AusBiotech submission in response to the *Prostheses List Reforms Consultation Paper 7 - Proposed measures for compliance, assurance and information sharing*

To: Department of Health
GPO Box 9848
Canberra ACT 2601
Australia
prosthesesreform@health.gov.au

15 August 2023

From: AusBiotech Ltd
ABN 87 006 509 726
Level 33, 477 Collins Street
Melbourne Victoria 3000 Australia
0437 126 843
www.ausbiotech.org

Introduction

AusBiotech welcomes the opportunity to submit a response to the Department of Health's (DoH) consultation paper on proposed measures for the Prescribed List (PL) on compliance, assurance and information sharing.

AusBiotech represents a national network of over 3,000 members in the life sciences industry, which includes medical technology (devices and diagnostics) and digital health, biotherapeutics, and agricultural biotechnology sectors. The sector employs in excess of 290,000 Australians and industry consists of more than 1,425 biotechnology companies. The majority of its membership comprises primarily of small and medium sized enterprises in the early stage of commercialisation.

Key comments on Consultation Paper 7

A. The concept of "Shared Responsibility"

AusBiotech supports the concept of a 'shared responsibility' for safeguarding the PL. However, measures imposed on stakeholders must be fit-for-purpose, without creating additional unnecessary and unreasonable burden and/or administrative red tape and also take into account the introduction of Cost Recovery as part of Prostheses List Reform.

Furthermore, any 'shared responsibility' measures must not impact on confidential commercial arrangements between sponsors and purchasers of PL listed products (e.g. private hospitals, State Government Health Departments and other stakeholders like Australian Federal agencies and any overseas entities). Contractual arrangements with purchasing partners include confidentiality agreements which would be breached should many of the proposed measures in Consultation Paper 7 be implemented.

B. Proposed measures for sponsors

Record Keeping. As a matter of course, AusBiotech supports record keeping and notification measures in accordance with TGA requirements to safeguard the safety and efficacy of products listed on the PL. However, concern arises from the proposed obligation to maintain records on the comparative clinical and cost-effectiveness versus alternative treatments on the PL.

After a product has been listed on the PL, such records may not be updated as a matter of routine, and mandated obligations to do so would require significant additional resources from Sponsors. As noted earlier, most AusBiotech members are small and medium sized enterprises in the early stage of commercialisation and, as such, routinely use independent consultants for PL applications and interactions, making the resource implications of this proposed sweeping obligation very significant indeed. AusBiotech's understanding is that in a Health Technology Assessment (HTA) regulated system, only new listing requests require demonstration of clinical and cost-effectiveness versus the standard of care at the time of the application. Sponsors do not routinely undertake assessments to compare their existing products to new market entrants. However, as part of the modernisation of the PL, the Department will utilise post-listing reviews in specific situations. If a post-listing review uncovers circumstances that violate the conditions for PL listing, those would be appropriate targets for compliance or other actions.

Providing overseas/international costs, including pricing in the Health Products Portal (HPP) and elsewhere should be on a voluntary basis for Sponsors. Any mandated obligation for Sponsors to provide this information is considered unnecessary and unreasonable. Product cost is the outcome of complex, health system-specific determinations relating to price and volume considerations, supply chain characteristics, market structures, service requirements, product indemnity and liability, regulatory processes and imposed stock requirements.

The appropriate PL Benefit relative to public pricing in the Australian health care system and/or the incremental clinical effectiveness (and cost-effectiveness where relevant) is determined for the Australian context during the PL listing process. As such, Australia has a long history – and in fact takes pride – in the rigour of its price referencing within the Australian health care system in determining value for money in the context of Australian health care. As a point of reference and precedent, other Australian Government pricing and HTA bodies/processes have not recognised a need to use overseas/international pricing to determine value for money in Australia. These other bodies include, but are not limited to, the PBAC and MSAC. Any mandated obligation to keep and provide records on overseas prices for PL price setting in Australia is therefore deemed inconsistent, unnecessary, and not relevant to modernising the PL through the PL Reform process.

C. False or misleading information – administrative sanctions and criminal sanctions

AusBiotech deems the enforcement powers proposed for Sponsors to ensure compliance and assurance to be excessive. PL listing processes are mainly administrative, and PL listing is closely linked to information provided to the TGA and can only occur subsequent to a well-established and rigorous risk-based TGA review. Irregularities giving rise to investigations are more likely than not to reveal minor errors not requiring enforcement of penalties to regain compliance. The idea of withdrawing products from patient access is disproportionate to any foreseeable failure to meet the requirements of PL listing.

Accordingly, the proposed creation of a separate offence scheme is not supported given the existing current offences included in the Criminal Code.

D. Disclosure of Protected Information

As noted earlier, any 'shared responsibility' measures must not impact on confidential commercial arrangements between Sponsors and purchasers of PL listed devices (e.g. private hospitals, State Government Health Departments and other stakeholders like Australian Federal agencies and any overseas entities). Contractual arrangements with purchasing partners include confidentiality agreements which would be breached to fulfil many of the proposed measures in Consultation Paper 7.

E. Public Summary Documents

AusBiotech acknowledges the proposed introduction of Public Summary Documents (PSDs) where public sharing of the information is 1) relevant to stakeholders and/or 2) not duplicative. AusBiotech appreciates that these are intended to be provided by the Sponsor, despite the additional resource burden on Sponsors and the implementation of PL Cost Recovery, and as such should be brief (no more than two pages) and use language appropriate to the Australian public. To ensure these PSDs fulfil the purpose of appropriateness and relevance while increasing transparency, AusBiotech requests that the information requirements and structure of any PSDs should be mutually agreed between the PL Branch and representatives of Industry Sponsor stakeholders prior to implementation.

Regarding relevance, we recommend the Department consider including information in PSDs on the decision making by the MDHTAC for Tier 2 applications only, and specifically for Tier 2b applications (where a Clinical Assessment plus an Economic Assessment is needed) and a subset of Tier 2a applications where an incremental clinical benefit over the PL comparator(s) is requested by the Sponsor. PSDs should not be required for Tier 1 applications (Department Assessment Pathway), Tier 2a applications where no incremental Benefit determination is requested by the Sponsor, and Tier 3 applications (Full HTA via MSAC with accompanying MSAC Public Summary Document). For a staged introduction, a priority would be Tier 2b applications with a later stage implementation for the subset of Tier 2a applications.

In conclusion, implementation of any measures improving compliance, assurance and information sharing must be in accordance with and respect commercial arrangements between Sponsors and purchasers of PL listed devices. Should measures be unnecessarily arduous by creating significant resource burden, additional red tape or require sponsors to breach confidentiality arrangements, there is a risk of reduced attractiveness of the Australian health care market for sponsors. Unintended consequences may be that medical technology, both developed locally and internationally, will be commercialised late or not at all in Australia.