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Department of Health
GPO Box 9848
Canberra ACT 2601

Via email: PBSpotmarket@health.gov.au

To whom it may concern,

RE: Public Consultation on the assessment of co-dependent technology chapter of the draft revised Pharmaceutical Benefits Advisory Committee (PBAC) Guidelines Review

Thank you for providing Pfizer Australia with the opportunity to comment on the co-dependent technology chapter of the draft revised PBAC Guidelines Version 5.0.

Pfizer Australia is one of Australia's leading providers of prescription medicines and consumer health products. We deliver medicines and vaccines that millions of Australians use every day to live longer, healthier and more productive lives. We are proud of the active role we play in Australia's health system.

Pfizer Australia fully supports the Government's review of the PBAC Guidelines. Guidelines that remain contemporary, comprehensive and world's best practice ultimately help ensure Australians have timely access to safe, clinically proven and cost-effective medicines, while safeguarding the sustainability of the Pharmaceutical Benefits Scheme so it can benefit future generations.

Pfizer Australia is one of the few innovative pharmaceutical companies that has direct, recent experience with the co-dependent technology pathway in Australia. In our experience, the co-dependent technology process entailed more bureaucratic burden, added complexity and longer timelines, when compared to the reimbursement process for a non-targeted medicine. This additional bureaucratic burden appears counterintuitive, as part of the value of targeted medicines is the ability to identify patient populations who may have a greater likelihood of response to the medicine. Our submission (Attachment 1) provides feedback on the co-dependent technology chapter of the draft revised PBAC Guidelines Version 5.0 through this lens. In particular, the submission outlines four key recommendations to improve the efficiency of the assessment process. Ultimately, we appreciate that improving the co-dependent process may require *revolution* rather than *evolution*. Such an approach will be crucial to ensuring patients receive timely and affordable access to new, innovative and, particularly in this case, targeted medicines.

Pfizer Australia is a member of Medicines Australia (MA), the peak body representing innovative pharmaceutical companies in Australia and was involved in the preparation of MA's submission to this Review. We support MA's submission and encourage the Department of Health to carefully consider the information and recommendations presented within.

Thank you again for the opportunity to make a submission to this Review. We are available at any time to provide further information, as required.

Yours sincerely

Louise Graham
Director Access & Public Affairs

ATTACHMENT 1

Submission to the Department of Health's Public Consultation on the assessment of co-dependent technology chapter of the draft revised Pharmaceutical Benefits Advisory Committee (PBAC) Guidelines Review

1. Introduction

Targeted medicines are, in many ways, at the forefront of medical innovation. Simply put, having the ability to tailor treatments to the genetic makeup of individual patients increases the likelihood of a therapeutic response. In addition, targeted medicines provide benefits to the broader healthcare system through a more coordinated and directed distribution of health care expenditure and resources.

Pfizer Australia appreciates the unique challenges posed by co-dependent technologies in Australia's health technology assessment process. We agree that the assessment of cost-effectiveness and the budget impact of targeted medicines should include the costs associated with diagnostic testing. However, we believe that, in its current form, Australia's co-dependent technology process creates a number of complexities which, together, may hinder a sponsor's ability to bring life-changing and life-saving new medicines to Australian patients.

2. Complexities of the co-dependent technology process

(i) The diagnostic test and targeted medicine may not be owned by the same company

The co-dependent technology process requires sponsors to provide a single economic model for the targeted medicine and the diagnostic test. This means that if the targeted medicine and diagnostic test are not owned by the same company, two (or more) commercial entities must submit a joint application. Commercial entities are thus forced to share proprietary clinical evidence, commercial forecasts and pricing data, creating both legal and commercial risk, as well as an additional cost burden for the companies involved. Many companies require legal guidance and, more often than not, global approval to share such data where no commercial imperative exists. These requirements may cause unnecessary delays in the preparation of applications and could deter companies from bringing new, innovative medicines to the Australian market by weakening intellectual property protection and potentially exposing such companies to liability under relevant Australian competition laws.

To address this issue, Pfizer Australia urges Government to take a pragmatic approach to the co-dependent technology assessment process and accept two separate submissions in instances where the sponsor of the targeted medicine and the sponsor of the diagnostic test are different commercial entities.

Recommendation 1: Allow companies to make two separate submissions to the co-dependent technology assessment process in instances where the sponsor of the targeted medicine and the sponsor of the diagnostic test are different commercial entities.

(ii) Research questions for MSAC open for public consultation

Under the existing guidelines, MSAC's Protocol Advisory Subcommittee (PASC) is responsible for confirming the research question(s) to be addressed by the sponsor within their submission. During this process, PASC publishes the proposed research question(s) for public consultation. In Pfizer Australia's most recent experience, this publication occurred twelve months prior to the lodgement of the reimbursement dossier. In contrast, the reimbursement activities for *non*-targeted medicines remain confidential until the publication of the PBAC agenda, ten weeks prior to the PBAC meeting.

Whilst Pfizer Australia supports the early engagement and consultation that this process provides, we believe that, in some cases, there is limited additional information provided during the period of public consultation required under the guidelines. For example, in instances where a diagnostic test and medicine have been co-developed, the resource burden for the Sponsor, the PASC and the relevant 'craft-groups' may outweigh the added value of the public consultation. We, therefore, recommend that the requirement for public consultation is assessed on a case-by-case basis (i.e. it becomes the exception rather than the norm).

Recommendation 2: Adjust the requirement for public consultation on the research question(s) for the PASC to be on a case-by-case basis

(iii) PBAC and MSAC meeting schedules are not aligned

Under the current co-dependent technology process, a targeted medicine is reviewed by the PBAC before its corresponding diagnostic test is reviewed by MSAC, which occurs approximately four weeks after the first PBAC meeting. Following, a recommendation from MSAC must be assessed by PBAC at their next meeting. For targeted medicines, this additional step adds at least 17 weeks to the decision-making period (a minimum of 34 weeks in total)¹.

Pfizer Australia acknowledges Government's efforts to date in making this process more efficient by reducing the time between MSAC and PBAC meetings. However, we believe that additional process efficiencies could be gained through a joint meeting of PBAC and MSAC, as occurs for the joint meeting of the Economic Subcommittees of MSAC and PBAC. As co-dependent technology submissions are rare, we believe this joint meeting of MSAC and PBAC could occur within the existing PBAC meeting schedule, as required.

Recommendation 3: Schedule a joint meeting of PBAC and MSAC for the relatively few submissions that are co-dependent.

(iv) Ongoing consideration of the efficiencies in the co-dependent technology assessment process

Pfizer Australia welcomes the greater clarity provided in the co-dependent technology chapter of the draft revised PBAC Guidelines Version 5.0 and encourages an ongoing consideration of the validity of the current structure for the assessment of co-dependent technology submissions. Patients who could benefit from targeted medicines should not be penalised by greater complexity and longer timeframes to access than non-targeted medicines - particularly given the additional and unique benefits provided by co-dependent medicines.

Through the reimbursement of crizotinib and ALK-testing, Pfizer Australia has gained many insights associated with the co-dependent technology process that we would be happy to share with the Department of Health.

Recommendation 4: Regularly consider the validity of the current structure for the assessment of co-dependent technology submissions, seeking input from Sponsors who have interacted with the co-dependent technologies process, and make timely practical changes that improve this process.

¹ The evaluation of a non-targeted medicine takes a minimum of 17 weeks.