REVIEW OF MEDICINES AND MEDICAL DEVICES REGULATION SUBMISSION COVER SHEET

Please complete all parts of this document, sign it, and attach it to your submission.

1. Contact information

Name and work title	Dr Sasha Bennett – Executive Officer, NSWTAG and SHPA Federal Councillor
Organisation	NSW Therapeutic Advisory Group The Society of Hospital Pharmacists of Australia (SHPA)
Contact email address	nswtag@stvincents.com.au
Contact phone number	02 8382 2852

2. Consent to publish on the internet

It is the intention of the Panel to publish submissions that it receives, along with the name of the individual or organisation that made the submission, on the Review's webpage, located on the Department of Health website. Please indicate your willingness for your details to be published on the website by checking the appropriate box below.

☒ I CONSENT to the attached submission being published in its entirety on the Department of Health website.

☐ I CONSENT to a redacted version of my submission being published on the Department of Health website. If you check this box please provide a copy of your submission with the information you do not want to be published redacted and clearly mark the submission *Redacted for Publication*.

☐ I CONSENT to my name (if an individual) **or** the name of my organisation being included in a list of submissions received on the Department of Health website but **do not consent** to any part of my submission being published on the site.*

☐ I DO NOT CONSENT to any information about my submission, including my name or the name of my organisation, being published on the Department of Health website. *

Signature____A.A. Bennett___ Date___7/1/15_____

***NOTE:** The Panel will consider submissions in formulating its report to Government and may cite particular submissions. If your submission contains confidential information that cannot be cited, please clearly mark these parts of your submission as 'in-confidence'.

REVIEW OF MEDICINES AND MEDICAL DEVICES REGULATION SUBMISSION COVER SHEET

Please complete all parts of this document, sign it, and attach it to your submission.

1. Contact information

Name and work title	Ms Helen Dowling – Chief Executive Officer, SHPA
Organisation	The Society of Hospital Pharmacists of Australia
Contact email address	hvdowling@shpa.org.au
Contact phone number	03 9486 0177

2. Consent to publish on the internet

It is the intention of the Panel to publish submissions that it receives, along with the name of the individual or organisation that made the submission, on the Review's webpage, located on the Department of Health website. Please indicate your willingness for your details to be published on the website by checking the appropriate box below.

☒ I CONSENT to the attached submission being published in its entirety on the Department of Health website.

☐ I CONSENT to a redacted version of my submission being published on the Department of Health website. If you check this box please provide a copy of your submission with the information you do not want to be published redacted and clearly mark the submission *Redacted for Publication*.

☐ I CONSENT to my name (if an individual) **or** the name of my organisation being included in a list of submissions received on the Department of Health website but **do not consent** to any part of my submission being published on the site.*

☐ I DO NOT CONSENT to any information about my submission, including my name or the name of my organisation, being published on the Department of Health website. *

Signature_____ Date___9/1/15_____

***NOTE:** The Panel will consider submissions in formulating its report to Government and may cite particular submissions. If your submission contains confidential information that cannot be cited, please clearly mark these parts of your submission as 'in-confidence'.

3. Abstract

This joint NSW TAG / SHPA submission is provided in six sections with issues and recommendations provided under each section. We have primarily focussed on medicines but believe that many of the same principles and possible solutions apply equally to devices and blood products. References have been provided that both SHPA and NSW TAG believe will be useful for the Panel's consideration.

Section 1 concerns the use of a 'trusted regulator' with regard to informing marketing approvals of new chemical entities. We discuss the issues to be considered when steamlining approval processes and using adaptive regulatory frameworks, in particular the accompanying need for augmentation of post-marketing surveillance. We have suggested criteria in order to be considered a 'trusted' regulator, and discuss the possible consequences for Australia of using a 'trusted' regulator. We note current gaps in pharmacovigilance and discuss the TGA's role with regard to oversight of non-marketed medicines. Recommendations with regard to potential changes to the regulatory framework for medicines in Australia have been provided. These include increased post-marketing surveillance (accompanied by a review of national and international post-marketing surveillance programs); consultation with experts in genetic variation, front-line clinicians and consumers; modelling of issues prior to adoption with subsequent staged approach to adoption of trusted regulator's recommendations if modelling results are positive; pro-active exploration of electronic reporting systems; and further recommendations regarding use of off-label medicines, online learning modules and non-pharmaceutical sponsorship.

Section 2, the role and function of the Poisons Schedule and Scheduling Decisions, discusses the perceived gaps in scheduling evaluations, issues identified regarding state and national scheduling, and provides recommendations to improve scheduling and rescheduling of medicines and chemical substances, whether or not they are currently synthesised.

Section 3 discusses the Special Access Scheme (SAS) and using scenarios faced specifically by NSW hospitals (and likely faced by hospitals in other jurisdictions), highlights the current flawed system and offers solutions to these issues including the use of an online approval system; what this should include and be able to provide; as well as recommendations for monitoring of SAS product applications.

Section 4 regarding direct to consumer advertising (DTCA) of Schedule 3 products includes a literature review of the evidence for its benefits and harms; our recommendations that DTCA not be allowed; that provision of product information be improved; and that handling of complaints regarding advertising be handled by the TGA.

Section 5 discusses transparency and accountability of the Therapeutic Goods Administration (TGA). This highlights experiences of NSW TAG members, in particular, when sending issues to the TGA and the lack of clear pathways for follow-up and acknowledgment by the TGA. A recommendation with regard to how the TGA should manage such a situation is provided. We also highlight difficulties experienced when the TGA has not consulted frontline clinicians prior to approving packaging and labelling changes.

Finally, Section 6 deals with another potential 'red tape' issue which we would like explored.