Consumers Health Forum of Australia

29 March 2019

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

Dear TGA Transparency Reforms and Evaluation Support Section,

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

I would like to thank you for the invitation for the Consumers Health Forum of Australia to provide input into your consultation on whether the TGA should publish that a prescription medicine is under evaluation.

The CHF strongly supports the concept of the TGA establishing a public register that advises what medicines are currently being evaluated and have been evaluated by the TGA.

We believe this register should contain all the information relevant to the specific medicine and its application. This includes, but is not necessarily limited to, the date applied, all ingredient(s), proposed therapeutic areas, indications, sponsor name, manufacturer name, if innovative or generic, the date application is approved/rejected, reasons for approval/rejection, location(s) of manufacturing and processing, potential contraindications and potential adverse event (including expected rates of potential adverse events)

Understandably not all of this information could be present immediately upon the medicine application being received for evaluation for a variety reasons, such as commercial restrictions. However, by the time a medicine is approved for sale to consumers, we believe those restrictions are no longer a factor and informing consumers takes priority. As such, we would advocate for listings in the register to update with additional information as the medicine progresses through the evaluation process.

We would also note that the public register and information provided within would need to be presented in consumer friendly language and format. This would require significant work as the TGA's current website, where the register should be held, is overwhelmingly unfriendly to consumers.

To that end, we support a modified version of Option 2. Our position is that new chemical entities, extension of indications and generic/biosimilar medicines applications for evaluation should be published on a public register that is easily navigable and searchable. With the

modification that additional pieces information such as those listed earlier are also included the register.

This register will benefit consumers by allowing them to learn what medicines are currently being evaluated. For example, if a consumer obtains a medicine while overseas but is unable to obtain it in Australia they can find if it is currently being evaluated.

It will also allow them to understand, with our suggested modifications, a variety of key information that they are likely to be concerned about including why particular medicines were or weren't approved for use in Australia. This is particularly important for medicines available overseas that are not approved for sale in Australia.

Finally by publishing both the date of application and date of decision both consumers and industry will be able to gain an understanding of the timeframes required by the TGA to process and approve applications to make new medicines available on the market.

Yours sincerely

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