29 March 2019

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

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

Dear Sir/Madam

Roche thanks the TGA for the opportunity to provide comments on the consultation on *Whether the TGA should publish that a prescription medicine is under evaluation*.

As members of Medicines Australia's Regulatory Affairs Working Group (RAWG), Roche has provided input into the Medicines Australia submission. Roche comments on the consultation are aligned with those provided in the Medicines Australia submission and as such Roche strongly supports transparency in regulatory decision making and therefore of the range of options presented in the consultation, believe option 2 - list all applications accepted for evaluation to be the only appropriate option to be considered.

Roche believes that by implementing Option 2, 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

In implementing option 2, Roche believe that the following information be included in a published list: active ingredient using INN, ANN/ABN (if available), tradename, therapeutic area and sponsor name. Roche do not support the inclusion of the proposed indication due to the potential for changes that may occur to the exact wording and potential target patient population during the course of evaluation.

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

Yours sincerely,
Roche Products Pty Limited

[redacted]

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