

Transparency, Reforms and Evaluation Support Section
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

tgaregreforms@health.gov.au

Closing date: 29 March 2019.

Dear Sir/Madam,

Consultation: Whether the TGA should publish that a prescription medicine is under evaluation

Medicines Australia welcomes the opportunity to provide comment on the Therapeutic Goods Administration (TGA) consultation on whether the TGA should publish that a prescription medicine is under evaluation.

Medicines Australia represents the innovator pharmaceutical companies in Australia who also currently produce the majority of the biosimilar medicines available on the Australian market. As such, it is very well placed to provide comment on this consultation.

Medicines Australia has long argued that the amendments to the Therapeutic Goods Act 1989 to give effect to Australia's obligations under the Australia-United States Free Trade Agreement (AUSFTA) in relation to notifications of applications for the marketing approval of therapeutic goods in Australia were inadequate.

Medicines Australia strongly supports the TGA's commitment to the better health and wellbeing for all Australians and its efforts to be appropriately transparent about its regulatory activities. Transparency is an important part of ensuring public confidence in the regulatory review activities being undertaken. To this end, Medicines Australia's **preferred position is Option 2: list all applications accepted for evaluation. It is the ONLY option in this consultation paper that fully supports transparency of these activities** and can withstand public scrutiny as a robust policy option in the current operating environment. **The key reasons for the MA position are summarised in the attached Appendix.**

Medicines Australia **strongly opposes Options 3 and 4** as they apply very different criteria for the transparency of innovator medicines compared to generic medicines and will delay access to medicines for Australian patients. For the TGA to be appropriately transparent, all products must be treated equally. The TGA states that there is generally less interest in whether a biosimilar or generic is under evaluation compared with innovator medicines, however, in line with health policy in creating greater awareness of these products for health care professionals (HCP) and the general public, it would seem counter intuitive that interest would not significantly increase.

Medicines Australia believes that by implementing Option 2, viz., list all applications accepted for evaluation, the TGA will achieve the following:

1. Be appropriately transparent about its regulatory activities;
2. Allow for increased HCP and patient awareness regarding medicines under evaluation;

3. Be able to more easily engage in meaningful stakeholder engagement and education;
4. More closely align with other current Australian Government policies;
5. Achieve closer regulatory harmonisation with key Comparable Overseas Regulators; and
6. Provides additional time to resolve intellectual property disputes.

Medicines Australia considers the following information should be included in a published list to achieve the transparency objectives described above:

- **Active ingredient**
Aligned with the international non-proprietary name (INN) prescribing initiative, and reference information for HCP and consumers searching for new products, including generics and biosimilar medicines, that may be subject of local or overseas announcements. Will also assist in identifying potential options for medical alternatives as part of managing medicine shortages.
- **Tradename**
Reference information for HCP and consumers who may not be familiar with the INN information when searching for new products including generic and biosimilar medicines, that may be subject of local or overseas announcements. Useful to assist in identifying potential options for medical alternatives as part of managing medicine shortages.
- **Therapeutic area/disease state**
Information communicated should be suitable for being easily understood by consumers seeking information on new medicines including generics and biosimilar medicines. For example, treatment of lung cancer or high blood pressure.

Inclusion of the indication is not recommended as this can significantly change during evaluation and may lead to false expectations about the future availability of medicines for treatment of a particular population or indication.

- **Sponsor name**
For smaller organisations without global presence it is common for partnerships to be formed and thus the Sponsor name is very useful for HCP and consumers to identify the local Sponsor when searching for new products that may have been announced overseas. It is also of value to obtain medical information in relation to potential special access scheme requests as well as to assist in identifying potential options for medical alternatives as part of managing medicine shortages.

A standard monthly timetable for communication should be implemented with a means to easily identify updates that have occurred since the previous month.

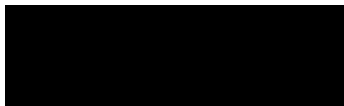
Medicines Australia notes that the TGA has not included Medsafe (the New Zealand regulator) in their international comparison of other regulators. Medsafe does provide such information when they list applications under review.

Further consultation with Industry on the exact content of what is to be disclosed, the timing of when the information will be published and from what date greater transparency will be introduced will be important.

We would be happy to discuss or provide further comment on any aspect of our response and we appreciate being kept up to date on further developments.

Please feel free to contact Betsy Anderson-Smith if you would like further clarification on any aspect of our submission (banderson-smith@medaus.com.au).

Yours sincerely



Dr Vicki Gardiner
Director, Policy and Research
Medicines Australia

Appendix:

Medicines Australia fully supports implementing Option 2: list all applications accepted for evaluation as the only appropriate approach for the TGA to take regarding whether the TGA should publish that a prescription medicine is under evaluation. By implementing Option 2, the TGA will achieve the following:

1. Be appropriately transparent about its regulatory activities.

Medicines Australia supports the TGA's efforts to be appropriately transparent about its regulatory activities. Medicines Australia strongly contends that **Options 3 and 4 as outlined in the paper should not be implemented** as they apply very different criteria for the transparency of innovator medicines compared to generic medicines. A two-tier system that treats innovator companies differently and favours generic/biosimilar applicants is not a fair and equitable approach to regulation. Medicines Australia strongly contends that for the TGA to be appropriately transparent, then all products should be treated equally.

2. Allow for increased HCP and patient awareness regarding medicines under evaluation.

There is a strong public interest in the availability of all medicines and not just 'new' medicines. Doctors, other HCPs and patients often seek information on medicines not available in Australia when overseas filings are announced. In addition, awareness of all available options that may broaden treatment access is important to HCP and consumers. Transparency is also increasingly important to maintain confidence in the regulatory review process for new medicines and meet the expectations of public scrutiny in the current operating environment.

3. Be able to more easily engage in meaningful stakeholder engagement and education.

As stated in the consultation paper under Option 2 where the "TGA would publish that a prescription medicine has been accepted for evaluation" and that "this information would be of interest to both consumers and other interested parties including healthcare professionals and industry." Clearly, only through the implementation of Option 2 would the TGA be able to achieve its stated goal of "being able to more easily engage in meaningful stakeholder engagement and education". Not being fully transparent will mean prescribers and patients will be less aware of the upcoming choices and options they may have for their care.

4. More closely align with other current Australian Government policies.

Medicines Australia strongly contends that **Options 3 and 4 as outlined in the paper should not be implemented** as they contradict other existing Australian Government policies and initiatives.

The Australian Government is currently trying to raise awareness of and increase the use of biosimilar medicines in Australia. These initiatives in relation to biosimilar medicine uptake will increase HCP and public awareness and demand for information that warrants increased transparency. One of the key initiatives under consideration by the Government is increased awareness of the INN. Over time it is expected that consumer groups and the National Prescribing Service (NPS) would want to monitor new generic and biosimilar medicines to improve awareness of these medicines as they reach the market. Other ongoing Australian Government policy initiatives include funding the Generic and Biosimilar Medicines Association Education Grant designed to raise awareness of biosimilar medicines, as well as implementing uptake drivers to make it easier for prescribers to prescribe biosimilar medicines and therefore increase use.

Transparency around the entry of biosimilar medicines aligns well with Government policies in this area which are designed to support a sustainable PBS and ensure access to medicines aligned with the National Medicines Policy (NMP). It should also be noted that the EU, where the EMA have adopted the approach of publicly announcing when they accept a prescription medicine for evaluation, currently have the most biosimilar medicines available to patients.

Increased transparency will also facilitate planning in relation to risks of medicines shortages by identifying potential medical alternatives or additional suppliers that may enter the market.

The statement made in Options 3 and 4 that there is “less public interest in whether a generic or biosimilar medicine is under evaluation by TGA in Australia” contradicts the current Australian Government policies outlined earlier in this submission which demonstrates that there is a clear public interest in providing greater transparency and awareness of activities funded by the taxpayer to deliver medicines to Australia patients. Medicines Australia also questions whether the TGA is asserting that the public are not interested in this information and whether there is any evidence to support that claim.

Medicines Australia strongly contends that ONLY by implementing Option 2 will the TGA support these other Australian Government policy initiatives.

5. Achieve closer regulatory harmonisation with key comparable overseas regulators (CORs).

Registration of medicines using the Comparable Overseas Regulator (COR) Pathways and the option for Work-sharing with Canada, Switzerland and Singapore is open to all new medicines including generics and biosimilar medicines. For the COR pathway, TGA makes use of assessments reports from overseas regulators who are deemed to operate a comparable regulatory scheme. Currently, the list of CORs includes; the EMA in the EU, US FDA, UK MHRA, SwissMedic, Singapore HSA and Health Canada. Similarly, for work-sharing applications the TGA agree on a common evaluation plan to reduce duplication of workload.

Medicines Australia notes the current TGA approach as described in option 1, is significantly behind the international benchmark for transparency of CORs. Medicines Australia questions the rationale for providing an option similar to Japan’s approach to publication, when Japan is not a COR. It would appear highly inappropriate to more closely align with a country that is not recognised by the TGA as comparable. As such, Medicines Australia strongly contends that Option 4 is entirely inappropriate and should not be considered.

Option 2 is aligned with CORs who have implemented a transparency policy and Medicines Australia strongly contends this is the international benchmark to which the TGA should align;

- EU, Health Canada and Switzerland deliver transparency of all applications including new molecular entities, generics and biosimilar medicines
 - Submissions in Australia generally occur in a similar timeframe to those in CORs
 - EU has the highest numbers of biosimilar medicines authorised in the world and operates with transparency
 - Whilst the FDA regulatory framework does not allow publication of information, the requirements in place for SEC filings achieves the equivalent of transparency
- The introduction of work-sharing requires a common approach to transparency. To date Health Canada has been the predominant authority participating in work-sharing

- Health Canada has a transparency policy about submissions accepted for evaluation under a work-sharing procedure with the TGA whilst the information is not directly available from the TGA.

Option 2 also delivers a regime that is most closely aligned with the EU, which has been the longstanding regulatory regime which has influenced Australian regulatory practice.

6. Provides additional time to resolve intellectual property disputes.

Timely access to medicines at an appropriate price and maintaining a viable medicines industry in Australia are key principles of the NMP. The interaction of Australia's therapeutic goods regulation framework and Australia's encouragement of research and development in medicines via the protection of intellectual property is complex. The current notification arrangements provide limited transparency. A fully transparent mechanism, Option 2, offers the only opportunity, from the proposed options, for additional time to resolve any potential disputes regarding intellectual property. It is therefore not in the public interest or in the interest of a sustainable PBS for the current status quo (Option 1) or an inequitable transparency policy for new, generic or biosimilar medicines (Options 3 and 4).