Response

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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.

Yes, I consent to my identified submission being published

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What is your name?

Tom Hardy

7

Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Selected Choice

Consulting

8.1

What is the name of your organisation? - My organisation is called: - Text

IQVIA

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Are you making feedback on behalf of your organisation?

Your organisation

13

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.

1. Transparency, communication, and stakeholder involvement in HTA,3. Methods for HTA for Australian government subsidy (technical methods),4. Health technology funding and purchasing approaches and managing uncertainty

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Please select the topics within the chapter(s) you would like to provide feedback on. 1. Transparency, communication and stakeholder involvement in HTA

1.2. Consumer, clinician and other stakeholder engagement and consideration in HTA,1.4. State and territory government collaboration in HTA

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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)

3.2. Clinical Evaluation Methods

17

Please select the topics within the chapter(s) you would like to provide feedback on. 4. Health Technology funding and purchasing mechanisms and decisions

4.1. Approaches to funding or purchasing new health technologies,4.3. Understanding the performance of health technologies in practice

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Taking all Options within this section: 1.2. Consumer, clinician and other stakeholder engagement and consideration in HTA into account.

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

Don't know

29.1

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Develop an engagement framework

Don't know

29.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Strengthen consumer evidence

Very positive

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If you would like to expand on your answer above you can do so below -Strengthen consumer evidence

IQVIA agrees with the recommendation to provide more explicit guidance on the preparation and use of RWD/RWE and other patient-relevant evidence (including qualitative input, PROs, patient preference data, and patient experience data) as an input to the HTA decision-making process. This guidance should clearly specify the types of evidence and data that would be most informative to the HTA decision-making process.

We believe that such guidance has the potential to improve the overall quality of the evidence being submitted, and accelerate access by extension. Additionally, it would help to ensure more efficient investment of research resources into studies that will have the greatest impact and utility in decision-making.

IQVIA also agrees with the importance of establishing a multi-stakeholder advisory group to guide next steps to optimise access and use of RWD in HTA. It will be critical for this group to provide balanced recommendations that appropriately account for known operational constraints and challenges in the generation of high-quality RWE. With this, we see value in inclusion of an independent third-party research organisation with specialist expertise in RWE (such as IQVIA) as part of the advisory group, in order to 1) provide practical perspectives on what works / pitfalls to avoid based on extensive experience working across the industry on a wide range of Real World studies, and 2) advise on latest emerging best practice methodologies.

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Taking all Options within this section: 1.4. State and territory government collaboration in HTA into account.

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

Don't know

41.1

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

Very positive

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

Don't know

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)

Don't know

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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

IQVIA strongly agrees with the need to invest in improving data infrastructure and access in Australia. A wide range of valuable Real World datasets exist today, but they are often difficult to access due to long, complex and unclear approval processes. Additionally, Australia's RWD landscape is highly fragmented, with different datasets (covering different aspects of the patient care experience) governed by disparate data custodians. This makes it difficult to create a comprehensive picture of patients' overall health resource utilisation and outcomes.

Interestingly, we frequently encounter research questions from industry that could be well-answered via a combination of existing datasets (e.g., PBS, MBS, admitted patient data collections, birth & death data, etc.) '" but often these studies do not move beyond concept development due to the data being too difficult and time-/resource-intensive to access and link. Improved mechanisms for data sharing and access would consequently help increase both the quantity and quality of evidence generated, and enable more informed data-driven decision-making by all parties.

Notably, in the interest of transparency, any future data collection and sharing systems should enable equitable access to data across stakeholder groups (including government, industry and researchers), whilst maintaining appropriately high data privacy and security standards.

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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)

A new wave of CAR T-cell therapies opens the need for increased capacity to relieve pressure on the healthcare system. There were 852 CAR-T trials globally in 2022, and in February 2024, the FDA approved the first autologous cellular therapy for a solid tumour.

In Australia, CAR-T service delivery is restricted to a limited number of public hospitals, leading to inequity of access. The Commonwealth should recognise the need to ensure equitable access regardless of public vs private setting. In Australia, practitioners can prescribe Commonwealth funded PBS medicines in private hospitals. However, CAR-T delivery is not permitted in private hospitals, despite there being multiple private hospitals with the capability and capacity to do so (demonstrated through CAR-T clinical trials and autologous SCT services).

The NHRA Mid-Term Review states that 'œthere could be an opportunity to explore opportunities to leverage capacity in CAR-T cell treatment centres in private hospitals where eligible public patients could be treated' (also reflected in Recommendation 30). However, capacity challenges and the non-public delivery of HSTs, including CAR-T, are ignored in this paper.

The HTA Review Options paper also ignores the need for a national costing review for CAR-T. CAR-T delivery costs are not well understood and varied between states who submit their own unique costs. A full costing review conducted by IHACPA is needed to understand the true cost and funding risk for CAR-T.

84

Taking all Options within this section: 3.2. Clinical Evaluation Methods into account.

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

Don't know

86.1

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Overarching principles for adopting methods in Australian HTA

Don't know

86.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Methods for the assessment of nonrandomised and observational evidence

Don't know

86.3

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Methods for the assessment of surrogate endpoints

Don't know

86.4

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Generate a curated list of methodologies that are preferred by decision-makers, in collaboration with evaluation groups and sponsors.

Don't know

86.5

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Develop an explicit qualitative value framework

Very positive

86.6

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Therapies that target biomarkers (e.g. tumour agnostic cancer therapies, therapies that target particular gene alterations)

Don't know

86.7

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

Don't know

105.1

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Recognising competition between new health technologies that deliver similar outcomes:

Alternative option 1: In conjunction with options for proportionate assessment of cost-minimisation submissions, require offers of a lower price for health technologies that provide no added benefit

Don't know

105.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Recognising competition between new health technologies that deliver similar outcomes:

Alternative option 2: In conjunction with options for proportionate assessment of cost-minimisation submissions, incentivise offers of a lower price for health technologies that provide no added benefit

Don't know

105.3

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Investigate further options to address budget impact implications of high-cost/high impact health technologies

Don't know

105.4

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Pricing offer (PO) and negotiation guidance framework

Don't know

105.5

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Post-listing re-assessment of health technologies

Don't know

105.6

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Approaches for managing uncertainty - bridging funding coverage for earlier access to therapies of likely HATV and HUCN

Don't know

105.7

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Approaches for managing uncertainty - revised guidance on the uses of different managed entry tools

Positive

121

Taking all Options within this section: 4.3. Understanding the performance of health technologies in practice into account.

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

Mostly address the issue(s)

123.1

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Oversight " reforms to optimise access to and use of RWD in HTA

Very positive

123.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Develop a strategic approach to increase confidence, awareness, and acceptance of cross-jurisdictional and cross-sectoral RWD access and use in HTA

Very positive

123.3

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

Very positive

123.4

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

Very positive

123.5

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Develop Guidance framework

Very positive

123.6

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Collection of utilisation and outcome data for provisionally listed health technologies

Positive

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If you would like to expand on your answer above you can do so below -Oversight " reforms to optimise access to and use of RWD in HTA

As stated in Section 1.2, IQVIA agrees with the importance of establishing a multi-stakeholder advisory group to government to guide next steps for optimising access and use of RWD in HTA. It will be critical for this advisory group to contain a well-rounded mix of stakeholder perspectives, with adequate representation from the commercial sector, in order to produce realistic and implementable recommendations that appropriately account for known operational challenges and limitations (including budget and timeline constraints). With this, we see value in inclusion of an independent third-party research organisation with specialist expertise in RWE (such as IQVIA) as part of the advisory group, to provide practical perspectives on what works and pitfalls to avoid, based on extensive experience working across the industry on a wide range of Real World studies.

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If you would like to expand on your answer above you can do so below -Data infrastructure

IQVIA agrees with the perspective that further investment is required to advance and future-fit Australia's infrastructure, processes and systems for enabling high quality RWE generation. Although a wide range of interesting Real World datasets existing in Australia today, they are largely fragmented in nature, and data access and linkage remain challenging.

Importantly, the benefits of investing in data infrastructure are multi-factorial. Availability of a comprehensive, high-quality, accessible Real World Data ecosystem could support a broad range of research applications beyond the generation of RWE for HTA purposes. For example, high-quality RWE can also help healthcare professionals answer a range of relevant clinical questions, and assist patients in making more informed decisions about their own care. While these use cases fall outside the scope of the present HTA Review, we would be remiss not to consider the broader whole-of-system benefits. Moreover, it is worth noting that investment in building a world-leading data infrastructure and capability has the potential to attract incremental global investment of Real World research funding to the Australian market.

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If you would like to expand on your answer above you can do so below -Develop Guidance framework

As stated in Section 1.2, IQVIA agrees with the recommendation to provide more explicit guidance on the types of RWD/RWE that would be most informative to the HTA decision-making process.

Interestingly, we have previously heard anecdotal feedback from industry that lack of clear guidance around what RWE will be accepted '" and associated uncertainty around ROI '" disincentivises investment in high-quality RWE generation for HTA submission purposes. Availability of an aligned set of guiding principles could help to address this barrier, resulting in an increase in the overall quantity and quality of evidence being submitted.