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Therapeutic Goods Administration
PO Box 100 Woden
Canberra ACT 2600

Consultation: Remaking Therapeutic Goods Order No. 78

Will the reintroduction of pills to the remade Order will affect community pharmacy?

As there appear to be no community pharmacies that manufacture pills for Traditional Chinese Medicines (TCM), this does not appear to be an issue that will affect community pharmacy generally.

Is the 12 month transition period for the inclusion of pills suitable?

This time period seems to be suitable. It may depend on the shelf life of pills however as there is a possibility that after 12 months there will still be pills that have been manufactured prior to remaking of Therapeutic Goods Order No.78 that are being sold to customers and they may not comply with the new Order.

Which impurity limits should apply to medicines not following an individual monograph?

The impurity limits that align with internationally agreed limits. This will allow greater ease of marketing different products in Australia.

Will the introduction of heavy metal limits in the remade Order will affect community pharmacy?

This will have a positive effect on community pharmacy, as they will be able to sell complementary products such as herbal supplements with a guarantee of an upper limit of heavy metals contained in the products.

Are the requirements specified in the remade Order suitable?

The requirements appear to be suitable.

Should unapproved goods be excluded from the application of the remade Order?

It would be beneficial for unapproved goods to not be excluded from the application of the remade order, as this will help to ensure quality of products that are sold. However, if the goods are unapproved, enforcing this may be problematic. It may be more practical for them to be excluded.

How useful is the proposed guidance document?

The proposed guidance document is useful. It is clear, informative and easy to comprehend.

Are there any suggested improvements to either document?

There are no suggested improvements to either document.

Any alternative options if you do not support the proposal?

Not applicable, I support the proposal.

Provide an assessment of how the proposal will positively and adversely impact on you.

There should be a generally positive impact on my practice as a community pharmacist as there will be consistency in standards applicable to the complementary products that I am providing to customers.

Kind regards,

Gwynn McLeod