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Complementary Medicines Reform Section
Complementary and OTC Medicines Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2609
Australia

To whom it may concern:

RE: Consultation: Reforms to the regulatory framework for complementary medicines
Assessment pathways

Thank you for providing Pfizer Australia with the opportunity to comment on the Review of Medicines and Medical Devices Regulation in particular the reforms to the regulatory framework for complementary medicines assessment pathways.

Pfizer Australia is a member of the Australian Self Medication Industry (ASMI), the peak body representing companies involved in the manufacture and distribution of consumer healthcare products in Australia. Pfizer has contributed to and is fully endorsing the response/comments provided by ASMI to this consultation on behalf of, and in consultation with their members.

In principle, Pfizer Australia supports a three-tiered risk-based hierarchy of indications to distinguish the three medicine pathways for complementary medicines (CMs). However, some of the concerns that Pfizer Australia has with the proposal are outlined below:

Assessment Pathways

Pfizer does not support the proposed definitions provided for each of the pathways or the outlined evidence requirements. As stated in the consultation document, two of the objectives of these reforms are:

- to provide additional flexibility to allow sponsors to access higher level indications that are currently appropriate for Listed medicines

- to encourage the industry to improve the standard of evidence regarding the efficacy of complementary medicines.

Pfizer believes that the proposal outlined in the consultation is inconsistent with these objectives and that it introduces further barriers than flexibility. We do not support the restriction of products that are currently regulated as Listed medicine or registered CMs through the introduction of new definitions.

Listed medicines that draw from coded indications and are currently appropriate as Listed medicines should remain in this pathway (low risk). They should not have additional regulatory burden applied.

Pfizer does not support the proposed evidence requirements as these are also inconsistent with the recommendations and introduce a disproportionate evidence requirement for each assessment pathway. The evidence requirements to support the indications for the new pathway and Registered CMs are not aligned with the evidence requirements in ARGOM for Non-prescription OTC medicines. The evidence requirements proposed in the CM reforms are significantly higher or far rigorous than those required for OTC medicines.

Permitted Indications:

Pfizer agrees with the establishment of a Permitted Indications list from which indications must be exclusively drawn for Listed medicines and the removal of the free text from the listing system. However, this support is conditional on the following provisions. This list must be:

- Comprehensive and easy to use
- Easy to amend / add new indications / conditions (provided these meet the definition of Listed medicines).

In addition, Permitted Indications list should not introduce new limitations for Listed medicines or regulatory controls that are not aligned with the MMDR recommendations. [redacted]

[redacted]

Claimer:

Pfizer do not support the introduction of efficacy claimer and/or symbol (logo) for products assessed though the new pathway or for Registered CMs.

The introduction of a claimer does not foster level playing field as this is not permitted to be claimed for Non-prescription OTC medicines and Rx medicines that have undergone pre-market assessment for Quality, Efficacy and Safety as well as for Listed medicines that have been evaluated via post-market compliance program.

Pfizer Australia thanks the Panel for the opportunity to contribute to this consultation, and look forward to further participation in the ongoing advancement of the Australian regulatory system.

Pfizer would be grateful if you would publish only the redacted copy that has been included in this submission.

Many thanks for your assistance with our submission.

Yours sincerely,

Nina Balangue
Regulatory Manager