Pharmaceutical Society of Australia

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

MAY 2017

Purpose

The Pharmaceutical Society of Australia (PSA) makes this submission to the Therapeutic Goods Administration (TGA) on the consultation on *Options for the future regulation of "low risk" products.* Comments are provided on selected types of low-risk products.

About PSA

PSA is the peak national professional pharmacy organisation representing Australia's 29,000 pharmacists[1] working in all sectors and locations.

PSA's core functions relevant to pharmacists include:

- providing high quality continuing professional development, education and practice support to pharmacists
- developing and advocating standards and guidelines to inform and enhance pharmacists' practice
- representing pharmacists' role as frontline health professionals.

PSA is also a registered training organisation and offers qualifications including certificate and diploma-level courses tailored for pharmacists, pharmacy assistants and interns.

Background

In the Medicines and Medical Devices Regulation Review[2] (the 'Review'), the Panel noted that the level of regulation applied to a range of products listed in the Australian Register of Therapeutic Goods (ARTG) was not commensurate with the risk posed by those products.

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[1] Pharmacy Board of Australia. Registrant data. Reporting period: 1 Oct 2016 – 31 Dec 2016. At: **www.pharmacyboard.gov.au/documents/default.aspx?record=WD17%2f22786&dbid=AP&chksum=6tglf5%2b1PY5fnmPNgcDM0g%3d%3d**

[2] Expert Panel, Review of Medicines and Medical Devices Regulation. Report to the Minister for Health on the regulatory framework for medicines and medical devices. 31 Mar 2015. At: **www.health.gov.au/internet/main/publishing.nsf/Content/8ADFA9CC3204463DCA257D74000EF5A0/$File/Review%20of%20Medicines%20and%20Medical%20Devices%20Stage%20One%20Report.pdf**

The Panel's recommendations relevant to this consultation are as follows:

> ***Recommendation Fourteen:*** The Panel recommends that the Australian Government undertake a review of the range of products currently listed in the ARTG (not including complementary medicines) and subject to regulation under the medicines framework, with a view to ensuring that:
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> 1. Products that might be best regulated under other regulatory frameworks, without undermining public health and safety, are removed from the auspices of the Act; and
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> 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.
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> ***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.
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> ***Recommendation Forty-Eight:*** The Panel recommends that the Australian Government undertakes a review of the range of complementary medicine 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.

The Australian Government accepted[3] the recommendations to undertake reviews to potentially streamline the regulatory framework for certain low risk products and possibly increase consumer access to the products.

General comments

Australian context

PSA notes and appreciates the complexities involved in considering reforms around the regulation of low risk products. This is due, in part, to the need to consider the impact of reforms in the context of various frameworks, for example:

- therapeutic goods regulation
- standards administered by the National Industrial Chemicals Notification and Assessment Scheme
- the Food Standards Code (administered by Food Standards Australia New Zealand)
- Australian Consumer Law (which has oversight by the Australian Competition and Consumer Commission).

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[3] Australian Government Department of Health. Australian Government response to the Review of Medicines and Medical Devices Regulation. May 2016. At: **www.health.gov.au/internet/main/publishing.nsf/Content/CCB4916435683A5BCA257FA100839F95/$File/govresp.pdf**

In determining what aspects of regulation (for low risk products) could be streamlined or aligned with international standards or arrangements, PSA would emphasise the importance of implementing standards which are relevant and appropriate to the Australian context.

Status quo options

In canvassing options for reform, the consultation paper includes 'maintaining the status quo regulation' as one option for most product types. On page 16 of the paper there is mention that an advantage of the 'status quo' option is that "sponsors and manufacturers who are already familiar with the regulatory framework would not need to understand or implement any regulatory changes". PSA has also noted the statement in the paper that some of the 'status quo' options may be superseded by the implementation of other Review recommendations.

While PSA overall supports changes aimed at minimising regulatory burden, we feel that the main focus of reforms must be on determining the level of risk posed by each product type and designing regulatory requirements commensurate with those risks in the interests of public safety. If sponsors and manufacturers are already familiar with particular regulatory requirements and, as a consequence, regulatory changes do not need to be implemented, PSA accepts this could be regarded as a flow-on benefit. However, we do not believe it should be regarded as an advantage as that has stronger implications around the selection of a preferred approach.

Comments on specific product types

The PSA's preferred options, reasons and comments are summarised in the following section in relation to specific product types.

Medicines and other therapeutic goods (other than herbal complementary medicines)

Ear candles

PSA believes ear candles should be removed from the therapeutic goods regulatory framework (Option 3). Given the lack of evidence of therapeutic benefit and the potential to cause serious injury (and actual reports of injury) these products should not be making therapeutic claims and should be removed from consideration as therapeutic goods.

Nappy rash cream

Nappy rash is commonly encountered in infants and toddlers. The goals of treatment are to resolve the rash and to minimise the risk of recurrence. Treatment can consist of application of barrier preparations or emollients or use of antifungal and/or anti-inflammatory topical preparations. Medical history and lifestyle factors can impact on the patient's condition and choice of treatment options.

PSA understands the concerns that low-risk nappy rash and skin care products may be seen to be over-regulated. The products themselves may be classified as low risk but they are intended for use in a young and vulnerable patient group. In addition, treatment options are wide-ranging and an optimal therapeutic regimen may involve a combination of a low risk product and a registered (higher risk) product and hence, require careful consideration regarding suitability for each individual.

Due to these complexities, PSA believes maintaining the current regulatory oversight (Option 1) is the most balanced and beneficial approach and will continue to support the availability of high quality therapeutic products for consumers.

Other low risk registered non-prescription (OTC) medicines

The product types being proposed for inclusion in this category contain substances which are exempt from scheduling and therefore available for general sale. They are "well-known OTC products that have a long history of use at particular ingredient levels and dosage forms have been identified as lower risk".

PSA is aware that originally the Review identified several product types that may fall into a low risk category and that the list provided in the consultation paper is derived from a risk assessment being conducted and a level of risk assigned within the Low Risk Classification System (LRCS). For several product types listed, PSA would require further information on what substances or products are intended to be captured. One example is the inclusion of "certain laxatives". Although "the nature of the condition being treated or prevented" is assessed through the LRCS, constipation is a condition that may result from a variety of causes and therefore careful assessment of treatment options would be warranted. Therefore in PSA's view, inclusion of a class of medicine may in some instances not be the most appropriate approach.

PSA supports continued robust regulatory oversight for low risk registered non-prescription medicines. We also suggest that, for this product type, consideration of whether the assignment of a low risk category should be conducted at the substance level or product type level would be appropriate. In addition, exploration of options such as permitted ingredient lists or use of monographs would be beneficial.

Certain complementary medicine products

Aromatherapy products

In a previous submission, PSA acknowledged that non-oral aromatherapy products are most likely low risk, and indicated support for the removal of requirement to list them on the ARTG. They could then be regulated as consumer goods but would continue to be required to not make false or misleading claims. This would be closest to the proposal outlined in Option 2 (Exemption from listing in the ARTG and/or GMP).

PSA also gave consideration to Option 3 in the consultation paper which proposes to declare all essential oils to not be therapeutic goods. This would mean essential oil products would not be able to make therapeutic claims but could be labelled with general use statements and relaxation claims. However, PSA noted with concern that some essential oil products currently on the ARTG carry extensive lists of standard indications and warnings. Examination of the public summary document for one such product revealed a listing of:

- eight warnings, including:
    - if coughing persists consult your doctor (or a healthcare professional) (or words to that effect)
    - if pain or irritation persists for more than 48 hours, consult your doctor. The presence of blood in the urine warrants immediate medical attention (or words to that effect), and

- 69 standard indications, including:
    - may reduce the severity and duration of colds
    - temporary relief of bronchial cough by soothing bronchial airways
    - may assist in the management of rheumatism
    - aids or assists in the maintenance of peripheral circulation.

In this case, it is not clear how Option 3 could be applied to existing products in a fair and meaningful manner as it would require substantial amendments.

Rehydration or formulated sports products

PSA agrees with the proposal to review rehydration products on the ARTG given the reported confusion and difficulties experienced in regulating these products which are similar in presentation and composition to electrolyte (sports) drinks. PSA believes it is in the public's best interest to clarify the classification of these products based on criteria such as intended purpose, composition or claims so that they can be regulated appropriately (i.e. as therapeutic goods or as foods).

Vitamins and minerals

The consultation paper notes that not all vitamin and mineral supplements represent equal risk. By way of example, water soluble vitamins (e.g. vitamin C) which are readily excreted from the body are said to have a lower risk profile than fat soluble vitamins (e.g. vitamin A) which can be associated with toxicity. The paper also reports that oral water soluble vitamin products have been identified as candidates and objectively confirmed as 'low risk' by the LRCS developed for the purposes of this work.

PSA has previously stated that, while water soluble vitamins may be regarded as low risk overall, there can be exceptions to the notion of low risk. For example the water soluble vitamin B_6, pyridoxine, is classified as a Prescription Only Medicine (included in Schedule 4 of the Poisons Standard) if the product contains more than 200 mg of pyridoxine due to the risk of peripheral neuropathy at higher doses. Another example is vitamin C which can acidify urine and therefore affect drug excretion.

We acknowledge that some vitamin and mineral products may pose relatively little safety risk and could be considered, for example, as a food supplement. However, as the examples above indicate, the effect of these substances can be significant depending on factors such as dosage of the medicine or patient factors such as medical history or contraindications.

For these reasons, PSA has indicated previously that consideration of which (if any) vitamins and minerals can be classified appropriately as low-risk products and whether or not they remain regulated under a therapeutic framework would need to be determined on a case-by-case basis.

Homoeopathic products

PSA has recommended through a previous submission the removal of homoeopathic products from the ARTG and to allow for their regulation as consumer goods. This is consistent with PSA's

position[4] that homoeopathic products have no evidence base for efficacy. PSA's view is based on the findings of the National Health and Medical Research Council which, following the assessment of the evidence of effectiveness of homoeopathy, concluded that there are no health conditions for which there is reliable evidence that homoeopathy is effective.[5,6]

PSA has stated that it does not support the sale of homoeopathy products in pharmacy.[7]

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[4] Pharmaceutical Society of Australia. Complementary medicines [position statement]. Sep 2015. At: **www.psa.org.au/downloads/ent/uploads/filebase/policies/position-statement-complementary-medicines.pdf**

[5] NHMRC Statement: Statement on Homeopathy. Mar 2015. At: **www.nhmrc.gov.au/_files_nhmrc/publications/attachments/cam02_nhmrc_statement_homeopathy.pdf**

[6] NHMRC statement on Homeopathy and NHMRC Information Paper-Evidence on the effectiveness of homeopathy for treating health conditions: Mar 2015. At: **www.nhmrc.gov.au/guidelines-publications/cam02**

[7] Pharmaceutical Society of Australia. Complementary medicines [position statement]. Sep 2015. At: **www.psa.org.au/downloads/ent/uploads/filebase/policies/position-statement-complementary-medicines.pdf**