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

21 March 2019

Dear Madam/Sir,

We refer to the Therapeutic Goods Administration's (TGA) paper titled 'Consultation: Whether the TGA should publish that a prescription medicine is under evaluation' (Feb 2019).

Thank you for the opportunity to comment on *whether or not the TGA should in future disclose earlier that a prescription medicine prescription medicines should be published?*

We provide comments on the proposed four options:

Q1. We request that the following information should be included in a potential published list: active ingredient, tradename, strengths, dosage form, indications, sponsor name, shelf-life and storage conditions.

Q.4 and Q5 - Option 2
From the four options under consideration, Indivior recommends Option 2 - list all applications accepted for evaluation, i.e. the TGA would publish that a prescription medicine has been accepted for evaluation for:

a) New chemical entities (including biological prescription medicines);
b) Extensions of indications; and
c) All generic and biosimilar medicines.

Q4. Do you support Option 2?
Yes, we support this option 2 because this would display the highest level of application transparency and is a consistent approach especially with some comparable Regulatory Authorities.

Q5. What would be the impact of implementing Option 2 on you individually or your organisation (if affiliated)?

As a medicine sponsor in Australia, this change in the regulatory environment & communication would provide a major impact to our company. Option 2 would provide a significant early warning of future potential generic medicines that may enter into the Australian market.

Options 1, 3 or 4

We do not support the other three options (1, 3 or 4) due to the lack of transparency (option 1) and the information relating to generic submissions is too late in the process (option 3 at the time of approval) or not published (option 4 – generic submissions would not be listed once accepted for evaluation).

In responding to the related questions 3, 7 & 9, there would be a major financial significant impact to Indivior Pty Ltd as we would neither not be aware of generic medicines nor be able to prepare for our future should potential generic medicines enter the Australian market.

Thank you for the opportunity to provide feedback to this important future regulatory change in Australia.

Yours faithfully,
Indivior Pty Ltd

[redacted]

Allen Chu
Head, Regulatory Affairs, AustralAsia