

Response
<p><b>2</b></p> <p>The Department may, at its discretion, publish part or all of the information provided in your submission on the Department's website or in related documents. If information from your submission is published, the Department may identify you and/or your organisation as the author of the submission. All personal contact details will be removed prior to publishing.</p> <p>Yes, I consent to my identified submission being published</p>
<p><b>3</b></p> <p>What is your name?</p> <p>Marina Hanna</p>
<p><b>7</b></p> <p>Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Selected Choice</p> <p>Industry association / Peak body</p>
<p><b>8.1</b></p> <p>What is the name of your organisation? - My organisation is called: - Text</p> <p>Society of Hospital Pharmacists of Australia (SHPA)</p>
<p><b>9</b></p> <p>Are you making feedback on behalf of your organisation?</p> <p>Your organisation</p>
<p><b>13</b></p> <p>Please select which chapter/s you would like to provide feedback on. You may provide feedback on as many or few chapters as you wish.</p> <p>1. Transparency, communication, and stakeholder involvement in HTA,2. Health technology funding and assessment pathways,3. Methods for HTA for Australian government subsidy (technical methods),4. Health technology funding and purchasing approaches and managing uncertainty,5. Futureproofing Australia's systems and processes</p>
<p><b>14</b></p> <p>Please select the topics within the chapter(s) you would like to provide feedback on. 1. Transparency, communication and stakeholder involvement in HTA</p> <p>1.1. Transparency and communication of HTA pathways, processes and decisions,1.2. Consumer, clinician and other stakeholder engagement and consideration in HTA,1.3. First Nations people involvement and consideration in HTA,1.4. State and territory government collaboration in HTA</p>
<p><b>15</b></p> <p>Please select the topics within the chapter(s) you would like to provide feedback on. 2. Health technology funding and assessment pathways</p> <p>2.1. Streamlining and aligning HTA pathways and advisory committees,2.2. Proportionate appraisal pathways</p>
<p><b>16</b></p> <p>Please select the topics within the chapter(s) you would like to provide feedback on. 3. Methods for HTA for Australian government subsidy (technical methods)</p> <p>3.1. Determination of the Population, Intervention, Comparator, Outcome,3.2. Clinical Evaluation Methods,3.3. Economic evaluation</p>
<p><b>17</b></p> <p>Please select the topics within the chapter(s) you would like to provide feedback on. 4. Health Technology funding and purchasing mechanisms and decisions</p> <p>4.1. Approaches to funding or purchasing new health technologies,4.2. Approaches to incentivise development of products that address antimicrobial resistance (AMR),4.3. Understanding the performance of health technologies in practice</p>
<p><b>18</b></p> <p>Please select the topics within the chapter(s) you would like to provide feedback on. 5. Futureproofing our systems and processes</p> <p>5.1. Proactively addressing areas of unmet clinical need and gaps in the PBS,5.2. Establishment of horizon scanning programs to address specific informational needs within HTA and the health system,5.3. Consideration of environmental impacts in the HTA,5.4. Mechanisms for continuous review and improvement,5.6. Strengthen international partnerships and work-sharing</p>
<p><b>21</b></p> <p>Taking all Options within this section: 1.1. Transparency, communication and stakeholder involvement in HTA into account.</p> <p>Overall, to what extent could the options (if implemented) address the issues that relate to them?</p> <p>Mostly address the issue(s)</p>
<p><b>23.1</b></p> <p>If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Publish plain language summaries</p> <p>Very positive</p>
<p><b>23.2</b></p> <p>If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Improvements to the HTA webpage including development of a dashboard</p> <p>Very positive</p>
<p><b>25</b></p> <p>If you would like to expand on your answer above you can do so below -Publish plain language summaries</p> <p>By providing plain language summaries, PBAC enhances transparency, allowing stakeholders to understand the rationale behind decisions and the evidence considered. This transparency fosters trust in the HTA process and promotes accountability. Plain language summaries simplify complex information making it more accessible to a wider audience, including patients, caregivers, and policymakers. This accessibility empowers patients and caregivers to make informed decisions about their healthcare and facilitates meaningful engagement in healthcare discussions. Publishing PBAC guidelines also enhances consistency and clarity in decision-making. Clear guidelines help stakeholders navigate the HTA process, ensuring uniformity in submissions and evaluations. This reduces ambiguity and improves the efficiency of the HTA process, leading to timely access to innovative therapies for patients. Furthermore, the dissemination of plain language summaries and guidelines supports education and capacity building among healthcare professionals. By providing clear explanations of HTA processes and criteria, PBAC equips healthcare professionals with the knowledge and tools needed to engage effectively in the decision-making process, thereby promoting evidence-based practice. These summaries will also assist with parallel HTA processes in the healthcare system including assessments and decisions made in Drugs and Therapeutic Committees and Formulary Committees in public and private health services.</p>
<p><b>26</b></p> <p>If you would like to expand on your answer above you can do so below -Improvements to the HTA webpage including development of a dashboard</p> <p>The development of a visual, data-driven dashboard for the HTA webpage offers significant benefits, including increased transparency, evidence-based decision-making, accountability, and stakeholder engagement. These improvements contribute to a more efficient, equitable, and responsive HTA system, ultimately improving patient access to high-quality healthcare technologies in Australia. This dashboard can possibly also assist clinicians and health services who prescribe, dispense and administer these medicines and technologies, to prepare the capacity of their health services in anticipation of outcomes and decisions made by funders and regulators.</p>
<p><b>27</b></p> <p>Taking all Options within this section: 1.2. Consumer, clinician and other stakeholder engagement and consideration in HTA into account.</p> <p>Overall, to what extent could the options (if implemented) address the issues that relate to them?</p> <p>Mostly address the issue(s)</p>
<p><b>29.1</b></p> <p>If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Develop an engagement framework</p> <p>Positive</p>
<p><b>29.2</b></p> <p>If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Strengthen consumer evidence</p> <p>Positive</p>
<p><b>31</b></p> <p>If you would like to expand on your answer above you can do so below -Develop an engagement framework</p> <p>Further resourcing will be required to ensure these strategies aiming to enable transparency are delivered in a timely and reliable manner without impacting on the core functions of the TGA or PBAC.</p>
<p><b>32</b></p> <p>If you would like to expand on your answer above you can do so below -Strengthen consumer evidence</p> <p>These measures have the potential to enhance the quality, relevance, and inclusivity of HTA evaluations, ultimately leading to more informed decisions and improved patient outcomes. Consumer evidence can be even more important for technologies targeted at treating rare and less common diseases and conditions. However, effective implementation will require collaboration across stakeholders, clear communication, and ongoing evaluation to assess impact and address any challenges or barriers that may arise.</p>
<p><b>33</b></p> <p>Taking all Options within this section: 1.3. First Nations people involvement and consideration in HTA into account.</p> <p>Overall, to what extent could the options (if implemented) address the issues that relate to them?</p> <p>Address some but not most of the issue(s)</p>
<p><b>34</b></p> <p>If you would like to expand on your answer above you can do so below:</p> <p>A major issue impacting on First Nations peoples is their inability to access reduced co-payments of PBS medicines upon discharge from hospital. The proposed options in this paper do not address this significant issue that leads to lack of treatment poorer health outcomes for Aboriginal and Torres Strait Islander people. Hospital pharmacists must be enabled to supply medicines to Indigenous Australians under Closing the Gap PBS Co-Payment Measure.</p>
<p><b>35.1</b></p> <p>If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - First Nations peoples partnership in decision making</p> <p>Very positive</p>
<p><b>35.2</b></p> <p>If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Dedicated resource for HTA submissions and education</p> <p>Very positive</p>
<p><b>37</b></p> <p>If you would like to expand on your answer above you can do so below -First Nations peoples partnership in decision making</p> <p>The establishment of a dedicated Advisory Committee and including a representative on the PBAC, ensures that First Nations perspectives and priorities are integrated into decision-making processes from the outset. This promotes cultural sensitivity, inclusivity, and responsiveness to the unique health needs and priorities of First Nations peoples.</p> <p>SHPA recommends that the First Nations Advisory Committee has diverse representation including, Aboriginal Community Controlled Health Organisations (ACCHOs), non-ACCHOs, primary care, and both the private and public acute care settings, to ensure the committee considers the complete continuum of care in its decision-making.</p>
<p><b>38</b></p> <p>If you would like to expand on your answer above you can do so below -Dedicated resource for HTA submissions and education</p> <p>A dedicated resource for HTA submissions and education to assist organisations representing the health outcomes of First Nations peoples can help address barriers that may hinder meaningful participation, such as lack of familiarity with the HTA process or resource constraints.</p>
<p><b>39</b></p> <p>Taking all Options within this section: 1.4. State and territory government collaboration in HTA into account.</p> <p>Overall, to what extent could the options (if implemented) address the issues that relate to them?</p> <p>Mostly address the issue(s)</p>
<p><b>41.1</b></p> <p>If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Development of central standardised data sharing system for utilisation and outcome data</p> <p>Very positive</p>

41.2

**If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Increase opportunities for consultation and work sharing**

Very positive

41.3

**If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Health technologies that are jointly funded by the Commonwealth and state and territory governments (such as high cost, Highly Specialised Therapies (HSTs) delivered to public hospital inpatients)**

Very positive

43

**If you would like to expand on your answer above you can do so below -Development of central standardised data sharing system for utilisation and outcome data**

SHPA is pleased with the uptake of our recommendation to develop a repository of non-PBS, off-label and Special Access Scheme (SAS) medicines data gathered from all hospitals across Australia to facilitate more timely decision making and provide Australians with early access to medicines needed in the acute care setting. As the TGA is currently undertaking parallel consultations to inform the repurposing of medicines in Australia, SHPA believes these two areas of work should work together and further achieve collaboration and breaking down of silos in our healthcare system when it comes to medicines regulation and funding.

As expressed in SHPA's submission to the HTA Policy and Methods Review " consultation 1, the development of this data sharing system would be a useful resource to leverage off the experience of specialist clinicians and pharmacists, and a means of scanning the horizon for medicines commonly used in the acute care setting, to be considered for approval in Australia.

SHPA also recommends that the collection of data on the use of non-PBS medicines is across all care settings, including the use of unregistered medicines and off-label medicines, to inform future funding decisions, policies, regulations and clinical guidelines preventing future medicine-related hospital admissions.

44

**If you would like to expand on your answer above you can do so below -Increase opportunities for consultation and work sharing**

Once again, SHPA is pleased with this option to increase opportunities for consultation and work sharing by state and territory governments across the health technology lifecycle. However, SHPA recommends that hospitals should also be engaged and offered an opportunity to provide clinical input into PBS indications for conditions, given the extensive off-label use of medicines that is pertinent to medicines and technology regulation and funding, and has demonstrable impacts on patient access that can amount to a postcode lottery.

45

**If you would like to expand on your answer above you can do so below -Health technologies that are jointly funded by the Commonwealth and state and territory governments (such as high cost, Highly Specialised Therapies (HSTs) delivered to public hospital inpatients)**

SHPA strongly advocates for a nationally cohesive, efficient, and responsive HTA framework to inform government investment and disinvestment decisions in Australia. HTAs must consider the broader implications of a health technology on the health system and fund the whole cost of therapy, not just the individual health technology, if we are to ensure person-centred and equitable access to health technologies, as outlined in the National Medicines Policy (NMP). The current lack of suitable funding pathways that provide subsidy for the whole cost of therapy results in inequity in access and creates perverse incentives, ultimately impacting on consumer health outcomes and further costing the health system.

46

**Taking all Options within this section: 2.1. Streamlining and aligning HTA pathways and advisory committees into account.**

**Overall, to what extent could the options (if implemented) address the issues that relate to them?**

Mostly address the issue(s)

48.1

**If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Pathway for drugs for ultra-rare diseases (Life Saving Drugs Program (LSDP))**

Very positive

48.2

**If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Vaccine pathway**

Very positive

48.3

**If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Expanding role of PBAC**

Very positive

48.4

**If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Unified HTA pathway for all health technologies with Commonwealth funding**

Very positive

50

**Pathway for drugs for ultra-rare diseases (Life Saving Drugs Program (LSDP))**

Consolidating the HTA process under PBAC as the sole committee for drugs for ultra-rare diseases eliminates duplication and ensures a more streamlined evaluation process. Leveraging the expertise of the LSDP expert panel to inform PBAC's decisions enhances the rigor and robustness of assessments, leading to more evidence-based recommendations to the Minister.

60

**If you would like to expand on your answer above you can do so below -Vaccine pathway**

Once again, streamlining the pathway for listing of vaccines on the National Immunisation Program (NIP) will reduce duplication and add efficiencies to the system.

61

**If you would like to expand on your answer above you can do so below -Expanding role of PBAC**

By entrusting PBAC with a broader advisory role, stakeholders benefit from a centralised and expert evaluation process, reducing duplication and fragmentation across various HTA pathways. This consolidation promotes consistency, efficiency, and transparency in decision-making, streamlining the evaluation process for a wider range of health technologies.

Furthermore, decoupling HTA recommendations through PBAC from subsequent funding decisions through the PBS enhances flexibility and responsiveness in healthcare financing. This approach allows for tailored funding mechanisms based on the specific needs and characteristics of different health technologies.

62

**If you would like to expand on your answer above you can do so below -Unified HTA pathway for all health technologies with Commonwealth funding**

Whilst having a unified, national, HTA pathway is a priority, SHPA continues to advocate for the development of a single-funder model for health technologies. Development of single-funder models for medicines in hospitals will reduce inequity of patient access to high-cost and complex medicines, and enable patient-centred and timely provision of treatment when and where patients require them, aligning with Australia's NMP.

63

**Taking all Options within this section: 2.2. Proportionate appraisal pathways into account**

**Overall, to what extent could the options (if implemented) address the issues that relate to them?**

Address some but not most of the issue(s)