NOVARTIS

Senate Inquiry into the Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016

Submission to Senate Community Affairs

Legislation Committee

March 2017

Introduction

The Novartis Group of Companies (Novartis, Sandoz and Alcon) welcomes the opportunity to make this submission to the Senate Community Affairs Legislation Committee inquiry and report on the Therapeutic Goods Amendment (2016 Measures No. 1) Bill 2016.

The Novartis Group's mission is to use science-based innovation to deliver better outcomes for patients to live longer and healthier lives. We are proud of our ongoing contribution towards Australian economic and productivity growth in the key areas of innovative medicines and medical devices.

The Novartis Group operates businesses that develop innovative medicines, biosimilar and generics medicines (Sandoz), as well as eye care products and devices (Alcon). Our products span the range of therapeutic goods regulated by the Therapeutic Goods Administration (TGA). As such, the Novartis Group believes it can offer a balanced commentary on the recommendations of the Expert Review of Medicines and Medical Devices Regulation (the Review) and the proposed amendments to the *Therapeutic Goods Act 1989* (the Act).

The Novartis Group supports the timely implementation of the recommendations of the Review and the proposed amendments to the Act for the following reasons:

- The amendments follow an independent expert review and broad public consultation
- The amendments will deliver sustainable benefits to the Australian community
- The amendments will enhance safeguards for patients and improve outcomes

In support of transparency and accountability, we respectfully urge the Committee to allow the passage of the amendments to the Act through Parliament for these reasons, which we expand on in the following sections.

The amendments follow an independent expert review and broad public consultation

The Review was undertaken by an independent expert panel and followed a comprehensive consultation process that received input from a broad range of stakeholder groups, including the medicine and medicine device industries, professional bodies and patient groups.

The Review made a strong case for reform and delivered 58 recommendations, 56 of which were accepted by the Commonwealth and will deliver significant benefits for the Australian community. Novartis therefore welcomes the opportunity to make this submission on such an important issue for Australian patients.

The amendments will deliver sustainable benefits to the Australian community

Novartis believes the amendments to the Act strike the right balance between safeguarding the Australian community and creating a sufficiently flexible regulatory framework for pre-market

assessment that reduces the burden on industry and ensures sustainability and responsiveness to innovations. The Act provides the legislative basis for other legislative instruments – safeguarded by the TGA - such as the Regulations, Orders and Determinations, which are better means of codifying specific requirements and can be amended more easily to keep pace with new international standards, innovations or advances in medical technology and practice.

The amendments will support the implementation of key recommendations of the Review that aim to streamline ineffective regulations that cut across all regulated therapeutic goods, while maintaining the safety and quality of therapeutic goods available in Australia. In addition, the implementation of these reforms will facilitate quicker patient access to new life-saving medicines and devices that have significant advantages over existing treatments.

The benefits to the Australian community will be achieved not only through the introduction of new expedited review pathways, but also by the TGA adopting a more efficient approach to the management of routine post-marketing variations to existing medicines. Passage of this legislation will allow better use of decisions made by competent overseas authorities that have comparable regulatory frameworks to ours (Recommendation 13). This in turn will substantially reduce the overall regulatory burden on both regulator and industry without undermining the safety or quality of therapeutic goods and potentially enable earlier more manageable supply of medicines access for Australian patients.

The amendments will enhance safeguards for patients and improve outcomes

The amendments support earlier access to certain novel prescription medicine that offer substantial benefits of existing therapies or address high unmet clinical needs for Australian patients. These pathways will need flexible business processes to facilitate pre-market assessment, while maintaining the TGA's high standards. Maintaining a flexible approach at the operational level will also allow the TGA to better anticipate and adapt to as yet unimagined medical advances without the need for changes to the Act.

Importantly, expedited pathways will emphasise stepwise learning under conditions of uncertainty thereby reducing the risk to patients, as sponsors will be required to collect and submit post-market safety and efficacy data. Other conditions may be applied within the more comprehensive post-market monitoring scheme for medicines and medical devices, which was also recommended as part of the Review.

Conclusion

The Novartis Group believes that the passage of the Bill will help improve timely access to life-changing and life-saving medicines for Australian patients and reduce the burden on industry and the broader health care system. The changes will create a more efficient regulatory framework that is sustainable and responsive to innovations.

Novartis would be happy to assist with the Review and appear in person to answer any questions if needed.