



Consumers Health
Forum **OF** Australia

SUBMISSION

**CONSULTATION: REMAKING
THERAPEUTIC GOODS ORDER
NO. 78**

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Consumers Health Forum of Australia (year)
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Submission

Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers and those with an interest in health care consumer affairs. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF appreciates the opportunity to provide a comment to the Therapeutic Goods Administration (TGA) proposal on remaking *Therapeutic Goods Order No. 78 - Standard for Tablets and Capsules* and reintroducing pills into the remade Order.

At the heart of CHF's policy agenda is patient-centred care. Our responses to the TGA's consultation questions have been formed with a patient-centred approach in mind.

The CHF supports the reintroduction of pills into the scope of the remade Order. The omission of these from the current Order is an unfortunate regulatory oversight. Consumers implicitly trust the regulatory system to ensure any product made available to them undergoes rigorous assessment of quality, safety and efficacy. Currently that trust is being abused.

The CHF believes the proposed 12 month transition period is acceptable. Noting that given the proposed regulations are drawn from existing requirements in other jurisdictions (i.e. the Pharmacopoeia of the People's Republic of China), Sponsors should already be largely compliant with requirements upon their introduction.

CHF strongly supports in introduction of heavy metal limits into the remade Order. We do not have a position on which of the two suggestions is preferred, deferring to the relevant expert authorities as to which specific set of limits provides the greater security to consumer health.

Similarly the CHF does not have a position on the suitability of the requirements in the remade Order or the usefulness of the proposed guidance document.

The CHF does not support the proposal to exclude "unapproved goods" from the remade Order. The CHF contents that any medicine that is a tablet, capsule or pill that is intended for human use via oral administration should be subject to regulatory framework of the remade Order to provide the best protection for consumers, assuring the medicine is safe, effective and of top quality.

Overall, the CHF believes that the proposal has the potential to positively impact the ability of Consumers to reliably access quality, safe medicines. Consumers have an expectation that products made available in Australia are regulated for safety, efficacy and quality. The proposed remaking of Order No. 78 to reintroduce pills into the regulatory framework and to establish heavy metal limits for pills, tablets and capsules is step towards meeting that consumer expectation.