

Response
<p>2</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>3</p> <p>What is your name?</p> <p>Mirjana Rapaic</p>
<p>7</p> <p>Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Selected Choice</p> <p>Clinician (or representative organisation),Pharmaceutical / Medical technology company</p>
<p>8.1</p> <p>What is the name of your organisation? - My organisation is called: - Text</p> <p>BiomeBank</p>
<p>9</p> <p>Are you making feedback on behalf of your organisation?</p> <p>Your organisation</p>
<p>13</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,4. Health technology funding and purchasing approaches and managing uncertainty</p>
<p>14</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,1.4. State and territory government collaboration in HTA</p>
<p>15</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>2.2. Proportionate appraisal pathways</p>
<p>17</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>4.2. Approaches to incentivise development of products that address antimicrobial resistance (AMR)</p>
<p>21</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>23.1</p> <p>If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Publish plain language summaries</p> <p>Positive</p>
<p>23.2</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>Positive</p>
<p>63</p> <p>Taking all Options within this section: 2.2. Proportionate appraisal pathways 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>65.1</p> <p>If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Case manager</p> <p>Very positive</p> <p>If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Triaging submissions</p> <p>Positive</p>
<p>65.9</p> <p>If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Decouple the requirement for the TGA Delegate's overview to support PBAC advice</p> <p>Very positive</p>
<p>75</p> <p>If you would like to expand on your answer above you can do so below -Decouple the requirement for the TGA Delegate's overview to support PBAC advice</p> <p>BiomeBank fully supports enabling the full parallel processing of TGA and PBAC submissions by enabling the PBAC to communicate its advice to sponsors prior to receiving the TGA Delegate's Overview.</p>
<p>114</p> <p>Taking all Options within this section: 4.2. Approaches to incentivise development of products that address antimicrobial resistance (AMR) 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>116.1</p> <p>If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - HTA Fee exemptions for products that address AMR</p> <p>Very positive</p>
<p>116.2</p> <p>If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - HTA Policy and Guidance changes for products that address AMR</p> <p>Positive</p>
<p>116.3</p> <p>If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Funding and reimbursement-related changes to support availability of antimicrobials</p> <p>Very positive</p>
<p>118</p> <p>If you would like to expand on your answer above you can do so below -HTA Fee exemptions for products that address AMR</p> <p>BiomeBank welcomes the Reference Committees acknowledgement of high cost burden and we believe the fee exemption should cover the entire lifecycle of the therapy. BiomeBank has experience as a small biotech company bringing a product to a relatively small but important market (antibiotic refractory C. difficile infection). The Marketing Authorisation and Reimbursement submission costs are a barrier to small innovative companies such as ours and the ongoing regulatory costs place a significant burden on our ability to produce and maintain economic viability.</p>
<p>119</p> <p>If you would like to expand on your answer above you can do so below -HTA Policy and Guidance changes for products that address AMR</p>

BiomeBank welcomes review of HTA policy to enable flexibility and improve pathways to funding/reimbursement to enable newly developed technologies to reach consumers in a more efficient and rapid manner.

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If you would like to expand on your answer above you can do so below -Funding and reimbursement-related changes to support availability of antimicrobials

BiomeBank's product fights AMR, however is not by definition an antimicrobial but has a novel mechanism of action. Pathways to obtaining funding are expensive, extremely time consuming and hard to achieve for small companies. Ultimately this restricts access and increases costs to the healthcare system.

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In summary, considering all the draft reform options together:

How confident are you that the reform options (if implemented) will make health technology assessments better overall?

Somewhat confident

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Do you have further comments or concerns to add specific to this topic that should be considered? For example, here you can detail any unintended consequences or overlooked considerations if applicable.

As Australia has the challenge of being a small market combined with the high cost of registration in Australia we are limited with the availability of new technologies, the present reimbursement process where payments are attributed to sales volume places a burden to patients to receive crucial lifesaving and healthcare system medicines.

BiomeBank supports the Government's proposal to examine and test multiple payment and incentive modes, particularly pull incentives and full price/volume delinking and supports the delinked subscription style model piloted in the UK.