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

29 March 2019

Dear Sir/Madam,

Consultation: Whether the Therapeutic Goods Administration (TGA) should publish that a prescription medicine is under evaluation – Transparency Reforms

Vifor Pharma Pty Ltd welcomes the opportunity to comment on the proposed increased transparency on whether the TGA should publish that a prescription medicines is under evaluation.

Vifor Pharma is a world leader in the discovery, development, manufacturing and marketing of pharmaceutical products for the treatment of iron deficiency. The company's goal is to continue its leadership in iron deficiency, nephrology and cardio renal therapies and strives to help patients around the world with severe and chronic diseases to lead better, healthier lives. In Australia, Vifor Pharma is located in Melbourne and is classified as a small-medium size company.

Commentary on the transparency reform: As an innovative pharmaceutical company, Vifor Pharma welcomes transparency that is balanced between disclosure of confidential information that is commercially sensitive to the organisation and providing patients with information to make an informed healthcare decision. The informed decision is not just related to publishing that a prescription medicine is under evaluation it is also about informing and educating healthcare consumers about the registration process of medicines – not all patients have an equal understanding nor are they familiar with the different regulatory pathways.

Commercially Confidential Information: Commercially confidential Information is defined by the TGA as "any information which is not in the public domain or publicly available, and where disclosure may undermine the economic interest or competitive position of the owner of the information" *(TGA approach to disclosure of commercially confidential information, May 2014).* Vifor Pharma understands that the definition may change depending on the outcome of the consultation and we welcome further consultation on securing an appropriate definition that can be utilised across Government.

Consistency in Government application of transparency: Aligned with the above definition and the proposed increased in transparency it is critical to ensure Government is consistent in its approach to providing the public with information. It is important the same decisions and same level of transparency is provided for new medicines, new uses for medicines, generic or biosimilar medicines and future consideration of complex generics and/or nanomedicines.

Preferred Transparency Option: Vifor Pharma is **aligned with Option 2** – list all applications accepted for evaluation. Vifor Pharma supports a transparent approach that is consistently applied across all medicines considered by the TGA, there should not be different timing or different level of published information to the market between a new medicine, new indication, generic, biosimilar or nanomedicine. Vifor Pharma strongly opposes a system where different level of transparency would be available for innovator medicines compared to generic or biosimilars as proposed in Options 3 and 4.

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Nanomedicines: For complex medicines and especially their follow-on products we believe it is important to ensure there is transparency around how they are assessed. One class of complex medicines relates to pharmaceutical products that have a dimension in the nanoscale – nanomedicines. Due to their size, they are different from small molecules as their properties cannot be fully characterised and minor changes in manufacturing can affect their size and/ or morphology, influencing their quality, biological properties and therapeutic profiles. Clinical differences have been observed with nanomedicine follow-ons, demonstrating challenges in making identical copies of nanomedicines. As a result of this it is important that TGA provides clarity and transparency on the criteria used to approve nanosimilars.

Considerations for increased transparency: Vifor Pharma requests the following to be considered as part of what is published:

- **Active Ingredient:** Vifor Pharma is aligned with the active ingredient being published, as this is fundamental to the communication and aligned with the publication of other agencies such as the European Medicines Agency.
- **Therapeutic Area:** Vifor Pharma is aligned with the therapeutic area being published, with the ATC therapeutic sub-group being used as a consistent reference point.
- **Indication**: Vifor Pharma does not support the proposed indication to be published, since the indication may significantly change during the evaluation process. Therefore, it is important the TGA completes a benefit / risk assessment and a final indication is determined prior to being published and transparent in the public domain, in order to prevent false expectations on the future availability of treatments on patient's side. Currently none of the comparable overseas regulators (CORs) utilised by the TGA provide transparency on the indication.
- **Sponsor:** Vifor Pharma is comfortable with the sponsor of the medicine being made public at time of the evaluation. It will allow patients and healthcare providers to search the database for new treatments potentially available in Australia and approach the sponsor for information.
- **Publication and searchable format:** Vifor Pharma requests the information to be published in a similar format to the EMA, creating consistency in how medicines are published when under evaluation. Additional consideration should be given to the pending Department of Health consultation on a consumer medicines website, especially as the regulatory and reimbursement process are often interlinked it may be of greater value to patients

Further consultation: If the TGA agrees to progress with greater transparency it must consult on the timing of when the information will be published and from what date greater transparency will be introduced. The proposed change is of commercial significance to sponsors and as such a sponsor will need to make an informed decision on the timing of requesting approval of a medicine.

Alignment with Medicines Australia: Vifor Pharma further supports and is aligned with the Medicines Australia submission to this consultation.

As an innovative pharmaceutical company, Vifor Pharma is committed to help patients around the world with severe and chronic diseases to lead better, healthier lives - we put patients first and providing patients with timely information is one of our commitments.

If you have any questions or comments on the above, please do not hesitate to contact [redacted] on [redacted] or via email on [redacted]

Your sincerely

[redacted]

Vanessa Stevens
Director, Market Access
Vifor Pharma Pty Ltd