Australian Self-Medication Industry Ltd.
[redacted]

4 December 2018

The Director
Business Systems Review and Reporting Section
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir/Madam,

**Consultation Response: Transition to eCTD only for prescription medicines**

ASMI is pleased for the opportunity to respond to this consultation.

ASMI (Australian Self Medication Industry) is the peak body representing companies involved in the manufacture and distribution of consumer health care therapeutic goods (non-prescription over-the-counter and complementary medicines including vitamins, minerals and supplements) in Australia. ASMI also represents related businesses providing support services to manufacturers, including advertising, public relations, legal, statistical and regulatory consultants. More information about ASMI and our membership is available on our website.

ASMI members agree with the proposed exclusion of listed and registered OTC and Complementary Medicine applications/submissions from the scope of this proposal to transition to eCTD only.

The concerns of cost and training presented in the consultation paper from the survey of the prescription medicines sector on the proposed mandating eCTD, would be significantly further amplified for the non-prescription medicines sector.

ASMI members, regardless of whether they are multi-nationals or local Australian organisations, are not supportive of a mandated use of eCTD for over-the-counter or complementary medicines. We provide the following points in order to illustrate the unique circumstances facing Australian sponsors, regardless of their size, their corporate resources or their corporate product portfolios.

The majority of members do not have e-submission publishing systems or the skills within their teams. eCTD capability has been explored by some larger members and found to be a significant investment. Therefore while non-prescription sponsors may be able to obtain an eCTD dossier from their corporate head office for a new product, they have not been able to justify the business case for the investment to be able to maintain the ARTG entry locally. Equally it must be recognised that the size of the non-prescription market in Australia is relatively small in global terms and that the Australian regulatory framework is of a different scope and structure. The specific local regulatory and market requirements and the additional risks to the local business of having to compete for head office resource to meet the local regulatory priorities and timeframes are not conducive to a centralised dossier maintenance approach.

While some multi-national companies may have both prescription and non-prescription business units in Australia, it shouldn't be assumed that:

- the two units operate as a single sponsor,
- they operate within the same business systems,
- they are located together on the same site and can easily share facilities and expertise.

It therefore shouldn't be assumed that because one business unit has eCTD capability the other must naturally also have the capability – but is just not using it.

Moving to eCTD submissions for smaller/local member companies is generally not something that has even been explored beyond the recognition it represents a significant investment with no apparent tangible benefit.

Should TGA consider in future mandating eCTD for non-prescription medicine submissions, ASMI members would appreciate a considered consultation which understands the readiness and the resources of the industry, which accurately identifies and considers the cost/benefit across the sector, and which reflects the unique Australian regulatory environment. Any resulting reforms must be accompanied by an effective transition process that mitigates the burden.

We hope this response is helpful, if not for this consultation, for a general understanding of the status of eCTD in the non-prescription sector and for future considerations. Please don't hesitate to contact me should you have any queries.

Yours sincerely

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