# Statement to ATMS Members
# 60 Minutes report on Complementary Medicines

**11 February 2019**

In Australia and globally, consumers are increasingly using complementary medicines as one of their primary health care options. In 2015, 8.1 million Australian consumers used a complementary medicine on a regular basis. This was up 22.7 %, from 6.6 million consumers in 2011. Complementary medicines have a long history of use with an increasing number of research articles being regularly published validating their traditional and scientific uses.

Australia has one of the most developed, vigorous, and strictest regulatory systems for the manufacture of complementary medicines in the world. Australia has a risk-based approach with a three-tiered system for the regulation of all medicines, including complementary medicines. Some medicines, such as homeopathic medicines, are exempt from the system. Lower risk medicines are listed (AUSTL) on the Australian Register of Therapeutic Goods (ARTG). Higher risk medicines must be registered (AUSTR) on the ARTG. The majority of complementary medicines are AUSTL listed medicines due to their low risk. Australia has the strictest regulatory system for complementary medicines in the world with quality assurance, Good Manufacturing Practice (GMP), a permissible ingredients determination, a permissible indications determination, and a rigorous system for reporting of adverse reactions.

**Permissible ingredients determination**

- The Act (Subsection 26BB(1), Therapeutic Goods Act 1989) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in, or exported from, Australia.
- One of the controls established by the Act is to require that medicines that are listed in the Australian Register of Therapeutic Goods only include ingredients which have been evaluated for safety and quality.
- AUSTL and AUSTR products use only ingredients assessed as safe and allowed at safe levels by the Therapeutic Goods Administration (TGA). Some ingredients have a stated maximum allowed limit per dose, and per day, that cannot be exceeded.
- The TGA publishes an updated Permissible Ingredients Determination quarterly.

**Quality and Good Manufacturing Practice**

- Australia is one of the few countries in the world to manufacture complementary medicines to pharmaceutical standards and Good Manufacturing Practice (GMP) standards.
- GMP describes a set of principles and procedures that when followed helps ensure that therapeutic goods are of high quality. Manufacturers follow the Guide to GMP for Medicinal Products.
- Manufacturers in Australia are licenced and inspected and follow the highest standard of GMP. This is not only for products for the Australian market but also for those manufactured in Australia and exported overseas.
- The TGA mandates verification testing of all raw materials before a product is manufactured. This provides assurance to Australian sponsors of products and consumers that they receive what is stated on the label is in the product.
- Batch testing of finished products verifies appearance, weight, uniformity of mass, disintegration, consistency, along with the quantity of the active ingredients within the

product (label) claim. Additionally, microbial testing is conducted as a safety measure of the finished product.
- Quality must be built into each batch of product during all stages of the manufacturing process.
- Each product undergoes stability testing. Stability studies ensure that the product contains the ingredients at their stated levels (within TGA imposed limits) and is safe throughout its shelf life.
- Product quality reviews ensure that quality data is aggregated and tracked over time, allowing the industry to identify and act on any emerging trends or issues.

**Permissible indications determination**

- The Therapeutic Goods Permissible Indications Determination specifies the indications that are permitted for use with a medicine listed in the Australian Register of Therapeutic Goods.
- It is a list of pre-approved indications which have been assessed and determined to be low level and appropriate for listed medicines, and related requirements designed to support the safe use of medicines for which these indications are to be used.
- When applying to list their products in the Register, sponsors of these medicines select an indication that is specified in the Determination, and may not use an indication which the Determination does not cover.
- If a person incorrectly certifies as to these matters, the Secretary may cancel or suspend their goods from the Register (paragraphs 30(1)(e) and 29D(1)(b) of the Act refer). Offences and civil penalty provisions may also apply if a person makes a false or misleading statement in, or in connection with, a certification of a matter under subsection 26A(2) of the Act, including in relation to permissible indications and related requirements (sections 21A and 21B of the Act refer).
- When submitting a product for listing on the ARTG, the submitter must have evidence for all of the indications for their product. This evidence can be either scientific or traditional and is typically in the form of a referenced evidence package.

**Reporting of adverse reactions**

- The TGA maintains a rigorous system for recording, monitoring and responding to adverse events for all medicines, including complementary medicines.
- The TGA also works closely with other regulators around the world to share information and improve safety.
- Adverse event reports can be made by sponsors (eg. the company that owns the product released for supply), state and territory health departments, hospitals, health professionals, and consumers.
- An adverse event should be fully investigated with a detailed history taken, including all medicines, complementary medicines, and surgeries.

**Purchase of products by consumers**

- Consumers should only buy products listed on the Australian Register of Therapeutic Goods (ARTG) from trusted health professionals and retailers (https://www.tga.gov.au/artg). These products display an AUST-L/AUST-A/AUST-R number, usually on the front panel of the product label or carton.
- Products purchased online from overseas may not be subject to the same high level of scrutiny as those manufactured in Australia, with no surety that the product contains what it says it does on the label. In an increasing number of cases, the product may contain the wrong ingredient, be contaminated with pollutants and heavy metals, and even be intentionally adulterated with undeclared pharmaceutical drugs.

- Unless they are included on the ARTG, complementary medicines cannot legally be sold in Australia.
- Therefore, it is suggested that health professionals and consumers do not buy products from overseas online sites which are not subject to the Australian regulations.

**Use of products**

- Use therapeutic goods only as directed, and consult a health professional if symptoms persist.
- Consumers should always follow label instructions and warning statements.

**Consult an ATMS accredited practitioner**

ATMS recommends that Australian consumers seeking complementary medicines, as an alternative health choice, should always consult an ATMS accredited practitioner.

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