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HTA Improvement & Cost Recovery Section
Technology Assessment and Access Division
Department of Health
GPO Box 9848,
Canberra ACT 2601

To whom it may concern,

RE: Public Consultation – Proposal to Introduce a Cost Recovered Pathway for Medical Services Advisory Committee (MSAC) Applications

Thank you for providing Pfizer Australia with the opportunity to make a submission to the above consultation.

Pfizer Australia is one of the nation's leading providers of prescription medicines and vaccines. We manufacture medicines and vaccines that millions of Australians use every day to live longer, healthier, and more productive lives. Every day our people work with the sole purpose of ensuring that Australians can access new and innovative medicines that are being used to treat some of the most feared conditions of our time. We are proud of the active role we play in Australia's health system and the wider contribution we make as an innovator, employer, and manufacturer.

Pfizer Australia acknowledges the basis for cost recovery as it relates to MSAC-related activity and is committed to working towards improved processes that will benefit Australians accessing the wide range of health technologies assessed by MSAC. We are a proud member of Medicines Australia, the peak body representing innovative pharmaceutical companies in Australia, and encourage the careful consideration of the detailed recommendations in their submission to this consultation. In particular, the need for further consultation on the proposed pathway itself, in order to allow identification of the priorities for improved speed and efficiency, and co-design of the revised pathway with industry and other stakeholders, prior to considering relevant costs. Cost recovery for a pathway which may not be fit-for-purpose could undermine the objective of increasing the speed and efficacy of MSAC assessments, and not achieve the faster patient access which is sought by all stakeholders.

Pfizer's submission to this proposal builds on the key themes outlined in Medicines Australia's submission. It also draws on our own experience with the MSAC process and the opportunities we see for improving the pathway. Cost recovery should accompany improvements that provide clarity, transparency and certainty of timeframes for sponsors and most importantly, reduce the time taken to achieve equitable access to innovative health technologies for Australians. It is Pfizer's view that this current proposal needs more work as it has fallen short of these objectives.

Finally, Pfizer is disappointed that the first recommendation to be progressed from the New Frontiers report is a proposal for cost recovery, as there were many other meritorious recommendations that have the potential to make a more lasting impact to Australian patients.

Thank you again for the opportunity to contribute to this consultation and we are hopeful that there will be subsequent rounds of consultation that allow us to work collaboratively to refine this proposal further.

Yours sincerely,

Anne Harris
Managing Director

Louise Graham
Head of Market Access ANZ

ATTACHMENT 1

Pfizer Submission to Public Consultation - Proposal to Introduce a Cost Recovered Pathway for Medical Services Advisory Committee (MSAC) Applications

Response to Consultation Issues

1. Progressing the recommendations from the New Frontiers report

As the consultation paper states, this proposal seeks to address one of the key recommendations from the House of Representatives 'Inquiry into approval processes for new drugs and novel medical technologies in Australia'. This recommendation includes that the Department should, in consultation with relevant stakeholders, introduce fees for MSAC applications on a cost recovery basis as a means to increase the speed and efficacy of MSAC assessments.

The house inquiry into novel medicines and medical technologies was a landmark forum that went to great lengths to give every interested party a voice. The sheer volume of submissions and engagement in the inquiry is a clear indication that more needs to be done to increase the transparency, accountability and efficiency of our medicine's assessment processes, particularly if we are to accommodate the next generation of treatments in development.

Pfizer remains committed to working collaboratively with all partners to achieve this goal. To this extent, it is disappointing that the first recommendation to be progressed of the 31 recommendations made is a framework focused on the introduction of cost recovery and not a recommendation that could make a more lasting impact to Australian patients. Pfizer acknowledges Government is yet to respond to the New Frontiers report, however there were several recommendations that could have been prioritised ahead of the introduction of cost recovery for established HTA processes.

Importantly, this proposal does not address the key aspects of the recommendation 'to increase the speed and efficacy of MSAC assessments'. The proposal 'standardises' timeframes for the MSAC process. Whilst it is important to provide certainty and predictability to the MSAC process, Pfizer would challenge that committing to upholding the current MSAC timeframes is not 'increasing speed' in any meaningful way. More work needs to be done with the model to ensure alignment and consistency with other processes, including those that are interdependent on MSAC processes, and to transparently demonstrate the basis for and methods used for any cost recovery framework.

Consultation process and timing

The recently signed Strategic Agreement between Medicines Australia and the Commonwealth sets out a number of major initiatives that will commence in 2022 to examine HTA in Australia. The Health Technology Assessment Review should encompass policies and methods for the full range of innovative health technologies which require assessment by multiple committees, including the MSAC for health technologies to be funded through the Medicare Benefits Scheme.

Introduction of a cost recovered pathway for MSAC applications in advance of this review commencing is premature, may lead to overlap, confusion and redundancies in each review and importantly, undermine the shared goal of reducing the time to access to health technologies for Australian patients.

The Department of Health should delay further consultation on the cost recovered pathway for MSAC applications and focus on co-designing a fit-for-purpose pathway with industry and other relevant stakeholders, prior to considering the appropriate cost recovery arrangements.

It is critical that any introduction of cost recovery fees and charges it is done in a manner that allows sponsor companies to reasonably prepare for the substantial increase in operating expenditure. Pfizer Australia therefore proposes that, in any case, the earliest appropriate implementation timeframe would be with a minimum of 12-18 months advance notification. This would be consistent with the approach taken for the introduction of PBS cost recovery fees and changes to those fees.

2. Applications considered by the MSAC

2. 1 Co-dependent assessments

Pfizer Australia provides a number of targeted medicines which require a companion diagnostic test, funded through the Medicare Benefits Scheme (MBS), to identify the population of patients eligible for treatment with medicine through the PBS. We have therefore engaged in the PBAC/MSAC co-dependent assessment process required to establish appropriate clinical use, cost-effectiveness and price of both the medicine on the PBS and diagnostic test on the MBS.

It is important to clarify that while such co-dependent applications are typically generated by commercial entities which will receive a direct financial benefit from the PBS listing of the medicine, in most instances, these commercial entities do not receive any direct financial benefit from the funding of the medical service for the diagnostic test. Furthermore, such co-dependent technologies which identify the subset of the overall population who are most likely to benefit from the targeted treatment, by their very nature, result in a substantially reduced population of patients ultimately being eligible to receive treatment with the medicine through the PBS.

We are concerned that the indicative cost recovery fees for MSAC will significantly increase the cost of seeking reimbursed access for medicines which require an integrated co-dependent submission. Under the proposed cost recovery model, integrated co-dependent submissions will be required to pay full fees for both PBAC and MSAC evaluations, totaling over $300k for the submission fees alone, plus the costs associated with pre-submission meetings and PASC requirements and the significant costs related to evidence generation and submission preparation. Given the majority of submissions require at least one re-submission to achieve a positive recommendation, the cost associated with securing access for targeted medicines through the PBS may be more than $700k. Such cost recovery fees may prove prohibitive, particularly for rare and less common indications for which targeted therapies are frequently developed.

The Consultation Paper acknowledges that the HTA assessment process for co-dependent technologies has focused on supporting an integrated approach to reduce duplication of effort across the respective committees. Pfizer Australia believes that there are a number of aspects in the process of evaluating integrated co-dependent applications which delivery efficiencies across the evaluation for the two committees:

- Integrated co-dependent applications are submitted as a single evaluation document for use by both the MSAC and the PBAC.
- Integrated co-dependent submissions seeking listings on a cost-effectiveness basis typically present a single economic evaluation and financial estimates model incorporating both the diagnostic and treatment components.
- A single external HTA evaluation group may be contracted to evaluate the submission for both the test and the medicine.
- Submissions are considered by the economic subcommittees of PBAC and MSAC at a joint meeting.
- A single joint Economic Subcommittee (ESC) Advice document is prepared for the PBAC and MSAC.

The inherent efficiencies of an integrated approach to the co-dependent evaluation process must be reflected in the cost recovery arrangements for co-dependent applications.

We call for further consultation so that a more efficient path for medicines with companion diagnostics requiring assessment by both the MSAC and PBAC can be developed. It is our view that, for this objective to be achieved, the whole HTA process, including both PBAC and MSAC assessments, must be considered together.

This will be particularly important for new cell and gene therapies for which the HTA and funding pathways can be unclear or not well aligned. Of the two gene therapies currently recommended for reimbursement in Australia (Zolgensma and Luxturna), one followed the MSAC pathway with joint Commonwealth-state funding expected under the NHRA, while the other was recommended by

PBAC. There was confusion in the advice from the Department over the choice of evaluation committee for one of these therapies, lending further support to the MSAC and PBAC processes being considered together, so that clear guidance on the appropriate pathway can be provided.

In addition, given the scope of MSAC has expanded to include gene therapies, it is imperative that any cost recovered pathway is based on a fit-for-purpose evaluation model which considers the unique requirements of cell and gene therapies, and ensures the expertise of MSAC evaluators to assess these personalised medicines and companion diagnostics.

2.2 High cost, highly specialised therapies (HSTs)

MSACs role advising on high cost, highly specialised therapies (HSTs) as per the 2020-25 National Health Reform Agreement (NHRA) and how this process is expected to work is somewhat unclear. Clarity on the pathway and processes for highly specialised therapies and how the MSAC and PBAC processes intersect is needed in order to verify how the revised MSAC process will assist in delivering faster access to medicines administered in a public facility.

3. Waiver of cost recovery fees

Pfizer Australia is concerned that rare diseases have not been treated equitably in the proposed cost recovery model. Included in the PBS cost recovery arrangements is a 'Fee Exemption' provision which is available to drugs which have a valid orphan drug designation for the indication by the Therapeutic Goods Authority (TGA). There is no such provision for an exemption of MSAC assessment fees for either co-dependent applications to MSAC and the PBAC for medicines with an orphan designation, or for other health technologies seeking funding through the MBS only to diagnose and treat similarly rare conditions.

Pfizer Australia seeks further consultation on the matter of fee waivers and exemptions, with the aim of achieving changes that deliver efficiency and improved speed in a manner that considers HTA holistically, in order to better meet the needs of patients, applicants and Government.