Submission to Inquiry into Approval Processes for New Drugs and Novel Medical Technologies in Australia

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House Standing Committee on Health, Aged Care and Sport
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Introduction

As the national professional body for Australia Medical Oncologists and a speciality Society of the Royal Australasian College of Physicians, the Medical Oncology Group of Australia Incorporated (MOGA) and the Private Cancer Physicians of Australia (PCPA), a membership organisation for medical oncologists and clinical haematologists in private practice in Australia, provide the following advice to the House Standing Committee on Health, Aged Care and Sport, Department of the House of Representatives Inquiry into approval processes for new drugs and novel medical technologies in Australia.

In late February 2015 MOGA made a submission to the Senate Standing Committees on Community Affairs in response to the Inquiry on the Availability of new, innovative and specialist cancer drugs in Australia on these issues and few changes were enacted as a result of this process. Hence, MOGA welcomes this Inquiry which provides a timely opportunity for Australian oncology professionals as a key stakeholder group to again raise key issues, with a view to developing sustainable solutions that will contribute to addressing oncology drugs and treatments access issues for new, innovative and specialist cancer drugs in Australia; and in positioning our nation to best provide access to new drugs and novel medical technologies for all Australians now and into the future.

This submission addresses the Inquiry's terms of reference as follows:

The range of new drugs and emerging novel medical technologies in development in Australia and globally, including areas of innovation where there is an interface between drugs and novel therapies;

MOGA and PCPA understand that a rigorous regulatory and reimbursement approval process is fundamental to ensuring the quality, safety, efficacy and cost- effectiveness of new, innovative and specialist cancer drugs and therapies in Australia. MOGA and PCPA welcome recent process improvements including the development of a TGA fast track approval pathway but many components of the current approval processes require attention.

In some instances, multiple submissions to the PBAC are required to achieve a PBS listing. In addition, over the last decade some important new oncology drugs and therapies in areas of high unmet clinical need in Australia have received positive recommendations from the PBAC, however the decisions have been followed by delays due to Government fiscal considerations, or prolonged and often unsuccessful negotiations between the sponsor and Government regarding price. These delays to PBS listing have negatively impacted on timely access to key oncology treatments in Australia.

There are a range of concerns with PBS listed indications that do not reflect clinical practice, standard cancer care and treatment recommendations. The PBS has inadequate coverage of indications that have a sound evidence base, but are outside of TGA-approved indications; TGA indications do not keep pace with evidence development. This is due to many factors including the complexity of the approval process; only drug sponsors can lodge an application for a new indication; lack of commercial incentives; off-label prescribing is clinically acceptable if supported by evidence; and, new evidence can be developed without the involvement of the original sponsor. Addressing these issues may improve the responsiveness of the registration process to changes in the clinical setting. The PBS listing process can mitigate this issue by moving a restricted listing to a general listing without restriction and this has been particularly

suitable for medicines that have had a significant price reduction following loss of market exclusivity. A number of oncology drugs have been 'de-restricted' but there is currently no formal process whereby this can be enacted.

MOGA and PCPA believe that regulatory evidentiary requirements in Australia do not always adequately reflect the needs of oncology drugs and treatments thereby causing delays in access. There is a need to review and harmonise evidentiary requirements in Australia and overseas, and, address concerns about their delivery. For diseases with significant unmet clinical need and technologies that have proven to be efficacious and safe, making decisions based on surrogate endpoints may be appropriate, on the condition that the sponsor is obliged to undertake post-marketing evaluation.

The evidence base for cancer medicines may have some levels of uncertainty. The current system has a low level of acceptance for uncertainty, and has not implemented any process or practical solutions to address this. Hence, the current system may not be sufficiently sensitive to assess the complexity of many cancer treatments, particularly those intended to treat small patient populations with rare cancers.

MOGA and PCPA are of the view that publicly reimbursed access to oncology drugs is significantly delayed in Australia compared to other OECD countries. There are increasing instances of access delays in Australia compared with other countries above all with respect to what is recommended in US and European evidence-based cancer treatment guidelines. This impacts negatively on the quality and availability of the cancer care and therapies for Australian patients.

Incentives to research, develop and commercialise new drugs and novel medical technologies for conditions where there is an unmet need, in particular orphan, personalised drugs and off-patent that could be repurposed and used to treat new conditions;

MOGA and PCPA acknowledges that the challenges to accessing new cancer medicines and therapies in Australia in a timely and affordable manner are increasing, including delays in access in comparison with the US and Europe. However, the causal factors are unclear and warrant detailed analysis. For example, do the recent protracted processes leading to the approvals/rejections of listings reflect system inefficiency or necessary process requirements? Related questions that need to be addressed include; do sponsors postpone applications in Australia?; is the increasingly uncertainty regarding reimbursements in recent years contributing to access issues?

Oncology drugs and therapies are expensive to develop, manufacture and purchase. Maintaining a viable medicines industry in Australia by providing sufficient commercial incentives for industry to pursue drug development and marketing is crucial. However, there is a need for greater transparency regarding how drug prices are set in Australia and globally; including the justification of high prices, and what are perceived as unrealistic price expectations, with the provision of clear ROI and manufacturing data.

The Pharmaceutical industry in Australia is composed of affiliates of global companies, and as subsidiaries they have limited influence over the development of new cancer medicines, both in terms of trial design and price setting, particularly for those intended to treat a small group of patients. This means that Australian patients in these smaller population groups may be denied access to affordable treatments and therapies through the PBS.

In Australia setting reimbursed prices for new oncology drugs with reference to older comparators is problematical and may be an obstacle to access. Generic competition following patent expiry and PBS reform has combined to reduce the price of generic medicines. In some cases, reference pricing methods have resulted in a price that fails to demonstrate cost-effectiveness of a new drug to the PBAC, or that is viable for the sponsor to list the on the PBS. The system should be structured to guarantee the supply of generic cancer medicines, which are more costly in Australia than in other countries, including identifying appropriate remuneration to ensure consistency of supply.

Changes to make older and/or off-patent, drugs more easily available for different (often rarer) conditions should be also be a focus for policymakers.

Measures that could make Australia a more attractive location for clinical trials for new drugs and novel medical technologies; and

Clinical Trials

MOGA and PCPA are of the view that the current access and approval system in Australia impacts negatively on the delivery and development of clinical trials in Australia. The current barriers posed by the national system have the potential to disengage the medicines industry from Australia and to cause them to divert investment to other countries. Similarly, delays in securing

reimbursement also effects clinical trials, as companies may reconsider placing clinical trials and access programs in Australia if there is little or no chance of reimbursement. The increasing number of special pricing arrangements is a related concern and suggests that the current reimbursement system is not delivering a fair return on innovation.

Rare Cancers

MOGA and PCPA are concerned that research priorities, commercial imperatives and advocacy favours access to oncology drugs and treatments for more common cancers in Australia. For instance, clinical trials for rare cancers are often conducted through collaborative trials groups with less industry support and the data collected may be less suited to registration and reimbursement requirements. The Australian regulatory process and our Government seem reluctant to fund effective treatments for rare cancers even though the overall impact on the health budget would be minimal. The negative impact of this situation on the quality care of Australian rare cancer patients and the lack of available treatment options is unacceptable. Our national systems for research and development, oncology drugs regulation and reimbursement need to be reviewed and revised to be supportive of drug development and access for rare cancers.

Without compromising the assessment of safety, quality, efficacy or cost-effectiveness, whether the approval process for new drugs and novel medical technologies, could be made more efficient, including through greater use of international approval processes, greater alignment of registration and reimbursement processes or post market assessment.

MOGA and PCPA are is of the view that the pipeline for oncology drugs and therapies is rapidly growing and is anticipated to increase over the next decade. Biomarkers, associated co-dependent technologies and tests, immunotherapies and a raft of other advances in the oncology sector have and will continue to add complexity to the approval, reimbursement and access arrangements for oncology drugs in Australia. The Australian system needs to be able to meet the challenges that the high number and, increasing complexity of applications, will have on the assessment framework, and be responsive and adaptive in its requirements to facilitate and ensure that Australian patients have access to them. Without compromising the assessment of safety, quality, efficacy or cost-effectiveness MOGA believes that the national approval process for new drugs and novel medical technologies, must be made more efficient and responsive to international best practice. Remedies that we recommend include continuing to align the Australian system with international approval processes where possible, enhanced alignment of registration and reimbursement processes and post market assessment.

Other issues concerning the timing and affordability of access to new, innovative and cancer drugs for Australian patients that are of major professional concern include;

- The Australian system favours a user pays approach that discriminates against patients without the ability to pay for non-subsidised oncology drugs and treatments. Regrettably, access arrangements are dependent on where a patient lives, who their physician is, their access to specialised cancer treatment and their level of private health insurance. Additionally, even when an oncology drug or therapy is made available through the PBS patients are often required to pay substantial out of pocket expenses that causes them an additional financial burden and psychological distress, that often further complicates their treatment. Significant time lags in approving new drugs and therapies in comparison with overseas determinations and guidelines as well as limited special access options also result in similar patient outcomes. The interplay of these factors means that access is inequitable and lacking in compassion.
- The different coverage of on-label and off-label indications in hospital and PBS formularies may also affect the continuity and affordability of treatment for patients.
- Delayed access to reimbursed cancer drugs and treatments means that the Australian system is more reliant on compassionate and early access programs and these have their own associated problems including operational and funding demands for hospitals. A related equity issue also arises because not all cancer patients (e.g. those from regional and rural areas) receive treatment at a major treatment centre where such programs are commonly available also require attention.

Conclusion

This submission details a range of factors that have and will adversely impact on the quality of care available to cancer patients that arise from the current approval processes for new drugs and novel medical technologies in Australia. These include a reduction in the number of special access schemes in Australia providing patients and clinicians with vital access to new, innovative and specialist cancer drugs; the erosion of the Australian oncology research, clinical and pharmaceutical sectors and their ability to compete internationally; impeding the ability of Australian oncology professionals and clinicians to provide best practice, international standard of care to their patients.

Australia has performed well in providing affordable and equitable access to new oncology drugs and novel oncology treatments but the system faces significant challenges from the growing cancer burden, the emergence of many new cancer treatments and

the expectation that these new advances should be made available in a timely, affordable and compassionate manner. MOGA and PCPA makes the following recommendations:

- The governance culture and silo-approach within various authorities and government departments need to be challenged and a single, co-ordinated agency and decision-making process with supporting legislation is required to achieve greater process efficiency We strongly recommend legislative reform that combines the TGA and PBAC process and MSAC process when appropriate. We also strongly recommend that the delay between PBAC approval and PBS listing be reviewed. Efforts should be made to reduce the time from PBAC recommendation to PBS listing as this is likely to have a positive impact on patient care.
- Procedural and structural improvements to streamline current regulatory and reimbursement processes and associated departments/authorities are necessary, notably for medicines with co-dependent diagnostic tests; including harmonisation of evidentiary requirements between regulatory and reimbursement authorities; and, prioritise healthcare resources in view of the different value perceptions of clinical benefits. We strongly recommend legislative reform that makes it easier for clinical groups like MOGA make submissions to regulatory bodies for approval of drugs especially for older, off-patent drugs with new indications, or for drugs to treat rarer conditions for which the budget impact is expected to be minimal.
- Resource allocation should be equitable and made with consideration to: population burden of disease; severity of disease, including consideration for end-of-life needs; unmet clinical need, above all where there is no alternative treatment; wider perspective in assessing economic merits, including costs for families and carers; and patient's productivity if a drug/treatment improves functionality; including ensuring adequate national investment in the treatment of rare cancers.
- Ensure a rigorous, national regulatory and reimbursement but, above all, compassionate assessment process for oncology drugs and treatments, without undue political interference and that ensures drugs and treatments in Australia are priced at a level that is affordable and sustainable to the system, providers and end users.
- Ensure Australia's attractiveness and competitiveness for undertaking clinical research.

We trust this advice will be of assistance.

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