

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

RE: Feedback on whether the TGA should publish that a prescription medicine is under evaluation, dated February 2019

Dear Sir/Madam,

Otsuka Australia Pharmaceutical thanks the Therapeutic Goods Administration (TGA) for this opportunity to provide comments in response to the Consultation paper mentioned above.

Please find enclosed our comments with regard to the list of proposals.

We look forward to positive consideration of these comments and would be interested in participating in future consultations on this issue.

Please do not hesitate to contact me on [REDACTED], or by email at [REDACTED] should you require clarification on any of our comments.

Yours faithfully,

[REDACTED]

[REDACTED]

General Comments

Otsuka welcomes TGA's increasing commitment to transparency by seeking feedback on releasing information about the acceptance of an application for evaluation in order to align with other overseas regulators that adopted a similar approach.

Transparency options for consideration

Otsuka reviewed all TGA's proposed options and supports **Option 2: list all applications accepted for evaluation**

We believe this option would provide a fair position to all medicines proposed under this option, i.e., new chemical entities (including biological prescription medicines), extensions of indications and all generic and biosimilar medicines.

We believe it would be of interest to all parties (consumers, prescribers and industry) to know when a prescription medicine (innovator or generic) has been accepted for evaluation for different reasons and therefore we consider adopting this option would provide the highest level of transparency and a consistent approach.

The impact of adopting Option 2 on our organisation would be that we would have more visibility over generics applications and other innovator prescription medicines which will help us in strategizing and planning our resources. The availability of information it's an important part of informed decision making and this information will help us to be more efficient in bringing new medicines to the Australian patients.

In regards to our preference in terms of information that should be included in a potential published list, we believe TGA should adopt EMA model.

Otsuka believes the proposed Option 3 and Option 4 would provide an unfair advantage to generic companies and a disadvantage for the innovator companies by not knowing when a generic company submitted an application and therefore not providing the same level of transparency and objectivity. Applying the standard of "highest public interest" would be challenging since the consumers, prescribers and industry have different interests and it is not clear how this criteria would apply.

Conclusion

Otsuka appreciates the opportunity to provide comments on the Consultation paper entitled Whether the TGA should publish that a prescription medicine is under evaluation, dated February 2019. Otsuka is supportive of the TGA's proposal to increasing commitment to transparency by releasing information about the acceptance of an application for evaluation.