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

29th March 2019

Dear Sir/Madam

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

AstraZeneca supports the TGA's efforts to be appropriately transparent about its regulatory activities. Consistent with the views expressed by Medicines Australia in their submission to this consultation, AstraZeneca supports the implementation of **Option 2 (list all applications accepted for evaluation**) of the TGA's proposed transparency options. Option 2 represents the only option that provides an appropriate level of transparency and is consistent with that seen with comparable overseas regulators.

The implementation of option 2 will all the TGA to achieve the following:

1. Be appropriately transparent about its regulatory activities.
2. Adopt a consistent approach with that of comparable overseas regulators (including New Zealand, which it is noted is not considered in the TGA consultation document).
3. Provide additional time to resolve intellectual property disputes.
4. Drive increased Healthcare Practitioner (HCP) and patient awareness regarding medicines under evaluation.
5. Be able to more easily engage in meaningful stakeholder engagement and education.
6. More closely align with other current Australian Government policies, notably the current policy on increasing awareness amongst HCPs and patients about biosimilar medicines.

The AstraZeneca position is that the information included in communications regarding medicines under evaluation should be consistent with the approach adopted by the European union in this area, namely: -

a) **Active ingredient** – consistent with the international non-proprietary name (INN) convention.

b) **Therapeutic area/Disease state** – presented in a manner which can be understood by the range of stakeholders who will access the information, including patients or their care givers.

   Inclusion of the specific proposed indication is not supported, as this can evolve during evaluation and may lead to false expectations about the future availability of medicines for treatment of a particular population or indication.

c) **Sponsor name** – Clarity on the local Sponsor name will help stakeholders know who to approach for information about the medicine, early patient access schemes or for information concerning possible management of medicines shortages.

AstraZeneca's position on the other options presented in the consultation document are as follows:-

Option 1: Maintain the TGA's current publication arrangements

Adopting the status quo position would be inconsistent with AstraZeneca's support for increased transparency by the TGA in this area and the benefits possible by the adoption of option 2 above. Thus, this option is not supported.

Options 3 and 4: Different timing for information publication or partial information disclosure

AstraZeneca opposes these options. The scenarios presented in options 3 and 4 apply different criteria for the transparency of innovator medicines compared to generic or biosimilar medicines and could delay access to medicines for Australian patients. From a transparency perspective there is no justification for this approach. The AstraZeneca view is that in this matter all products must be treated equally. We do not support the notion suggested by the TGA that there is generally less interest in whether a biosimilar or generic is under evaluation compared with innovator medicines. The disclose of relevant information for all medicines under evaluation, consistent with that suggested in Option 2, is the only appropriate response to the desire for increased transparency and is in line with the government's own health policy agenda regarding increased awareness of biosimilar and generic medicines by HCPs and the general public.

In the situation where the TGA is not prepared to adopt option 2, AstraZeneca would be very much opposed to the adoption of Options 3 and 4.

Yours sincerely

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