Technical Alert

Consultation: Options for the future regulation of "low risk" products

The Expert Panel Review of Medicines and Medical Devices Regulation (MMDR) made three recommendations in relation to performing further reviews of the regulation of 'low risk' products (MMDR recommendations 14, 23 and 48). In making these recommendations, the expert panel expressed the concern that "there are a range of products listed in the ARTG that are subject to a level of regulation which is not commensurate with the risk posed by these products to Australian consumers".

Therefore, the Therapeutic Goods Administration (TGA) is now seeking comments on a set of proposed options for future regulation of 'low risk products'. The options presented in the consultation paper represents a range of possible regulatory directions for the identified 'low risk' products.

This consultation closes on **12 May 2017**.
Comments in relation to this paper can be sent to CMA submissions@cmaustralia.org.au .

The consultation paper identifies the following product types which may be of interest to members.

- Classified as **very low risk**
  - Oral homoeopathic products
  - Aromatherapy products
- Classified as **low risk**
  - Rehydration or formulated sports products
  - Lozenges – relief of sore throats, contain anti-microbial active ingredients (OTC)
- Classified as **Medium risk**
  - Oral vitamin and mineral products (eg. water soluble vitamins & minerals such as calcium have a lower risk profile)

The Review of certain complementary medicine products (referring to recommendation 48) can be found from page 40 of the consultation document.

Three recommendations will be addressed in this paper:

- Recommendation **Forty-Eight**: The Panel recommends that the Australian Government undertakes a review of the range of complementary medicinal products, currently listed in the ARTG and subject to regulation under the medicines framework, with a view to ensuring that products that might best be regulated under other regulatory frameworks, without undermining public health and safety, are removed from the auspices of the Act.

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- Recommendation **Fourteen**: The Panel recommends that the Australian Government undertake a review of the range of products currently listed in the Australian Register of Therapeutic Goods (ARTG) (**not including complementary medicines**) and subject to regulation under the medicines framework, with a view to ensuring that: 1. Products that might best be regulated under other regulatory frameworks, without undermining public health and safety, are removed from the auspices of the Act; and 2. Goods remaining under the auspices of the Act are subject to regulatory requirements that are commensurate with the risk posed by the regulated products.

- Recommendation **Twenty-Three**: The Panel recommends that the Australian Government undertake a review of the range of products currently classified as Class I medical devices, with a view to reclassifying products as consumer goods in circumstances where the product poses little or no risk to consumers should it not perform as specified or malfunctions.

ENDS

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