Australian Government

Department of Health

Deputy Secretary

Mr Wayne Poels
Executive Director
Office of Best Practice Regulation
Department of the Prime Minister and Cabinet

Dear Mr Poels

Sunsetting of Therapeutic Good Order No. 78 – Standard for tablets and capsules

I am writing to the Office of Best Practice Regulation (OBPR) regarding the Therapeutic Goods Order No. 78 Standard for tablets and capsules (the Order). This instrument, as per the Legislative Instruments Act 2003, sunset on 1 April 2019.

The Department consulted with peak industry bodies and there was a consensus that the instrument was operating efficiently and effectively when compared to no regulation. However, industry agreed that improvements and greater international alignment could be made without impacting regulatory burden. The Department therefore determined that the Order be remade without significant amendment.

The Australian Government Department of Health certifies that the Therapeutic Goods Order No. 78 Standard for tablets and capsules was operating effectively and efficiently, and that therefore a Regulation Impact Statement was not required for this instrument to be remade. This was confirmed with OBPR under ID 24085.

The process of re-making the Order involved a public consultation, during which responses were received by a broad range of stakeholders including industry bodies, sponsors, manufacturers and consumer groups.

The original Order required that medicines must meet the requirements of relevant specific monographs in the British Pharmacopeia (BP), where one exists. In the absence of a BP monograph, Australian specific requirements were applied. The re-made Order offers sponsors a choice to stay with existing requirements (be it BP or Australian specific), or to use requirements set out in an applicable monograph in either the European Pharmacopoeia (EP) and the United States Pharmacopeia – National Formulary (USP). The re-made order allows sponsors of medicines to choose to comply with any relevant standard, BP, EP, USP or Australian, to achieve the least regulatory burden.

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Consistent with the intent of increasing international harmonisation, some active ingredient assay limits have been widened in the Australian-specific requirements and certain internationally-harmonised limits for impurities have been adopted. These apply to medicines which are not covered by a relevant monograph in the EP/BP/USP.

The re-made instrument also reintroduces quality requirements for 'pills'. Requirements for pills were in the standard preceding TGO 78 – TGO 56 - General standard for tablets, pills and capsules. Pills were omitted from TGO 78 with the stated intention to include them in a separate order, however this did not occur. The peak industry body of sponsors of products that would be affected by this change welcomed this proposal, noting that the proposed requirements are generally aligned with the requirements for pills within the Pharmacopoeia of the People's Republic of China with which they already follow internationally.

I acknowledge that OBPR will publish this letter for transparency purposes.

If you have any queries about this advice, please contact Dr Jane Cook on 02 6232 8656 or via email, jane.cook@health.gov.au.

Yours sincerely

Adj. Professor John Skerritt
Health Products Regulation Group

30 April 2019