



12 October 2020

Mr Trent Zimmerman MP  
Chair  
House of Representatives Standing Committee on Health, Aged Care and Sport  
PO Box 6021  
Parliament House  
CANBERRA ACT 2600

Dear Mr Zimmerman

**Re: Submission to the inquiry into the approval processes for new drugs and novel medical technologies in Australia**

AbbVie is a global, research-driven biopharmaceutical company committed to developing innovative advanced therapies for some of the world's most complex and critical conditions. Our heritage in Australia reaches back more than 80 years and we employ more than 450 people with our therapies currently benefiting more than 30,000 Australians. The company's mission is to use its expertise, dedicated people and unique approach to innovation to markedly improve treatments. Recently, we acquired Allergan which immediately diversified our business across several therapeutic areas: Immunology, Oncology, Virology, Neuroscience and Aesthetics.

Our commitment to making a remarkable impact doesn't end at developing medicines; it begins there. We provide broader support to our patients and help address the health needs of underserved communities. We strive to protect our environment and to make a positive impact in the areas where we live and work.

AbbVie welcomes the opportunity to make a submission to the Committee in response to the Terms of Reference for the inquiry and agrees that Australia must continue to be well positioned to access new drugs and novel medical technologies in a timely manner and respond to emerging global trends.

The scope of this inquiry is wide ranging; AbbVie will focus on three elements of importance, broadly relating to the fourth Term of Reference. AbbVie welcomes the opportunity to expand on these or other points in an oral evidence hearing.

**Recommendations:**

1. Australia should consider the international context of developing and commercialising medicines and new medical technologies – it is critical that companies can afford the risk

that innovation requires to ensure future improved medicine options as well as innovative products for unmet needs

2. Incremental innovation should be acknowledged with appropriate pricing. Consideration of total cost should be removed from PBAC deliberation so that assessment is based on health outcomes provided by the treatment and value for money, rather than budget impact
3. Improved mechanisms for patient and expert clinician input are required to ensure that patients' needs are appropriately understood by HTA decision makers

### 1. The International Context

Australia faces significant health challenges during and beyond COVID 19, and a robust health system is essential to Australia's long-term future. Most medicines today and into the future are developed by multinational pharmaceutical companies and therefore Australia is necessarily reliant on the global industry to provide solutions to Australia's health problems of today and tomorrow.

There is good reason for multinational pharmaceutical companies to be central to the development of medicines. In many instances, there is considerable collaboration in the journey of drug discovery including support from multinational pharmaceutical companies of research in academic institutions across the globe. Despite the success of Australian research scientists in the discovery of new and novel compounds, the cost to commercialise a medicine is immense. Medicines must be proved safe and effective through Phase I, II and III clinical trials and secure regulatory approval. Trials invariably include participants from multiple countries to ensure speed of recruitment and testing across a variety of patient populations. The average cost of a trial program is estimated to be greater than AUD\$2.7billion,<sup>i</sup> a figure that is well beyond most local research enterprises or governments. Additionally, 9 out of 10<sup>ii</sup> compounds fail in the development process. The development of vaccines for the prevention of COVID 19 has demonstrated the importance of multinational pharmaceutical companies in partnering with governments and research agencies globally to bring new treatments to the population.

It is critical that companies can afford the risk that innovation requires to ensure future improved medicine options as well as innovative products for unmet needs.

### 2. Access to new and innovative medicines

Australia is widely regarded as having one of the best healthcare systems in the world including timely and affordable access to medicines <sup>iii</sup>. The health technology assessment process for medicines has been successful in allowing Australian patients access to new treatments at a price that is affordable for the taxpayer and patient. It should be noted that Australia has medicine prices that are among the lowest in the world <sup>iv</sup> and although the population has increased by more than 15% since 2012, real expenditure on the PBS has not increased over the same time (commensurate with the growing and ageing population) despite the addition of new



treatments, for instance the immunotherapies that have had a major impact on life expectancy for thousands of cancer patients.

Access to new and improved treatments is under threat in Australia. Although there are frameworks in place to support access, including improved regulatory pathways and especially for rare or orphan indications, there is an opportunity for the reimbursement pathway to adopt similar concepts to Project Orbis to accelerate access to medicines. The TGA has introduced positive actions to reduce approval timelines through Project Orbis, the international collaboration between regulatory authorities.

AbbVie is focussed on making a difference to patients' lives. Notwithstanding that, there are numerous issues that impact companies' decisions to pursue listings in each country, including:

- The opportunity in that country relative to other jurisdictions: factors such as the underlying need (the treatment options already available to patients and the number of patients who would benefit from treatment); the risks of being granted registration and /or reimbursement for a different or limited population relative to other larger markets – bearing in mind that the market in Australia is approximately only 2% of global revenue
- The overall commitment a company has made/is making in each country, such as the level of investment and financial commitment. It should be noted that there is a substantial cost associated with operating in each country such as for pharmacovigilance reporting and site audits
- How straightforward and streamlined it is for a company to pursue local 'frameworks' and the cost of the local approvals required
- The broader pricing and business environment in each country – such as intellectual property protection and price opportunity and maintenance.

The PBS was established as an uncapped program with the legislated remit of the PBAC to recommend for PBS listing medicines that are safe, effective and cost effective. Although the Department of Health's website<sup>v</sup> continues to describe the PBS as uncapped, measures have been implemented over time that serve to significantly limit expenditure on the PBS thereby negatively impacting a company's ability to launch a new medicine. For instance, PBAC recommendations that are conditional on prices being linked to the lowest cost comparator; Government expenditure caps that significantly underestimate the PBS population; or significant ongoing statutory price reductions, are three such impediments. If the company agrees to supply the medicine under these conditions, patients have access to the new treatment, but the company is impacted by the lower than anticipated price and frequently experiences price reductions even during the period of patent protection.



In other instances, patients' needs are being disregarded. Incremental improvements are not rewarded under the current system due to the introduction of policies to contain price. Examples include comparator price erosion (where, instead of evaluating cost relative to the most clinically relevant alternative, older, less expensive and less relevant medicines are used to artificially decrease cost effectiveness) and the interpretation of s99ACB of the National Health Act (where the value of new formulations that have easier administration or fewer side effects - things that are important to patients - are disregarded in the assessment process).

Ultimately, if national reimbursement on the PBS is dependent on extremely low prices (or price reductions continue to occur) or if access is restricted by caps on Government expenditure, the overall effect is that Australia is a less attractive place for global pharmaceutical companies to operate including conducting global clinical trials in Australia. The impact of this is delayed access despite any specific frameworks that might be in place to support access.

The PBS should provide access for necessary medicines<sup>vi</sup> for all Australians, not only treatments for rare diseases. Consideration of total cost should be removed from PBAC deliberation so that their assessment is based on health outcomes provided by the treatment and value for money, rather than focusing on opportunity cost or the budget impact.

### **3. Other measures to improve access to new medicines and medical technologies**

The reality of new technologies and new modalities for drug discovery and development will only increase over the next five years. We have witnessed the early stages in Australia with the introduction of the CAR T cell therapies that use specially altered cells to directly and precisely target cancer cells – and required new approaches to the evaluation of efficacy and value.

Effectively identifying, treating and preventing diseases and their complications will require medicine developers and regulators to optimise the use of novel evidence in decision making, will require stronger collaboration with all stakeholders including the patient community, health care professionals, HTA bodies and academia.

For example, when unmet medical need is high and where randomisation is not ethical or feasible, other options such as Real World Evidence could be a viable option to provide pivotal evidence of the benefit of new medications. Fit for purpose HTA processes which allow more flexible evidentiary requirements which take into account the clinical and ethical complexity will need to be developed. Early dialogue between the TGA and PBAC, for orphan medicines, paediatric oncology medicines and advanced therapies for rare diseases where the patient population is small, would be particularly beneficial, and the incorporation of specialist expert input and the expansion of consumer engagement would enhance decision making processes.



Improved mechanisms for patient and expert clinician input are required to ensure that patient needs are appropriately understood by HTA decision makers. This is especially important for innovative therapies which enhance the lives of patients and their families in a myriad of ways and provide significant benefits to Australian society beyond the limited analysis framework of direct health costs.

AbbVie would be happy to provide clarification or further expand on these or other points in an oral evidence hearing.

Yours sincerely

CHRISSTEMPLE

Vice President and General Manager Australia and New Zealand

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Abbreviations:

PBAC: Pharmaceutical Benefits Advisory Committee

PBS: Pharmaceutical Benefits Scheme

TGA: Therapeutic Goods Administration

HTA: Health Technology Assessment

CAR T: Chimeric antigen receptor cell therapy

<sup>i</sup> Innovation in the pharmaceutical industry: New estimates of R&D costs.

<https://doi.org/10.1016/j.jhealeco.2016.01.012>

<sup>ii</sup> <https://www.forbes.com/sites/matthewherper/2017/10/16/the-cost-of-developing-drugs-is-insane-a-paper-that-argued-otherwise-was-insanely-bad/#31aa56192d45>

<sup>iii</sup> <https://www.health.gov.au/about-us/the-australian-health-system>

<sup>iv</sup> <https://www.medbelle.com/medicine-price-index-usa>

<sup>v</sup> <https://www.pbs.gov.au/info/about-the-pbs>

<sup>vi</sup> <https://www.pbs.gov.au/info/about-the-pbs>