**Information Sheet**

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# Quality control of herbal medicines: Commonly adulterated herbal medicines

CMA provides this information to members with to increase both industry and consumer understanding of the risk-based framework applied to the regulation of complementary medicines in Australia. In particular, this document aims to provide information about the most common causes of potential adulteration of herbal substances for all members, and for retail members to consider the source and quality of products that they subsequently supply to customers.

Worldwide concerns about potential adulteration of herbal medicines stem from a range of countries regarding the nature of the adulteration and the nature of documented adverse events. Most of the herbal substances covered by the therapeutic goods regulatory domain within Australia are available for supply in other countries under significantly less-stringent regulatory controls. Possibly the most documented reason for adverse reactions to herbal products globally is the presence of adulterants. In this context, the term 'adulterant' can be defined as the intentional or unintentional presence of undeclared ingredients that adversely impact the quality and safety of the medicine.

## Concerns with purchasing therapeutic goods while overseas or via internet

CMA encourages retailers to assist in increasing consumer awareness about the need to be vigilant when buying herbal or other complementary medicine products, either when overseas or via websites based in other countries. The Therapeutic Goods Administration (TGA) and the CMA urge consumers to exercise caution when purchasing goods via these avenues. Sometimes, websites from other countries are made to look like they are Australian, for example, converting to Australian dollars or using an "au." at the start of the web address. These can usually be identified by looking up the company. Most products permitted for supply in Australia can be found by searching for their name, or important parts of their product name, at this TGA website address.

Medicines authorised for sale and supply in Australia are regulated by the TGA and are required to meet specific standards of manufacturing and quality that aim to ensure that complementary medicines do not contain unsafe levels of adulterants or contaminants. These products can be identified by an AUST L or an AUST R number on the product label. Additional information about AUST L and AUST R products, such as formulation details and the company and manufacturer details, are publicly available via the TGA's Australian Register of Therapeutic Goods: (https://www.ebs.tga.gov.au/ebs/ANZTPAR/PublicWeb.nsf/cuMedicines?OpenView)

No such assurance can be provided about the standards of manufacturing of finished medicines in other countries.

Many people mistake natural substances such as those found in complementary medicines to be free from harm or adverse effects, and further, often do not mention that they are consuming such medicines when asked by a healthcare professional. The adulteration of any food or medicine, including a complementary medicine has the potential to cause adverse effects. Where there is the possibility of adulteration, members should always discuss any concerns with their relevant industry body such as CMA.

CMA, with industry members, can work with the TGA to specifically find solutions to any problems that are identified. For example, some years ago there was a situation where the harmless substances, rutin or quercetin were used to make a material look like there was more Ginkgo biloba in the material than claimed; this did not present a safety issue.

A regulatory solution was found so that now, sponsors and manufacturers of Ginkgo supplied in Australia must perform a special identification to ensure that Ginkgo supplied with an "AUST L" (or "AUST R") number has the amount of Ginkgo claimed on the label.

To be aware of problems through education, some examples are provided below.

**Examples of intentional adulteration for profit (economically motivated adulteration) include:**

- addition of chemical compounds to increase efficacy (the addition of sildenafil to aphrodisiac herbs which is not uncommon in products sourced from overseas without an 'AUST' number.
- addition of other compounds to herbs (the addition of colour to Bilberry);
- addition of marker compounds already present in the herbal ingredient (the addition of rutin and/or quercetin to Ginkgo extract);
- mixing species type (the use of Elderberry, Blueberry or Mulberry in Bilberry extract);
- use of a different plant part with the same component (use of Ginseng leaf to increase the levels of ginsenosides in Ginseng root extract).

**Examples of unintentional adulteration include:**

- presence of environmental contamination (pesticides or heavy metals), microbiological contamination, aflatoxins, and artefacts from the manufacturing process such as solvents – however these are regulated and controlled for in Australian complementary medicines;
- misidentification due to confusion in common names between indigenous systems of medicine and local dialects (identification is controlled for in Australian complementary medicines);
- misidentification due to careless collection practices, poor supply chain controls, poor identification techniques and similarity in morphology/physical characteristics (for example,

aristolochic acids in some herbs especially TCM herbs, which are regulated and controlled for in Australian complementary medicines.

These problems can usually be overcome by a commitment to pharmaceutical level of good manufacturing practice (GMP) in finished product manufacturers, which is mandatory for products with an 'AUST L' or 'AUST R' number. These products are required to use robust vendor qualification processes, identification testing methods, and other assays and risk management protocols for heavy metals and other contaminants, as well as conforming with a relevant pharmacopoeia standard(s).

**Some other examples of adulterated herbal materials**

The list below aims to create an awareness of those species most commonly adulterated. **It is important to keep in mind that Australia applies one of the most stringent quality and safety controls to listed and registered medicines**.

- ***Cimicifuga racemosa*** (Black Cohosh) – adulterated with other species such as Asian *Actaea* species;
- ***Eleutherococcus senticosus*** (Siberian Ginseng) – adulterated with *Periploca sepium* (Chinese silk vine);
- ***Ginkgo biloba*** (Ginkgo) - rutin, quercetin or *Sophora japonica* to enhance flavonoid content;
- ***Hoodia gordonii*** – adulterated with Prickly Pear that bears similar identity testing results (note that Hoodia is not currently available in AUST L or R products);
- ***Illicium verum*** – (Star Anise) adulterated with Japanese star anise (*Illicium anisatum* – also known as *shikimi*).
- ***Punica granatum*** (Pomegranate Extract) – standardisation increased with added ellagic acid (a natural antioxidant found in fruit and vegetables);
- ***Serenoa repens*** (Saw Palmetto) – adulterated with carotenoid enriched palm oil;
- ***Scutellaria lateriflora*** (Skullcap) – adulterated with other species of Scutellaria with no known safety concern or rarely with the hepatotoxic *Teucrium* spp. including *Teucrium canadense.*
- ***Vaccinium macrocarpon*** *(*cranberry) – adulterated with peanut skins, grape seeds, mulberry fruit, hibiscus, calyx, black bean skin, and black rice.