a) Are the functions and membership composition of the Regulatory Advisory Committee appropriate?

The MPTG Bill represents the main legislative framework in which hospital pharmacy operates in managing scheduled substances. Hospital pharmacists are integral to the Bill's effective administration. It is hospital pharmacy who manages and who are charged with the operational aspects of medicines in hospitals to which this Act applies and who can understand wider implications to changes in the Act.

SHPA proposes hospital pharmacy representation as part of the Regulatory Advisory Committee.

SHPA supports a skill-based membership of the Committee but with the inclusion of hospital pharmacist representation.

b) Are the functions and membership composition of the Clinical Advisory Committee appropriate?

SHPA strongly advocates for the inclusion of specialist pharmacists within the Medical Committee in recognition of the functions and skills which currently relate to the prescribing or supply of scheduled medicines.

10. Regulation-making power

10.1. Restrictions on prescribing and supply

10.2. Manufacture

Question 15:

Are there any other manufacturing activities that should be regulated under the Draft MPTG Bill?

SHPA welcomes the change to no longer require a Schedule 8 manufacturer to be licenced within NSW and accepts the adoption of Cth laws. SHPA also acknowledges the ongoing ability of NSW to identify any local risks and regulate necessary controls as required.

SHPA additional comments:

SHPA would like to bring attention to Part 2.8 section 52 (pg. 20) which states:

"sterile compounded preparation means a compound of substances, whether or not containing scheduled substances, prepared for the purposes of
(a) an injection, except an intradermal or subcutaneous injection of an allergen extract, or

(b) use in connection with an ophthalmic application.

SHPA highlights that this definition is no longer fit-for-purpose in modern day compounding as it fails to include products for application to wounds and broken skin, certain otic preparation, as well as solutions for irrigation of bodily cavities (e.g. urinary bladder irrigations), implants, and more.

Products within this definition are not able to be exhaustively listed.

SHPA therefore proposes the addition of subsection (c) other medicines that must be administered sterile.

SHPA recommends the updating of this provision to meet modern practices in sterile compound products in practice.

10.3. Regulation of advanced therapies including biologicals

Question 17:

Are there other goods that should be regulated under the Draft MPTG framework?

SHPA supports the inclusion of advanced therapies including biologicals as part of the regulation making power under the Draft MPTG. SHPA foresees the need to encompass future and evolving technologies and scientific advances in this space.