Introduction

Teva Pharma welcomes the opportunity to comment on the TGA's considerations. Our observations and comments in relation to the specific TGA proposals are outlined below. For ease of reference, they are presented in the same sequence as the TGA consultation document.

It is acknowledged that the medicines considered within scope for this consultation are prescription medicines that are lodged as applications for:

- New medicines (new chemical entities, new biological prescription medicines, new fixed dose combinations)
- New uses for medicines (extension of indications)
- Generic or biosimilar medicines.

The scope of this response is aligned.

Q1: Please specify your preference in terms of information that should be included in a potential published list (e.g. active ingredient, tradename, therapeutic area versus indication, sponsor name)?

Teva Response:

The public access benefits would be realised through publication of the following application attributes; molecule name, therapeutic area, Sponsor name.

Other elements such as nuances around indication wording and Brand name acceptability can be the subject to change during the review process and would therefore be better regarded as confidential until formally agreed with the regulatory agency.

Option 1: maintain TGA's current publication arrangements

Consideration for this kind of approach is that:

- Less information is published by the TGA than some comparable overseas regulators which provide information on medicines under evaluation.
- If the information is not publically available, consumers and healthcare professionals have only one option to become aware of the submissions under evaluation in Australia – to seek it from sponsors.
- The applicant determines, according to its commercial interest, whether to disclose the fact of its application and, if so, the optimum moment at which to do so.

Q2: Do you support Option 1?

Teva Response:

1. No

Reasons: It is preferable to establish a baseline level of access to community relevant information that is commensurate with other major markets. Applications in evaluation are currently identified by the EMA, Health Canada and Switzerland. Although not published by the regulatory agency in the USA the material nature of the milestone is publically and promptly announced via alternate channels.

Industry observers can currently make reasonable estimates regarding the likelihood of competitor applications within the regulatory system, through indicators such as the publication of an Australian approved name (AAN/ABN), scheduling notices, availability of an EU dossier and publication of molecules on upcoming Pharmaceutical Benefits Advisory Committee (PBAC) agendas.

However, the audience who would most benefit from such information is not privy to the same level of information, unnecessarily creating populations within the community that are less informed than others. There are circumstances where interested parties maybe adequately motivated to seek out such information from potential sponsor. The success of such an approach is limited as company personnel are routinely guided not to enter in to discussion regarding unregistered medicines for fear of falling foul of the industry Code of Conduct promotional rules.

Publication of the minimum elements suggested above when an application has been accepted for evaluation would deliver a level baseline for the entire community.

Q3: What would be the impact of maintaining Option 1 on you individually, or for your organisation (if affiliated)?

Teva Response
Our organisation would continue to have unsatisfactory conversation with customers who are keen to be informed on the status of new products/indications.

Option 2: list all applications accepted for evaluation

Under this option, the TGA would publish that a prescription medicine has been accepted for evaluation for:

- **new chemical entities** (including biological prescription medicines);
- **extensions of indications**; and
- **all generic and biosimilar medicines**

Q4: Do you support Option 2?

Teva Response:

1. **Yes**

Reasons: A consistent rule applicable to all applications avoids questions of interpretation. There is potentially an additional application category that should be considered, which is major variations. This may on occasion be the category applicable to paediatric presentations or generic like applications that do fall fully within new indication or generic categories.

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

Teva Response:
An acknowledgement that the public could access the list of Teva applications that have been accepted for evaluation.

To date the fact that a generic application has been submitted to or approved by the TGA does not expose applicants to intellectual property (IP) infringement. On this basis it is not anticipated that an applicant would withhold an application due to publication.

Generic registrations in preparation for market access upon IP expiry is a well-established practise. Both generic applicants and innovator sponsors would anticipate such activity irrespective of confirmation through publication. It is conceivable that should confirmation of the potential number of market competitors indicate market saturation, additional applicant may be discouraged. This would be assessed on a case by case basis.

Option 3: list all applications at two different time points

Under this option, the TGA would publish that an application has been accepted for evaluation earlier than under Option 1 (on registration) but the time of publication would vary according to whether the medicine is a new medicine or a generic medicine or biosimilar.

(1) **new chemical entities** (including biological medicines) and extensions of indication would be on **acceptance** of application for evaluation;

(2) **generic/biosimilar medicines** would be later in the process, on **approval** of an application, but **before** registration on the ARTG.

Q6: Do you support Option 3?

Teva Response

2. No

Reasons: a consistent approach with regard to transparency is preferable. Historically the existence of a TGA application does not expose generics to allegations of IP infringement. It is acknowledged that upon registration of generics and/or biosimilars innovator routinely take the opportunity to assert their IP rights through communication with new sponsors. It is not apparent, given that such iterations do not impact the registrations status but rather potential launch dates, that earlier publication would have significant impact.

Q7: What would be the impact of implementing Option 2 on you individually, or your organization (if affiliated)?

Teva Response:
Continuation of planning based on informed assumption rather than established facts. Need to ensure internal and international stakeholders are aware of the different rules. The comment above on major variations equally applies here.

Option 4: list applications of innovator medicines of highest public interest, but not generic or biosimilar medicines

Under this option, the TGA will only publish when it has accepted high profile (innovator) prescription medicines for evaluation, i.e. publishing all **new chemical entities** (including new biological medicines) and **extensions of indication** when applications are accepted for evaluation, but not generic or biosimilar medicine applications.

Like option 2, this would provide information, at time of acceptance for evaluation, on all new innovator prescription medicines. However, the same information would not be available for generic medicines.

Q8: Do you support Option 4?

Teva response:

3. **No**

Reasons: The absence of consistent rule becomes an arbitrary application of transparency initiatives. Whilst the first of a new class of therapies may indeed be classified as being of high public interest. It may not the case that the fourth or fifth in a molecule class (albeit new molecules) would be of substantially more public interest than a biosimilar or first generic that may present expanded access opportunities.

Q9: What would be the impact of implementing Option 4 on you individually, or your organization (if affiliated)?

Teva response:
Continuation of planning based on informed assumption rather than established facts. Need to ensure internal and international stakeholders are aware of the different rules. The comment above on major variations equally applies here.