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OVERSEAS PRODUCTS:
Important Practitioner Information &
List of Potential Ingredients Subject to Expedited Approval

An increasing number of complementary medicine products are entering Australia illegally. This poses significant potential risks for complementary medicine practitioners.

Complementary Medicines Australia (CMA) is the peak body for the complementary healthcare industry and supports compliance with Australian law by complementary medicine healthcare practitioners. We are writing to you to alert you to risks related to the importation of overseas products: risks both to your patients and to your practice.

Unless specifically exempt, complementary medicines supplied in Australia are required to be entered onto the Australian Register of Therapeutic Goods (ARTG) maintained by the Therapeutic Goods Administration (TGA). Unless they are included on the ARTG, complementary medicines cannot legally be imported, exported, manufactured, or supplied to consumers. Medicines that are included in the ARTG have an AUST L or AUST R number displayed on the pack. If you have been supplied medicinal products that do not display such a number, you should investigate its status.

Illegal supply of overseas products

There are two main ways that illegal supply of overseas products may be occurring:

1. Products are being imported under the Personal Importation Scheme by practitioners, and then sold on to customers. This is not lawful, as the Personal Importation Scheme applies only to purchases made by individual consumers directly for their own use. The scheme does not permit retail sale.

   For further information on the Personal Importation Scheme and some other exceptions for unapproved products, please see *www.tga.gov.au/accessing-unapproved-products*

2. Practitioners may be receiving unapproved goods from local suppliers, when those suppliers have imported them from overseas. In some cases, the goods are clearly medicines and are not included on the ARTG. In other cases, the products may be categorised as "foods" in their country of origin, while falling within the regulatory framework for therapeutic goods in Australia. Products that contain ingredients that are not permitted by the Australia New Zealand Food Standards Code, and products that are in tablet or capsule form, with therapeutic directions for use on the label, are typical examples.

Risks for practitioners

Practitioners selling or supplying products like these to consumers are taking a significant risk.
Selling illegal products may leave them **without the protection of practitioner indemnity insurance**. In the event of an adverse reaction, a lack of indemnity coverage can leave the practitioner exposed to serious liability, and place patients at risk of harm.

Products that are medicinal in nature but not listed on the ARTG may not be made under Good Manufacturing Practice (GMP) principles, and **may not meet the quality and safety standards expected by**

Beyond Bank Building
105 Mawson Drive Mawson ACT 2607
PO Box 450
Mawson ACT 2607
www.cmaustralia.org.au
cma@cmaustralia.org.au
P +61 2 6260 4022
F +61 2 6260 4122
ACN 169 036 088

Australian consumers. Such products may have elevated levels of heavy metals, pesticides, or microbial contaminants, as these are not screened for in many countries. They may also contain low levels of stated herbal active ingredients, the wrong herb entirely, or be adulterated with other unknown ingredients. This poses a serious risk to unwell and vulnerable patients.

As a complementary medicine practitioner you are in a position of authority and trust within the natural healthcare industry in Australia, which relies on you to prescribe responsibly and ensure that all products you are dispensing meet Australian regulatory requirements.

What you can do

Medicines that are listed on the ARTG will carry an AUST L or AUST R number on the pack. The validity of these numbers and the associated product details can be confirmed by reference to the TGA website. For food products, compliance with the FSANZ Food Standards Code is required. A copy of the Code can be obtained from the FSANZ website: *www.foodstandards.gov.au/code/*

If you are concerned about the legality of any medicines used in your practice, you should ask your supplier for copies of the applicable ARTG certificates or search for details on the ARTG. The ARTG search facility can be located here: https://www.tga.gov.au/australian-register-therapeutic-goods . If no details for the medicine can be found, return the product for a refund.

By supporting the high-quality products that comply with Australian regulations, you will be supporting a viable natural and complementary medicine industry, ensuring the quality use of medicines, and protecting the well-being of your clients.

Complaints

If you are concerned that a product is being sold illegally, you may wish to lodge a complaint with the CMA's Complaints Resolution & Monitoring Committee. The major objective of CMA's complaint handling mechanism is to resolve advertising problems identified in the marketplace in relation to complementary healthcare products. Complaints about the advertising of foods and cosmetics are referred to the relevant regulatory authority. Complaints about products that may pose a risk to public safety or that are not included in the ARTG will be referred to the Regulatory Compliance Unit of the Therapeutic Goods Administration, which will take further action it deems appropriate.

More information about complaints processes can be found at *www.cmaustralia.org.au/Complaints*

YOUR VIEWS SOUGHT – FAST TRACK PROCESS FOR NEW INGREDIENT APPROVALS

CMA has been working proactively with the TGA to explore a more efficient approval pathway for new ingredients that are already available in other markets. These ingredients have already been the subject of evaluation reports by other regulatory authorities – for example, Evaluation Reports produced by Health Canada and could form the basis of an ingredient approval here. CMA has contributed to a proposed list of ingredients that could be given expedited risk assessment so as to be made available for use in Listed medicines in Australia. Your views on the List, and any suggestions, can help CMA to ensure that the process is as useful to the industry as possible.

You can view the list of ingredients and provide feedback to CMA by viewing the CMA member alert here:

CMA anticipates that these reforms will ease the burden on industry, and help to reduce the need for consumers to access unapproved therapeutic products from overseas.

Sincerely

Carl Gibson
Chief Executive Officer
Complementary Medicines Australia