



Pfizer Australia
Level 15-18, 151 Clarence Street
Sydney NSW 2000
38 - 42 Wharf Road
Australia

4 April 2019

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

To whom it may concern,

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

Pfizer Australia Pty Ltd (**Pfizer 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.

Pfizer 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.

Pfizer Australia's **preferred position is Option 2: list all applications accepted for evaluation**. This Option is the *only* option in the consultation paper which fully supports the concept of transparency in relation to the activities of the TGA and which would meet the expectations of all interested stakeholders, including the general public, on uncensored provision of information on applications made to TGA.

Pfizer Australia **strongly opposes Options 3 and 4** as they appear inequitable in that they apply very different criteria for the transparency of innovator medicines compared to generic medicines. For the TGA to be appropriately transparent, all products must be treated equally. The concept of true transparency does not allow for differentiation between types of application and should be agnostic with regard to any perception of level of interest. Subjective evaluation of what constitutes public interest may raise concerns around decision making in relation to specific applications and sponsors.

Pfizer Australia believes that by implementing Option 2 (i.e. list all applications accepted for evaluation), the TGA will achieve the following:

1. Be appropriately transparent about its regulatory activities;

2. Allow for increased healthcare professional (HCP) and patient awareness regarding *all* 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 order to foster consistency and confidence in the application of transparency, Pfizer Australia believes the adoption of a common format to be of value. The following information should be included in a published list to achieve the transparency objectives described above:

Active ingredient

Aligned with the International Nonproprietary Name (INN) prescribing initiative and reference information for HCPs and consumers searching for new products, including generics and biosimilars, that may be the subject of local or overseas announcements. Will also 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 biosimilars. 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

Useful for HCPs and consumers to identify the local sponsor when searching for new products that may have been announced overseas and to obtain medical information in relation to potential special access scheme requests.

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

Pfizer Australia is a member of Medicines Australia, the peak body representing innovative pharmaceutical companies in Australia. We encourage careful consideration of the insights, recommendations and requests presented within Medicines Australia's submission to this consultation.

Thank you again for the opportunity to contribute to this consultation. Pfizer Australia is available at any time to provide further input as required.

Yours sincerely,

