NOVARTIS

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Senate Community Affairs Legislation Committee
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Re: **Senate Community Affairs Legislation Committee 2017 Inquiry into the second TGA Bill, the Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017**

Dear Secretary

Novartis welcomes the opportunity to provide commentary on the Senate Community Affairs Legislation Committee Inquiry into the Therapeutic Goods Amendment (2017 Measures No.1) Bill 2017.

As a member of Medicine Australia (MA), Novartis endorses the submission made by MA in response to the provisional approval pathway established by the Bill. Our products span a broad range of therapeutic goods regulated by the Therapeutic Goods Administration (TGA). As such, we wish to provide balanced commentary on the proposed amendments to the *Therapeutic Goods Act 1989* (the Act).

Novartis supports the timely implementation of the proposed Bill, in particular the introduction of a provisional approval pathway to enable Australian patients to gain earlier access to promising new medicines. The drafting of this Bill is the culmination of over 2 years of extensive consultation with a range of stakeholders and has received broad support. Novartis would be deeply concerned if there passage of the Bill were unnecessarily delayed due to issue that are unrelated to the introduction of a provisional approval pathway for new innovative medicines.

Earlier access to innovative lifesaving medicines with appropriate safeguards

Novartis supports the TGA Bill's implementation of a provisional approval pathway to enable Australian patients to gain access to potentially life-saving new medicines earlier than currently possible. Appropriate safeguards have been put in place to ensure sponsors generate confirmatory data, as well as providing the TGA with a mandate to impose other conditions that will enhance the level of vigilance for provisionally registered medicines amongst health professionals and consumers.

As mentioned in our submission to the previous Senate inquiry, the introduction of these new regulatory pathways will enhance TGA's capabilities and give Australian patients access to potentially life-saving therapies at the same time as patients overseas.

Modernise Australia's framework for the approval and registration of innovative medicines

Substantial steps have been taken to reform the way Australia regulates medicines and medical devices. For instance, the recent introduction of a priority review process that will facilitate Australian patients' access to potentially life-saving medicines. The introduction of a provisional approval pathway will further align Australia with best practice amongst other comparable regulatory systems, which incorporate similar expedited access pathway. In 2012 the US Food and Drug Administration (FDA) took the lead through its 'breakthrough therapy designation' scheme, to review products of potential medical benefits at an accelerated pace. The scheme enabled a faster review process for medicines of untreatable rare diseases or new approaches to more common conditions that offer a substantive improvement over existing therapies.[1] Similarly, the European Medicines Agency featured a scheme called Prime, which increases regulatory support for the most promising drugs by cutting assessment times by nearly a third, from 210 days to 150 days.[2]

Novartis believes the comments made in this letter will assist the Senate Committee with its deliberations.

Yours sincerely,

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Peter Murphy
Director, Public Affairs and Communication

About Novartis

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, as well as eye care products and devices. Each year Novartis invests over $20 million into over 200 clinical trials and projects, supporting access to new medicines in development for many patients. In addition to our investment in Australian research and development, we also provide medicines to thousands of patients, predominantly via the Pharmaceutical Benefits Scheme (PBS) in various disease areas such as cancer, neuroscience, ophthalmology, respiratory and heart failure. For more information, please visit www.novartis.com.au

[1] FDA. Fast Track, Breakthrough Therapy, Accelerated Approval, and Priority Review. 2018. Available at: https://www.fda.gov/ForPatients/Approvals/Fast/default.htm

[2] European Medicines Agency. PRIME: priority medicines. 2017. Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000660.jsp