28th March 2019

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

Dear Sir / Madam,

Response to consultation:
Whether the TGA should publish that a prescription medicine is under evaluation

Biogen Australia Pty Ltd would like to thank the Therapeutic Goods Administration (TGA) for the opportunity to comment on the consultation as to whether the TGA should publish that a prescription medicine is under evaluation. Biogen Australia is a sponsor of innovator medicines listed on the Australian Register of Therapeutic Goods, including sponsor of the medicine SPINRAZA® (nusinersen) as used as an example in the consultation document.

In response to the consultation, Biogen Australia believe the best option would be ***Option 2***; that full transparency of all applications will inform the healthcare and patient community, manage expectations and alert the community to future opportunities for engagement. In addition, this option will ensure fairness across the pharmaceutical industry to be transparent with all types of applications and to harmonise disclosure akin to other countries around the world.

Biogen would like to highlight that aside from the commercial-in-confidence aspects that the TGA consultation document explains, a sponsor company may be prevented from making details of submissions to the TGA, such as new chemical entities and new indications to the public because of the perception that disclosure of such information could be seen to be promotional under the *Therapeutic Goods Act 1989,* the *Therapeutic Goods Advertising Code 2018* and also the Medicines Australia Code of Conduct.

Therefore, in the specific case of SPINRAZA, whilst information about registration and patient access was of great public interest because of the unmet medical need and severity of Spinal Muscular Atrophy (SMA), Biogen Australia were unfortunately limited to the amount of information which could be released into the public domain under these Australian regulatory requirements, compared to other global jurisdictions. Hence, Biogen Australia found it very challenging to manage the expectations of and appropriately engaging with the SMA community about SPINRAZA during this time.

Responses to questions and options can be found in **Attachment 1** to this letter.

[redacted]2

Should you have any questions or require further information, please do not hesitate to contact the undersigned below.

Yours sincerely,

Attachment 1 – responses to options

1. *Specify your preference of information that should be included in a potential published list*

Information which should be included in a potential published list include:
Date of TGA acceptance of application; proposed tradename, active ingredient, proposed therapeutic area and sponsor name. It should be noted that tradenames and indications can change during the course of the evaluation, and any transparency regarding these details needs to be declared that they are subject to change, or in no way guaranteed of a TGA approval.

Option 1: maintain TGA's current publication arrangements

1. *Do you support Option 1?*

b. No. Maintaining the status quo prevents sponsors to disclose information which could be seen to be promotional under the *Therapeutic Goods Act 1989,* the *Therapeutic Goods Advertising Code 2018* and also the Medicines Australia Code of Conduct. If the TGA published information about acceptance of applications, then sponsors as a default position would be able to refer the public to the TGA website for information.

2. *What would be the impact of maintaining Option 1 on your organization?*

Biogen Australia had firsthand experience to the impact of non-disclosure in relation to the SPINRAZA registration application. Information about the global registrational filings was published overseas, yet there was nothing in the public domain in Australia which served the informational needs of the patients, caregivers, community or healthcare professionals. Due to local regulations, the organisation were unable to disclose information which could have been seen to be breaching local regulations. Biogen Australia found it very challenging to manage the expectations of and appropriately engaging with the SMA community about SPINRAZA during this time.

Option 2: list all applications accepted for evaluation

1. *Do you support Option 2?*

a. Yes. The best option would be that information be disclosed to the point of which to support the public interest such as patients and healthcare professionals. Full transparency of all applications will inform the healthcare and patient community, manage expectations and alert the community to future opportunities for engagement. In addition, we also call upon the fairness across the pharmaceutical industry to be transparent with all types of applications and to harmonise disclosure akin to other countries around the world.

2. *What would be the impact of implementing Option 2 on your organization?*

Publication of application status on the TGA website would provide a consistent reference point for the sponsor company to use in communication to external groups. In addition, there would be fair disclosure of all applications accepted by the TGA, including innovator and generic applications, those of competitive and non-competitive interest.

Option 3: list all applications at two different time points

1. *Do you support Option 3?*

b. No. This option does not encourage fairness across the entire pharmaceutical industry for competitive reasons. All sponsor applications should be disclosed at the same time, regardless of the nature of the medicine whether they be generic, biosimilar or innovator.

2. *What would be the impact of implementing Option 3 on your organization?*

The later disclosure of generic or biosimilar applications provides a competitive unfair advantage to generic and biosimilar industry. Thus, this would greatly disadvantage our organization as an innovator company. In addition, there may still be public interest of disclosure of these types of applications by healthcare professionals and patients.

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

1. *Do you support Option 4?*

b. No. This option does not encourage fairness across the entire pharmaceutical industry for competitive reasons. All sponsor applications for generic, biosimilar and innovator medicines should be disclosed at the same time.

2. *What would be the impact of implementing Option 4 on your organization?*

The non-disclosure of generic or biosimilar applications provides competitive unfairness across the industry. Thus, this would greatly disadvantage our organization as an innovator company. In addition, there may still be public interest of disclosure of these types of applications by healthcare professionals and patients.