Medicines Australia

Better health through research & innovation

Scientific Operations Management
Scientific Evaluation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
DUE DATE: 8 February 2019

Dear Sir/Madam

Consultation: Therapeutic Goods Order 78 (TGO78) – Standard for tablets and capsules

Medicines Australia welcomes the opportunity to provide comment on the Therapeutic Goods Administration (TGA) consultation to remake the Therapeutic Goods Order 78 (TGO78) – Standard for tablets and capsules.

Our submission has been prepared with the expert input of Medicines Australia's Regulatory Affairs Working Group (RAWG). Members are selected for their regulatory and experience and industry knowledge, and bring a whole-of-industry perspective to the consideration of regulatory issues that stand to impact our sector.

Our detailed feedback on the guidance, are contained in Attachment 1 including answers to the specific questions included in the consultation paper.

We would be happy to discuss or provide further comment on any aspect of our response and we appreciate being kept up to date on further developments. Please feel free to contact [redacted] if you would like further clarification on any aspect of our submission [redacted]

Yours sincerely

[redacted]

Dr Vicki Gardiner
Director, Policy and Research
Medicines Australia

Page	Item	Comments and Rationale
-	**General Comments**	• Medicines Australia welcomes the proposals to remake TGO 78 and remove a number of Australian specific requirements that were not aligned with internationally accepted standards for prescription medicines. • There is a clear need to define standards for complementary medicines, including vitamin and mineral preparations and pill formulations where a comprehensive registration dossier with full quality information is not a mandatory requirement prior to listing or registration. Considering the existing default standards (PhEur, BP and USP) and TGA adoption of all ICH and CHMP guidance relevant to assure the acceptable quality of tablet and capsule dosage forms, it is unclear what value the Order provides in further defining standards for prescription medicine tablets and capsules. This is especially relevant for medicines containing new molecular entities in tablet or capsule form that usually have 'in house' specifications reflecting the absence of any existing monograph in a default standard. Included tests and acceptance criteria are developed based on the principles included in the relevant ICH guidelines and may include test methods specified in the default standards eg PhEur; USP. Appropriate limits are established and justified based on a comprehensive review of all available data, including consideration of the impurity profiles of batches used during non-clinical and clinical development. On this basis it is highly unlikely that Sponsors of new medicines will find the Order a useful reference point for defining 'standards' for tablet or capsule formulations including setting specification limits for impurities or heavy metals. Exclusion of prescription medicines from the order as discussed during the industry consultation meeting should therefore be reconsidered.
Q1	**How will the reintroduction of pills to the remade Order affect your business?**	• Medicines Australia supports the re-introduction of pills into the Order whilst recognising that this dosage form is not usually used in the innovative prescription medicines sector.
Q2	**Is the 12-month transition period for the inclusion of pills suitable?**	• Not applicable to the innovative prescription medicines sector.
Q3	**Which impurity limits should apply to medicines not following an individual monograph?**	• As noted under general comments the existing default standards and comprehensive ICH/CHMP guidance already set the standards required for prescription medicines not following an individual monograph, which applies to all new molecular entities not previously registered.

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Q4	**How will the introduction of heavy metal limits in the remade Order affect your business?**	• Proposed limits for heavy metals align with those included in default standards such as USP and PhEur. Provided the limits remain aligned with those adopted internationally these will not add any additional burden for prescription medicine Sponsors in Australia, as the necessary testing will be required for supply of tablets and capsules to other major markets.
Q5	**Comment on the suitability of the requirements specified in the remade Order**	• The requirements in the Order are suitable, however as noted in the General Comments it is unclear of their value in assuring the quality of prescription medicines
Q6	**Comment on the exclusion of unapproved goods from the application of the remade Order**	• Medicines Australia supports the exclusion of unapproved goods from the Order to simplify the regulatory requirements during development and optimize flexibility for Sponsors.
Q7	**Comment on the usefulness of the proposed guidance document**	• The guidance document provides additional context that is useful for understanding the requirements included in the Order
Q8	**Do you have any suggested improvements to either document?**	• No suggestions
Q9	**Please suggest alternative options if you do not support the proposal**	• The options relevant to prescription medicines are supported, whilst noting the General Comments above.
Q10	**Please provide an assessment of how the proposal will positively and adversely impact on you**	• The proposal addresses international harmonization of standards for prescription medicine tablets and capsules which is a positive impact. However legislation that duplicates requirements included in existing default standards and supported by comprehensive guidance requirements, offers little value and adds regulatory burden for both evaluators and Sponsors.