Code of Practice for Ensuring Raw Material Quality & Safety

Prepared by the Raw Material Quality Committee of the Complementary Healthcare Council of Australia

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Contents

1 Introduction 4
2 Objectives 4
3 Scope 4
4 General Principles 4
5 Administration 5
6 Enforcement and Sanctions 5

Appendix 1 Definitions 6
Appendix 2 General Principles for Ensuring Raw Material Quality and Safety 8
Appendix 3 Requirements for Certificates of Analysis and Specifications 9
Appendix 4 References 14
Appendix 5 Resources 15
Code of Practice for Ensuring Raw Material Quality & Safety

1 Introduction

1.1 The Complementary Healthcare Council of Australia (CHC) is the peak body representing the interests of the complementary medicine industry in Australia. It has, in consultation with key industry stakeholders established the Raw Material Quality Committee, to undertake development of this Code of Practice.

1.2 The source documents that were used in developing this Code of Practice are listed in Appendix 4 References.

2 Objectives

2.1 It is recognised that the conduct of an individual member can have significant impact on both the individual member and the broader industry.

The primary objective of this Code of Practice is to define the key principles and documentation that will ensure the quality and safety of raw materials being used in complementary medicines.

Compliance with this objective will assist in maintaining both the credibility and the ongoing viability of the complementary medicine industry.

3 Scope

3.1 Compliance with the principles and requirements described within this Code of Practice is mandatory for raw material manufacturers, suppliers, brokers, distributors, re-packers, bulk product manufacturers and sponsors that are members of the CHC.

3.2 Non-members are encouraged to adopt the principles and requirements described within this Code of Practice.

3.3 The principles and requirements described within this Code of Practice apply to all raw materials used in complementary medicines.

4 General Principles

4.1 Members shall not engage in any unfair or unconscionable conduct in normal commercial practice.

4.2 The ultimate responsibility for the quality and safety of raw materials used in therapeutic goods is the sponsor. The Therapeutic Goods Act 1989 requires as a condition of listing that all raw materials used in therapeutic goods meet acceptable standards of quality and safety.

4.3 Members shall ensure that they are familiar with, and comply with, the provisions of any relevant Commonwealth and/or State and Territory legislation and instruments applicable to the supply and use of raw materials in therapeutic goods.

4.4 Members shall ensure that the raw materials being supplied comply with Appendix 2 General Principles for Ensuring Raw Material Quality and Safety.

4.5 Members shall ensure that the certificates of analysis and specifications being provided for raw materials comply with Appendix 3 Requirements for Certificates of Analysis and Specifications.

4.6 Members shall ensure that they comply with any other guidelines and provisions that are applicable to the quality and safety of the raw materials being used in complementary medicines that are developed from time to time and adopted by this Code of Practice.

4.7 Members shall endeavour to bring to the attention of the CHC any information that they become aware of that may improve the quality and safety of the raw materials being used in complementary medicines.

4.8 Members shall ensure that if an issue arises that relates to the quality and safety of a raw material being used in complementary medicines, that they will undertake appropriate corrective action in a timely fashion and make the issue known to the CHC.
5 Administration

5.1 This Code of Practice shall be administered by the Raw Material Quality Committee and the Technical Director of the CHC.

5.2 This Code of Practice shall be monitored by the National Executive Committee of the CHC.

5.3 This Code of Practice shall be reviewed annually. The review shall be undertaken by an independent party nominated by the National Executive Committee. The recommendations of the review shall be submitted to the National Executive Committee and the Raw Material Quality Committee of the CHC for consideration and implementation.

6 Enforcement and Sanctions

6.1 Compliance with this Code of Practice shall be overseen by the Raw Material Quality Complaint Committee. Members of this committee shall be approved by the Raw Material Quality Committee. The committee shall comprise of up to seven members including three representatives of the Raw Material Quality Committee, two representatives from the Code Administration Committee and two representatives from the Manufacturers National Executive Committee of the CHC.

6.2 Any person who considers that a provision of this Code of Practice has been breached may lodge a complaint in writing with the Raw Material Quality Complaint Committee through the Technical Director of the CHC.

6.3 Members subject to a complaint will be contacted and requested to respond to the complaint.

6.4 Non-members subject to a complaint will be contacted and requested to respond to the complaint.

6.5 Members found to be in breach of this Code of Practice shall be requested to advise in writing the action being taken to remedy the problem including the time frame for compliance.

6.6 If the company will not take any action to remedy the breach, the National Executive Committee of the CHC or other relevant authority (if appropriate) will be notified.

6.7 Appeals against a decision of the Raw Material Quality Complaint Committee shall be in writing and directed to the National Executive Committee of the CHC within 14 days of formal notification of the decision. The National Executive Committee of the CHC may consider the appeal, or establish an expert panel to consider the appeal. The National Executive Committee of the CHC will advise the appellant of the outcome of the appeal after it has endorsed the decision of the expert panel, or taken its own decision. This decision is final and binding.
adulteration
substances present other than those that are supposed to be.

aflatoxin
a naturally occurring toxin found in some raw materials of botanical origin and produced by various types of mould.

batch
a quantity of a product that is uniform in composition, method of manufacture and probability of chemical or microbial contamination; and made in one cycle of manufacture.

batch number
a unique combination of numbers, letters, and/or symbols that identifies a batch and from which the production and distribution history can be determined.

botanical reference standard
an independently certified batch of botanical material shown by an extensive set of analytical and visual tests, to be authentic.

botanical name
the Latin binomial used to uniquely define the plant species. It may sometimes include the classification system being employed such as Linneaus (L.) as a suffix.

CAS registry number
a unique identifying number assigned to a substance when it enters the Chemical Abstracts Service (CAS) Registry database.

certificate of analysis
a document certifying the test results for a particular batch of raw material.

chemical Identification
a method that establishes the unique chemical composition of a substance.

client identification number
a unique number allocated by the Therapeutic Goods Administration to identify sponsors.

contamination
refers to contamination by foreign material including bacteria, yeast, mould, heavy metals, pesticides, radionuclides, insects, faecal matter, fur and dirt.

crude starting material
unprocessed herbal material used in the manufacture of a material of botanical origin.

DNA fingerprinting
a method of identifying materials of botanical origin by determining their unique genetic sequence.

dry
refers to materials of botanical origin that have been dried to reduce the moisture content to a specified level to allow storage and/or enable further processing.

endangered species
a plant or animal species that is in threat of extinction and as defined by relevant Commonwealth and/or State and Territory legislation.

enterprise identification number
see client identification number.

excipient
an ingredient that is added to a raw material for a specific functional role. It can include antioxidants such as butylated hydroxytoluene (BHT), microbiological preservatives such as methyl hydroxybenzoate and diluents, flow agents and anti caking agents that help to alter/improve the physical characteristics of a raw material.

expiry date
the period of time during which the raw material is expected to remain within the established specifications if stored under defined conditions. It is determined from the raw material manufacturing date.

final extract ratio
the amount of crude starting material compared to the amount of finished raw material. It should take into account the addition of any excipients.

fresh
refers to materials of botanical origin that have not...
been dried to reduce the moisture content.

**genetic modification status**
a statement certifying whether the crude starting material that is used to manufacture a raw material has undergone genetic modification.

**harvesting period**
the time period or season during which harvesting is undertaken.

**heavy metals**
metals including arsenic, cadmium, lead and mercury that can be present in raw materials.

**lot**
see batch.

**lot number**
see batch number.

**macroscopic taxonomic identification**
a method used to establish the identity of a species of plant by visual examination.

**material safety data sheet**
a document containing health and safety information on a raw material.

**mechanical processing**
refers to processing of crude starting materials of botanical origin including sorting, sieving and cutting or chopping by machines.

**microbiological contamination**
the undesired introduction of impurities of a microbiological nature into a raw material including bacteria, yeast and mould.

**microscopic taxonomic identification**
a method used to establish the identity of a species of plant by microscopy.

**native extract ratio**
the amount of crude starting material compared to the amount of finished raw material. It should not take into account the addition of any excipients.

**pesticide residues**
refers to residual levels of fungicides, herbicides, insecticides and rodenticides that may be found in a raw material.

**proprietary ingredient number**
a unique number issued by the Therapeutic Goods Administration for preparations in which the formulation is to remain confidential.

**radionuclide**
a radioactive species of atom.

**reference standard**
an independently certified batch of raw material shown by an extensive set of analytical tests, to be authentic and of defined purity.

**residual solvents**
residues that can remain from the extraction solvent that was used in the manufacture of the raw material.

**retention sample**
a sample that is taken from a batch of raw material to enable testing at a later time should it be necessary.

**sanitising treatment**
a process that is used to reduce levels of bacteria, yeast and mould that may be contained in a raw material. It includes processes such as chemical, dry heat, steam and gamma irradiation.

**shelf life**
refer to expiry date.

**solvent extraction**
a manufacturing process using solvents including water, ethanol, glycerin, oils, supercritical gases as extracting agents.

**specification**
the set of parameters and criteria that the raw material must conform with to be considered acceptable for its intended use.

**standardised component**
a component that is present in a defined amount in a raw material.

**transmissible spongiform encephalopathy status**
a statement certifying whether the crude starting material that is used to manufacture a raw material is of animal origin, and if so what methods have been employed to minimise the risk of transmissible spongiform encephalopathy.

**validation**
proving that there is a high degree of assurance that a specific process, method, or system will consistently produce a result meeting pre-determined acceptance criteria.
The information provided in this Appendix has been summarised from various documents including the Australian Code of Good Manufacturing Practice for Medicinal Products August 2002 Annex 7-Manufacture of Herbal Medicinal Products, and the Draft Australian Guidelines for Complementary Medicines (AGCM). More detailed information can be found in these and other source documents that are listed in Appendix 4 References.

Where the crude starting material is of botanical origin and has undergone mechanical processing or solvent extraction so that it is not possible to undertake macroscopic and microscopic taxonomic identification, a specification shall be provided for both the crude starting material and the raw material. This specification shall be referenced on both the raw material specification and certificate of analysis.

Where applicable raw materials shall comply with the requirements of the current edition of the British Pharmacopoeia, TGA Guidelines, TGA Standards and TGA Compositional Guidelines. In the absence of a monograph in the British Pharmacopoeia, TGA Guideline, TGA Standard or TGA Compositional Guideline, it is acceptable to comply with a monograph of another pharmacopoeia such as the European Pharmacopoeia or United States Pharmacopeia.

Where applicable raw materials shall comply with the requirements of the general monographs of the current edition of the British Pharmacopoeia relating to residual solvents and pesticide residues. In the case of raw materials of natural origin testing for pesticide residues can be undertaken on the crude starting material as long as validation has been undertaken to show that these contaminants are not concentrated during subsequent processing. Where applicable raw materials shall be tested for adulteration, contamination, microbiological contamination, aflatoxins and radionuclides. In the case of raw materials of natural origin testing for adulteration, contamination, microbiological contamination, aflatoxins and radionuclides can be undertaken on the crude starting material as long as validation has been undertaken to show that these contaminants are not concentrated during subsequent processing.

Where applicable raw materials shall be tested for physical properties such as, but not limited to specific gravity, pH, total solids, bulk density, loss on drying, solubility, taste, smell, total ash and particle size distribution.

Where applicable a Material Safety Data Sheet shall be provided prior to supply of any raw material.

Analytical methods used to test raw materials shall be validated.

Retention samples of both the crude starting material and raw material should be held by the manufacturer of the raw material.

Relabelling of containers and repackaging of already manufactured raw materials is considered a step in manufacturing by the Therapeutic Goods Administration and must be undertaken in a facility that has been licensed to manufacture therapeutic goods (if located in Australia) or has been given overseas GMP preclearance (if located overseas).
Appendix 3 Requirements for Certificates of Analysis and Specifications

The information provided in this Appendix has been summarised from various documents including the Australian Code of Good Manufacturing Practice for Medicinal Products August 2002 Annex 7 - Manufacture of Herbal Medicinal Products, and the Draft Australian Guidelines for Complementary Medicines (AGCM). More detailed information can be found in these and other source documents that are listed in Appendix 4 References.

Certificates of analysis

2.1 Certificates of analysis shall be provided with each lot of raw material.

2.2 Certificates of analysis shall only be provided on the original manufacturer letterhead and should not be transcribed or altered in any way. Copies of certificates of analysis should only be reproduced in full and methods employed to reduce the ability of third parties to alter or tamper with the integrity of the certificate of analysis.

2.3 Certificates of analysis for raw materials of botanical origin should include as a minimum the following information except where stated otherwise:

2.3.1 unique code
2.3.2 lot number
2.3.3 date of manufacture
2.3.4 expiry date
2.3.5 pharmacopoeial reference (where applicable)
2.3.6 reference to the specification for the crude starting material
2.3.7 botanical/scientific name
2.3.8 plant part/s used
2.3.9 preparation type
2.3.10 physical properties including reference to the analytical methods used (where applicable)
2.3.11 whether the crude starting material was fresh or dry
2.3.12 genetic modification status of the crude starting material including reference to the analytical methods used (where applicable)
2.3.13 endangered species status of the crude starting material (where applicable)
2.3.14 name and percentages of solvents used to extract the crude starting material including reference to the quality standard used (where applicable)
2.3.15 native extraction ratio (where applicable)
2.3.16 final extraction ratio (where applicable)
2.3.17 name and quantity of any excipients present including reference to the quality standard used (where applicable)
2.3.18 microbiology including reference to the analytical methods used (alternatively this can be tested in the crude starting material)
2.3.19 chemical identification including reference to the analytical methods used
2.3.20 chemical analysis of any standardised components including reference to the analytical methods used (where applicable)
2.3.21 heavy metals and pesticide residues including reference to the analytical methods used (alternatively these can be tested in the crude starting material)
2.3.22 aflatoxins and radionuclides including reference to the analytical methods used (alternatively these can be tested in the crude starting material)

2.3.23 residual solvents including reference to the analytical methods used (where applicable)

2.3.24 other tests as required including reference to the analytical methods used (where applicable)

2.3.25 source of the botanical reference standard used to perform the botanical identification

2.3.26 sanitising treatment including the dose the raw material is subjected to (where applicable)

2.3.27 signature, name, qualifications and position of the person authorising the certificate of analysis

2.4 Certificates of analysis for raw materials other than of botanical origin should include as a minimum the following information except where stated otherwise:

2.4.1 unique code
2.4.2 lot number
2.4.3 date of manufacture
2.4.4 expiry date
2.4.5 pharmacopoeial reference (where applicable)
2.4.6 physical properties including reference to the analytical methods used (where applicable)

2.4.7 genetic modification status of the raw material including reference to the analytical methods used (where applicable)

2.4.8 endangered species status of the raw material (where applicable)

2.4.9 transmissible spongiform encephalopathy status of the raw material including reference to the analytical methods used (where applicable)

2.4.10 name and quantity of any excipients present including reference to the quality standard used (where applicable)

2.4.11 chemical identification including reference to the analytical methods used

2.4.12 chemical analysis of any active or standardised components including reference to the analytical methods used (where applicable)

2.4.13 heavy metals, residual solvents and pesticide residues including reference to the analytical methods used (where applicable)

2.4.14 aflatoxins and radionuclides including reference to the analytical methods used (where applicable)

2.4.15 other tests as required including reference to the analytical methods used (where applicable)

2.4.16 source of the reference standard used to perform the chemical identification

2.4.17 microbiology including reference to the analytical methods used (where applicable)
2.4.18 sanitising treatment including the dose the raw material is subjected to (where applicable)

2.4.19 signature, name, qualifications and position of the person authorising the certificate of analysis

3 Specifications

3.1 Specifications shall be provided prior to supply of any raw material.

3.2 Specifications shall only be provided on the original manufacturer letterhead and should not be transcribed or altered in any way. Copies of specifications should only be reproduced in full and methods employed to reduce the ability of third parties to alter or tamper with the integrity of the specifications.

3.3 Specifications for raw materials of botanical origin should include as a minimum the following information except where stated otherwise:

3.3.1 unique code
3.3.2 botanical/scientific name
3.3.3 plant part/s used
3.3.4 shelf life
3.3.5 pharmacopoeial reference (where applicable)
3.3.6 reference to the specification for the crude starting material
3.3.7 storage conditions
3.3.8 preparation type
3.3.9 physical properties including reference to the analytical methods used (where applicable)
3.3.10 whether the crude starting material was fresh or dry
3.3.11 genetic modification status of the crude starting material including reference to the analytical methods used (where applicable)

3.3.12 endangered species status of the crude starting material (where applicable)
3.3.13 name and percentages of solvents used to extract the crude starting material including reference to the quality standard used (where applicable)
3.3.14 native extraction ratio (where applicable)
3.3.15 final extraction ratio (where applicable)
3.3.16 name and quantity of any excipients present including reference to the quality standard used (where applicable)
3.3.17 microbiology including reference to the analytical methods used and a statement as to whether the crude starting material or raw material is tested
3.3.18 chemical identification including reference to the analytical methods used
3.3.19 chemical analysis of any standardised components including reference to the analytical methods used (where applicable)
3.3.20 heavy metal and pesticide residues including reference to the analytical methods used and a statement as to whether the crude starting material or raw material is tested
3.3.21 aflatoxin and radionuclides including reference to the analytical methods used and a statement as to whether the crude starting material or raw material is tested (where applicable)
3.3.22 residual solvents including reference to the analytical methods used (where applicable)
3.3.23 other tests as required including reference to the analytical methods used (where applicable)

3.3.24 source of the botanical reference standard used to perform the botanical identification

3.3.25 raw material manufacturers enterprise identification number and proprietary ingredient number (where applicable)

3.3.26 sanitising treatment including the dose the raw material is subjected to (where applicable)

3.3.27 signature, name, qualifications and position of the person authorising the specification

3.4 Specifications for raw materials other than of botanical origin should include as a minimum the following information except where stated otherwise:

3.4.1 unique code

3.4.2 shelf life

3.4.3 chemical structure including CAS registry number (where applicable)

3.4.4 pharmacopeial reference (where applicable)

3.4.5 storage conditions

3.4.6 physical properties including reference to the analytical methods used (where applicable)

3.4.7 genetic modification status of the raw material including reference to the analytical methods used (where applicable)

3.4.8 endangered species status of the crude starting material (where applicable)

3.4.9 transmissible spongiform encephalopathy status of the raw material including reference to the analytical methods used (where applicable)

3.4.10 name and quantity of any excipients present including reference to the quality standard used (where applicable)

3.4.11 microbiology including reference to the analytical methods used

3.4.12 chemical identification including reference to the analytical methods used

3.4.13 chemical analysis including the analytical methods used

3.4.14 heavy metals, residual solvents, pesticide residues, aflatoxins and radionuclides including reference to the analytical methods used (where applicable)

3.4.15 other tests as required including reference to the analytical methods used (where applicable)

3.4.16 source of the reference standard used to perform the chemical identification

3.4.17 raw material manufacturers enterprise identification number and proprietary ingredient number (where applicable)

3.4.18 sanitising treatment including the dose the raw material is subjected to (where applicable)

3.4.19 signature, name, qualifications and position of the person authorising the specification
3.5 Specifications for crude starting materials of botanical origin should include as a minimum the following information except where stated otherwise:

3.5.1 botanical/scientific name

3.5.2 plant part/s used

3.5.3 whether the crude starting material was fresh or dry

3.5.4 genetic modification status of the crude starting material (where applicable)

3.5.6 endangered species status of the crude starting material (where applicable)

3.5.7 pharmacopoeial reference (where applicable)

3.5.8 country of origin

3.5.9 physical properties (where applicable)

3.5.10 whether the crude starting material was wild crafted or cultivated

3.5.11 harvesting period or any specific harvesting requirements (where applicable)

3.5.12 sanitising treatment including the dose the crude starting material is subjected to (where applicable)

3.5.13 macroscopic and microscopic taxonomic identification including reference to the analytical methods used

3.5.14 chemical identification including reference to the analytical methods used

3.5.15 heavy metals and pesticide residues including reference to the analytical methods used (alternatively these can be tested in the raw material)

3.5.16 aflatoxins and radionuclides including reference to the analytical methods used (alternatively these can be tested in the raw material)

3.5.17 source of the botanical reference standard used to perform the taxonomic and chemotaxonomic identification

3.5.18 sanitising treatment including the dose the raw material is subjected to (where applicable)

3.5.19 signature, name, qualifications and position of the person authorising the specification
1 Australian Guidelines for Complementary Medicines. Available from

2 Australian Code of Good Manufacturing Practice for Medicinal Products August 2002 Annex 7-Manufacture of Herbal Medicinal Products Available from

3 Supplementary Requirements for Therapeutic Goods for Minimising the Risk of Transmitting Transmissible Spongiform Encephalopathies (TSEs) November 2002. Available from


5 Microbial Limits Reviewed: The Basis for Unique Australian Regulatory Requirements for Microbial Quality of Non-Sterile Pharmaceuticals. PDA Journal of Pharmaceutical Science and Technology Vol 52 No. 3 May/June 1998.

6 TGA Compositional Guidelines. Available from

7 American Herbal Products Association Guidance Documents for the Manufacture and Sale of Botanical Extracts.
   www.ahpa.org/

8 British Pharmacopoeia 2002. Available from
   http://www.pharmacopoeia.co.uk/master.htm
Appendix 5 Resources

This list is provided as a guide only and is not definitive.
Inclusion does not imply endorsement by the
Complementary Healthcare Council of Australia

1 Addipharma
   www.addipharma.com/

2 Australian Centre for Complementary Medicine Education & Research
   www.uq.edu.au/accmer/

3 British Pharmacopoeia
   www.pharmacopoeia.co.uk/master.htm

4 Carl Roth
   www.carl-roth.de/deutsch/katalog.htm

5 Chromadex
   www.chromadex.com/

6 Extrasynthese
   www.extrasynthese.com/

7 European Pharmacopoeia
   www.pheur.org/index.php3

8 Herbal Medicine Research & Education Centre
   www.pharm.usyd.edu.au/hmrec/

9 Institute for Nutraceutical Advancement
   www.nsf-ina.org/

10 Merck
    http://pb.merck.de/servlet/PB/menu/1001723/index.html

11 Phytolab
    www.thenaturenetwork.net/phytolab_eng/index.html

12 Promochem
    www.lgc(promochem).com/

13 Royal Botanic Gardens Kew
    www.rbgkew.org.uk/index.html
14 Royal Botanic Gardens Sydney

15 Sigma Aldrich
www.sigmaaldrich.com/

16 United States Pharmacopoeia
www.usp.org/frameset.htm