



The Australia New Zealand Therapeutic Products Authority

Stakeholder Information Session

Proposed regulation of Homoeopathic medicines, Anthroposophic medicines and Essences

Session 1

Overview of the proposed regulatory scheme and process	30 mins
Outcome of Consultation on homoeopathic and related medicines (2005)	30 mins
Outline of the proposed regulatory approach	35 mins
Questions	30 mins
Break	20 mins

Session 2

Break

Introduction to issues	10 mins
1. Quality standards including GMP - discussion	30 mins
2. Permitted ingredients - discussion	30 mins
3. Evidence to support indications - discussion	15 mins
How to comment on proposals	5 mins



Session 1A

Overview of the proposed regulation of Complementary Medicines



Presentation Outline

- Scope of the joint therapeutic products regulatory scheme
- Legal instruments and Guidelines
- Office of Complementary Medicines
- Risk-based framework

Scope of the Joint Scheme

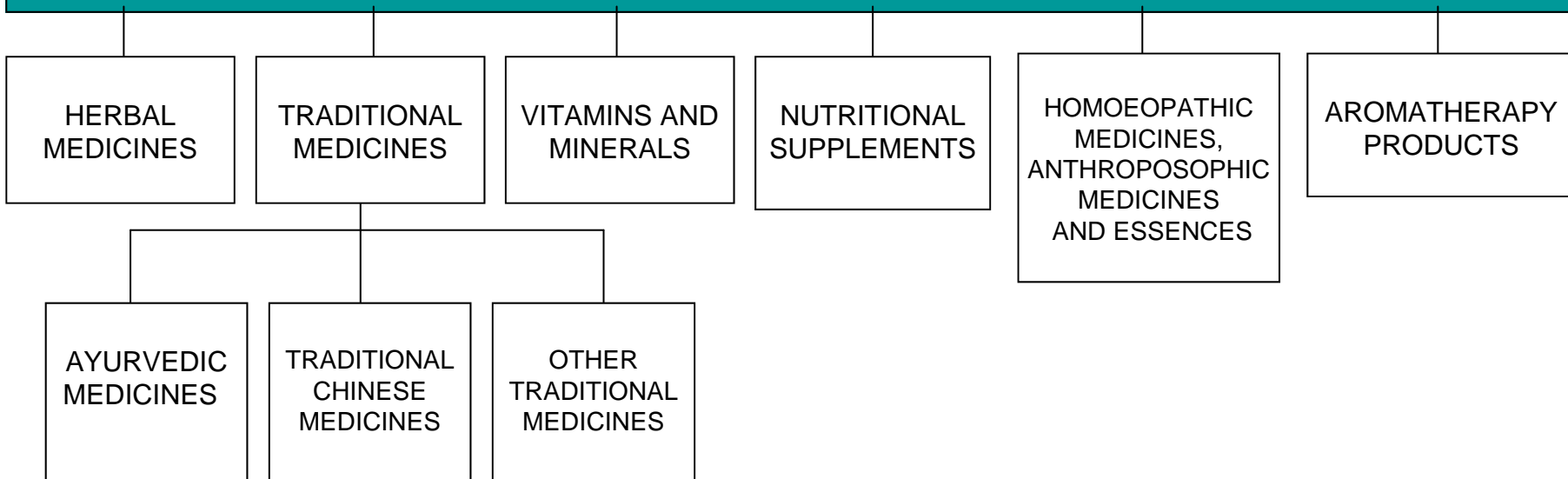
Products to be regulated:

- Medicines
 - Prescription medicines
 - Non-Prescription medicines
 - **Complementary medicines**
- Medical Devices
- Blood and blood components
- Tissue and cellular therapies



Overview

COMPLEMENTARY MEDICINES



Scope of the Joint Scheme

Primary objective

- To safeguard public health and safety
 - recognise different medicine paradigms
 - allow access to medicines of choice while providing assurance of their quality and safety



Scope of the Joint Scheme

Activities to be regulated:

- Manufacture
- Supply
- Import
- Export
- Promotion



THE JOINT REGULATORY SCHEME

- ANZTPA will regulate manufactured complementary medicines
- ANZTPA will not regulate dispensed or extemporaneously compounded complementary medicines
 - healthcare practitioners (eg naturopaths and homoeopaths) may prepare certain medicines for individual patients that will not require a Product or Manufacturing Licence
- ANZTPA will not regulate complementary healthcare practice or practitioners

THE JOINT REGULATORY SCHEME

Legal Instruments

- An Implementing Act in each country
- Ministerial Council Rules
 - Medicines and Administration
- Managing Director's Orders (MDOs)
 - Standards

Guidelines



THE JOINT REGULATORY SCHEME

Australian Act and a New Zealand Act

- Acts in each country to enable the establishment of the Authority
- Acts in each country will contain provisions for imposing fees and charges and offence and penalty provisions



THE JOINT REGULATORY SCHEME

Australian Act and New Zealand Act

Ministerial Council Rules:

Detail the regulatory requirements, for example: definitions, requirements for gaining approvals/licenses, and most aspects of governance and accountability



THE JOINT REGULATORY SCHEME

Australian Act and New Zealand Act

Ministerial Council Rules

Managing Directors Orders:

Orders will contain detailed technical matters such as Authority standards and labelling requirements

THE JOINT REGULATORY SCHEME

Guidelines

- Provide practical guidance on how to meet legislative requirements and outline processes for Licensing of complementary medicines
 - enhance transparency
- Indicate minimum requirements to support quality, safety and efficacy



OFFICE OF COMPLEMENTARY MEDICINES

Operation

- separate operational area within ANZTPA with responsibility for the regulation of complementary medicines
 - one of three proposed medicines regulators
- staff located in both Australia and New Zealand

OFFICE OF COMPLEMENTARY MEDICINES

Function

- assess and review complementary medicines ingredients and products
 - seek advice from the Expert Advisory Committee on Complementary Medicines
 - use external experts for assessment and review as required
- consult and liaise with stakeholders

REGULATORY FRAMEWORK

Two-tiered regulatory system based on risk

- **Complementary medicines may be regulated as:**
 - **Class 1 medicines (low risk)**
 - or**
 - **Class 2 medicines (higher risk)**

Determinants of Risk

- Ingredients
- Indications and claims
- Dosage form
- Significance of side effects
- Effects of prolonged use or from inappropriate self-medication

Complementary Medicines

Class 1 medicines

Class 2 medicines



Complementary Medicines

Prescription Medicines

OTC Medicines

OTC Medicines

Class 1 Medicines

Low-risk medicines:

- May contain ingredients selected from wide range of permitted Class 1 ingredients
- Not subject to restrictions on consumer access
- Have a level of pre-market assessment facilitating timely market access while providing assurance of quality and safety

Class 1 Medicines

- Will not be evaluated for efficacy prior to supply
- Indications and claims limited:
 - Reduction in risk or frequency of a disease/disorder
 - Aids/assists in managing symptoms/disease/disorder
 - Relief of symptoms
 - Health enhancement
 - Health maintenance, including nutritional support



Class 1 Medicines – Indications

- May help reduce joint inflammation associated with arthritis (M)
- May assist peripheral circulation (G)
- Relief of the symptoms of colds (M) (Warning required)
- Temporary relief of headaches (G)

Regulatory Framework

Key elements of the proposed regulatory scheme

1. Pre-market assessment of ingredients and licensing of products
2. Compliance with standards
3. Licensing and audit of manufacturers
4. Post-market regulatory activity

1. Pre-Market Assessment- Class 1 Medicines Ingredients

**Ingredients permitted to be used in Class 1
medicines assessed for quality and safety**

- Currently more than 2300 ingredients permitted as actives in Class 1 medicines

www.tga.gov.au/docs/html/listsubs.htm

- New ingredients: application to ANZTPA

1. Class 1 Medicines - Product Licensing

- Applicant to apply to ANZTPA via an electronic licensing facility (ELF) and certify that the product meets all requirements for Class 1 medicines
- ELF will electronically validate that entered data complies with the requirements for Class 1 medicines
- Provides rapid approval for Class 1 medicines to be supplied in, or exported from, Australia and New Zealand

1. Class 1 Medicines - Product Licensing

Applicant Certification for Class 1 medicines via ELF will include:

- the medicine is safe for the purpose for which it is designed to be used
- the medicine complies with applicable quality and safety criteria
- the applicant holds evidence to support all claims

1. Class 1 Medicines - Evidence

- Risk-managed approach will require a level of evidence commensurate with the indication(s) and strength of promise to consumers
- Guidance on the type and level of evidence to support indications/claims for Class 1 medicines will be developed
 - **will recognise both scientific evidence and evidence based on traditional use**

1. Pre-Market Assessment- Class 2 Medicines Product Licensing

- Complementary medicines assessed as higher risk individually evaluated for quality, safety and efficacy
- Separate, risk-based process and guidelines for Class 2 complementary medicines
- May be indicated for treatment, prevention, or management of serious diseases or conditions
- May be restrictions on consumer access

Regulatory Framework

Key elements of the proposed regulatory scheme

1. Pre-market assessment of ingredients and licensing of products
2. Compliance with standards
3. Licensing and audit of manufacturers
4. Post-market regulatory activity

2. Compliance with standards

Standards

- **Quality**
 - ingredient and products
 - Pharmacopoeias and MDOs
- **Labelling**
- **Packaging**
 - containers and closures

Regulatory Framework

Key elements of the proposed regulatory scheme

1. Pre-market assessment of ingredients and licensing of products
2. Compliance with standards
3. Licensing and audit of manufacturers
4. Post-market regulatory activity

3. Licensing and Audit of Manufacturers

- Manufacturers will be required to comply with the *Australian & New Zealand Code of GMP for Medicinal Products* to obtain a Manufacturing Licence
- Compliance will be ascertained by pre-licensing audits and thereafter by ongoing re-audits of manufacturers

Regulatory Framework

Key elements of the proposed regulatory scheme

1. Pre-market assessment of ingredients and licensing of products
2. Compliance with standards
3. Licensing and audit of manufacturers
4. Post-market regulatory activity

4. Post-Market Regulatory Activity

Risk-based approach will include:

- random and targeted desk-based audits of Class 1 medicines
- targeted laboratory testing of products and ingredients
- random and targeted surveillance in market place
- pharmacovigilance and monitoring of adverse reactions
- effective, responsive and timely recalls procedure



Session 1B

Outcomes of the Consultation on Homoeopathic and Related Medicines

Outcomes of the Consultation on Homoeopathic and related medicines

Consultation papers released for public comment in
January 2005:

- *Proposed Regulatory Definitions for Complementary Medicines and Homoeopathic Medicines in a Joint Australia New Zealand Therapeutic Products Agency*
- *Regulation of Homoeopathic and Related Medicines in a Joint Australia New Zealand Therapeutic Products Agency*

Why were the consultation papers released?

- Increasing concerns raised in relation to misleading presentation and validity of product
- Trans Tasman harmonisation provided the opportunity to review the current approach to the regulation of homoeopathic products in both New Zealand and Australia

What questions were asked?

Input was requested in relation to:

- Definitions
- Quality
- Safety
- Efficacy
- Naming, quantification and labelling



Consultation responses

Excellent response to the questions posed in the consultation

- 29 submissions related specifically to the regulation of homoeopathic and related medicines
- Many of the 33 received in relation to definitions, pertained to definitions for homoeopathic and other energetic type products

Submissions were received from:

- Industry organisations
- Manufacturers and sponsors
- Practitioners and practitioner groups

Definitions

1.1 How should remedies similar to homoeopathic medicine, but not consistent with the homoeopathic paradigm, be defined? (These medicines will be referred to as ‘related medicines in this paper)



Stakeholder responses

- Recognised need for separate definitions for different paradigms
 - Homoeopathy, isopathy, homoeotoxicology
 - Anthroposophic medicines
 - Flower, gem, shell etc. essences
 - Radionic remedies
- Suggestions for definitions provided for:
 - Homoeopathic medicines
 - Anthroposophic medicines
 - Essences



Stakeholder responses

- Many differences of opinion as to what should be termed a 'homoeopathic medicine'
 - Manufactured and used according to the traditional principles
 - Manufactured in accordance with Pharmacopoeia
 - Single potentised remedies only
 - Combination homoeopathics should be classified separately
 - NO ingredients other than homoeopathic ingredients



Quality

2.1 For regulatory purposes, what standards of quality should apply to homoeopathic and related medicines?

Stakeholder responses

Good Manufacturing Practice (GMP)

- Over half the submissions (including 2 peak industry bodies) supported the implementation of GMP
 - half of these indicated that interpretive guidelines would be necessary
- Another quarter supported some form of manufacturing standard (not necessarily GMP)

Stakeholder responses

GMP (continued)

- 2 proposed that registered or recognised pharmacies should manufacture these products
- 1 supported the current arrangements, and
- 1 specifically opposed GMP

Stakeholder responses

Pharmacopoeia

- Preparation in accordance with homoeopathic pharmacopoeia was identified as important
- Concern was expressed regarding the currency of monographs included in pharmacopoeia



Safety

3.1 What factors affect the safety of homoeopathic and/or related medicines?

Stakeholder responses

- Intrinsic safety of these remedies recognised
- 1/3 specifically identified the importance of manufacturing and standards to control safety
- Issues such as contamination and incorrect storage and/or processing were recognised
- Education and training of practitioners was identified as an issue



Stakeholder responses

- Concentration cut-offs were suggested
- Higher potency remedies were of concern for some

Efficacy

4.1 What factors affect the efficacy of homoeopathic and/or related medicines?

Stakeholder responses

- Issues raised included:
 - Selection of remedies by homoeopaths only
 - Recognition of the impact that different approaches to the practice of homoeopathy has on product use
 - The importance of identifying valid starting materials (where justification of use is possible)
 - Concern with 'new' dosage forms and excipients
 - Appropriate manufacturing in accordance with traditional principles



Naming, quantification and labelling

5.1 How should ingredients in homoeopathic and related medicines be quantified?



Stakeholder responses

- In general, quantification of homoeopathic ingredients on the label was not supported
 - Analysis not possible
 - Energy signature transfer
 - Confusing to consumers
- Acknowledgement that quantification may be warranted in certain situations
 - Below 12C
 - Below 4X



Stakeholder responses

- Simple approach of 'Contains homoeopathic ingredient 3X' or 'Contains equal parts of Ingredient A 3X, Ingredient B 6C'
- Industry groups support quantification, whilst conceding that approach needs to address potential for consumer misconception
- Single ingredient 'pure' homoeopathic remedies may not require quantification



Naming, quantification and labelling

5.2 How should homoeopathic and related medicines be labelled to ensure they are differentiated from other medicines?

Stakeholder responses

Differentiation

- Clear support of the view that ‘homoeopathic remedies should be clearly differentiated from other medicines on the label of the product to ensure that consumers are aware of the different nature of these medicines’
- Definitions to partly resolve the issue
- Suggestion that other vibrational remedies should state the relevant ‘stream’

Stakeholder responses

Differentiation

- Recommendation that the term 'Homoeopathic' be included in the name of the ingredient
- Supporting information to 'explain' what a homoeopathic (anthroposophic, etc) was suggested



Naming, quantification and labelling

5.3 How should ingredients in these medicines be expressed on the label?

Stakeholder responses

Naming

- Use of common Latin names suggested
- Selection of names from recognised pharmacopoeia or materia medica
- Referencing of pharmacopoeia as part of the name

Stakeholder responses

Naming

- Develop a list of approved names
- Include the term 'Homoeopathic' as part of the ingredient name

Stakeholder responses

Expression

- Use of internationally accepted terminology where possible
- Use of accepted name followed by potency
- Issue of naming of the product needs to be addressed

Stakeholder responses

Expression of potency

- Acknowledged as an area of dissention
- Issues stem from 'starting points' for the potentisation process
- BP and French system supported by some
- Different systems followed and range of product available
- Reference the pharmacopoeia used



Naming, quantification and labelling

5.4 Is it appropriate for indications for homoeopathic medicines to be included on the label?

Stakeholder responses

Indications

- Division as to the appropriateness of including indications on the label
- Suggested wording, such as ‘Use according to standard homoeopathic indications. If symptoms persist after 3 doses, consult a homoeopathic professional’
- More appropriate format for remedies, such as symptom picture

Stakeholder responses

Practitioner labelling

- Access to homoeopathic remedies by practitioners was a big issue
- Practitioner only category sought
- Separate labelling provisions for practitioners may not be possible under current legislative boundaries



Naming, quantification and labelling

5.5 Should consumers be given written guidance on labels as to how and when homoeopathic remedies should be taken?

Stakeholder responses

Label directions

- Dissent as to whether dosage instructions should be included
- Additional ‘warnings’ recommended, including:
 - Frequency of dosage and referral to professionals
 - Possibility of aggravations
 - Potential for side-effects
 - “This medication may not be ‘homoeopathic’ to your specific condition”

Stakeholder responses

Label directions

- Information regarding appropriate usage and care of remedies
 - Factors affecting efficacy, such as food, aromatic substances, EMR, teeth brushing, improper remedy selection
- Information regarding potency
- Responsibility lies with the sponsor, although label space may impact on what can be said



Other issues

6.1 How should excipient ingredients be expressed and quantified for homoeopathic and related medicines?

Stakeholder responses

Quantification of excipients

- Suggestion that excipients be disclosed to practitioners
- Maintaining the *status quo* was preferred by most
- Labelling of lactose and alcohol were raised as issues



Subsequent action

- Multiple viewpoints acknowledged
- Jurisdiction of the medicines regulator considered
- Consideration by working groups with representative expertise in:
 - Manufacturing and supply
 - Practice
 - Regulation



Subsequent action

- Proposed regulatory frameworks considered
- Position translated into legislative language
- Draft Medicines Rule put forward for public comment



Session 1C

Outline of the Proposed Regulatory Approach for Homoeopathic, Anthroposophic and Essence products

Consultative documents

- Draft Medicines Rule may be found on the ANZTPA website at:
www.anztpa.org/consult/consdocs1.htm
- The Plain English Guide on the Proposed Regulatory Scheme (Refer Appendix 1) may be found on the ANZTPA website at:
www.anztpa.org/about/regscheme.pdf
- Other consultation documents are also available via the ANZTPA website



**ANZTPA will not regulate
complementary healthcare practice or
practitioners**

Provisions relating to homoeopathic and anthroposophic medicines, and essences

Specific provisions included in:

- Part 1 – Preliminary
- Part 3 – Product licenses for medicines
- Part 5 – Exemption from standards and licensing
- Schedules



1.03 Definitions

anthroposophic medicine means a medicine that:

- (a) contains one or more anthroposophic preparations; and
- (b) may contain excipients necessary for presentation of the medicine in the final dosage form

1.03 Definitions

anthroposophic preparation means a preparation prepared:

- (a) from a mother substance specified, for the purpose of this definition, in an Order; and
- (b) in accordance with:
 - i. an anthroposophic manufacturing procedure described by an approved anthroposophic reference; or
 - ii. a homoeopathic manufacturing procedure described in an approved homoeopathic pharmacopoeia

1.03 Definitions

approved anthroposophic reference means an anthroposophic reference specified, for the purpose of this definition, in an Order

Suggested references currently include:

- *Homoeopathic Pharmacopoeia of the United States*
- *Homoopathische Arzneimittel* (German Homoeopathic Pharmacopoeia)
- *British Homoeopathic Pharmacopoeia*
- Homoeopathic monographs and methods in the *Pharmacopée française* and the *European Pharmacopoeia*
- *Anthroposophic Pharmaceutical Codex*

1.03 Definitions

approved essence manufacturing procedure means a procedure specified, for the purpose of this definition, in an Order

Manufacturing procedures are currently being developed by industry for feedback and consideration

1.03 Definitions

approved homoeopathic pharmacopoeia means a homoeopathic pharmacopoeia specified, for the purpose of this definition, in an Order

Suggested references currently include:

- *Homoeopathic Pharmacopoeia of the United States*
- *Homoopathische Arzneimittel* (German Homoeopathic Pharmacopoeia)
- *British Homoeopathic Pharmacopoeia*
- *Homoeopathic Pharmacopoeia of India*
- Homoeopathic monographs and methods in the *Pharmacopée française* and the *European Pharmacopoeia*

1.03 Definitions

essence means a preparation that:

- (a) is prepared in accordance with an approved essence manufacturing procedure; and
- (b) is derived from:
 - i. plant material; or
 - ii. a mineral; or
 - iii. non-human animal material; and
- (c) Is not derived from a substance that:
 - (a) is included in the Scheduling Standard; or
 - (b) has the characteristics of a substance that could be included in the Scheduling Standard; and

1.03 Definitions

essence means a preparation that:

- (d) may contain excipients necessary for presentation of the preparation in the final dosage form.



1.03 Definitions

Homoeopathic medicine means a medicine that:

- (a) Contains one or more homoeopathic preparations; and
- (b) May contain excipients necessary for presentation of the medicine in the final dosage form.



1.03 Definitions

homoeopathic preparation means a preparation prepared:

- from a mother substance specified, for the purpose of this definition, in an Order; and
- in accordance with a homoeopathic manufacturing procedure described in an approved homoeopathic pharmacopoeia.



1.03 Definitions

mother substance means homoeopathic, anthroposophic or essence starting material derived from a plant or a plant material, an alga, a fungus, a micro-organism, an animal material or a chemical, and may include a composition of starting materials

1.05 What is a complementary medicine?

For this Rule, a *complementary medicine* is:

.....

- (b) a homoeopathic medicine; or
- (c) an anthroposophic medicine; or
- (d) an essence.



1.06 Presentation that is not acceptable?

- (1) For this Rule, the presentation of a medicine is ***not acceptable*** if it is capable of being misleading or confusing as to the content or proper use or identification of the medicine.
- (2) Without limiting subsection (1), the presentation of a medicine is not acceptable:
 - a) If it states or suggests that the medicine has an ingredient, component or characteristic that it does not have; or.....

3.12 What is a Class 1 medicine?

A medicine is a Class 1 medicine if it:

- (a) contains only Class 1 permitted ingredients; and
- (b) is any of the following:

.....

- (ii) a homoeopathic medicine or anthroposophic medicine that complies with the criteria specified in section 1.02 of Schedule 2;.....

3.12 Class 1 permitted ingredients

- (1) For this Rule, a substance is a ***class 1 permitted ingredient*** if:
 - a) It is a substance included in a list of ingredients set out in the Orders that are specified as ingredients permitted in a Class 1 medicine; and
 - b) Its use as an ingredient is in accordance with any conditions or qualifications applying to the inclusion of the substance in that list.
- (2) For the purposes of subsection (1), the Orders may provide for separate lists of ingredients for substances of different kinds.

3.15 Permitted ingredient list – decision on application

- (2) The Authority, in making its decision, must have regard to:
- a); and
 - b) Whether the substance:
 - i. Meets the applicable requirements for not being included in the Scheduling Standard; or
 - ii. In the case of a substance permitted, for the purposes of paragraph (b) of item 1.02 of Schedule 2, in an Order – complies with the criteria specified in the Order..

3.17 What is a Class 2 medicine?

A medicine is a Class 2 medicine if it is not:

- (a) A Class 1 medicine; or
- (b) An export-only medicine; or
- (c) A medicine in respect of which an exemption or approval under Division 5.3 is in force.

Note: Division 5.3 relates to exemptions from the requirements of product licensing.

Schedule 2: Class 1 medicines – specified criteria (section 3.12)

1.01 Low risk medicines generally

For the purposes of subparagraph 3.12 (b)(i), the criteria are that the medicine:

- a) contains no ingredient that:
 - i. is a substance included in the Scheduling Standard; or
 - ii. is a substance listed in Appendix C to the Scheduling Standard; or
 - iii. has the characteristics of a substance that could be a substance to which subparagraph (i) or (ii) applies; and
- b) if the medicine contains a homoeopathic or anthroposophic preparation – the homoeopathic or anthroposophic preparation is of a mother substance specified, for the purposes of this paragraph, in an Order; and

Schedule 2: Class 1 medicines – specified criteria (section 3.12)

- 1.01 Low risk medicines generally
- (c) contains no ingredient that is a prohibited import; and
 - (d) is not required, by a standard, to be sterile; and
 - (e) Is supplied, imported or exported with no representations expressly or impliedly referring to a serious disease, disorder or condition, other than representations permitted by the Authority; and

Schedule 2: Class 1 medicines – specified criteria (section 3.12)

1.01 Low risk medicines generally

- (f) is supplied, imported or exported with no representations expressly or impliedly to the effect that it offers a treatment or cure for, or prevention or management of, a disease, disorder or condition, other than in the case of a sunscreen, a representation that is permitted under section 1.03

Schedule 2: Class 1 medicines – specified criteria (section 3.12)

1.02 Homoeopathic and anthroposophic medicines generally

For the purposes of subparagraph 3.12 (b) (ii), the criteria are that the homoeopathic medicine or anthroposophic medicine:

- a) contains no active ingredient other than a homoeopathic or anthroposophic preparation of a mother substance specified, for the purposes of this paragraph, in an Order; and
- b) Contains no ingredient that:
 - i. Is a substance included in the Scheduling Standard; or
 - ii. Has the characteristics of a substance that could be included in the Scheduling Standard;

unless otherwise permitted, in relation to the substance and for the purposes of this paragraph, in an Order; and



Schedule 2: Class 1 medicines – specified criteria (section 3.12)

- 1.02 Homoeopathic and anthroposophic medicines generally
(c) to (f) are the same as for 1.01



Schedule 4: Product licensing exemptions

Part 1 Unconditional exemptions

4. a medicine (other than a medicine used for gene therapy, xenotransplantation or somatic cell therapy) that is extemporaneously compounded, by a medical practitioner, pharmacist, or complementary healthcare practitioner for one particular person for therapeutic application to that person

Schedule 4: Product licensing exemptions

Part 1 Unconditional exemptions

5. A homoeopathic medicine or an anthroposophic medicine that:
 - (a) contains only one homoeopathic preparation or anthroposophic preparation; and
 - (b) contains a concentration of the mother substance of not more than 10mg/kg; and

Schedule 4: Product licensing exemptions

Part 1 Unconditional exemptions

- (c) includes on the label a statement to the effect that the medicine is only to be used in accordance with homoeopathic or anthroposophic principles (as the case requires); and
- (d) includes the manufacturer's manufacturing licence number on the label and otherwise complies with the requirements as to labelling specified in the Orders; and
- (e) is not promoted for therapeutic use; and

Schedule 4: Product licensing exemptions

Part 1 Unconditional exemptions

- (f) is not required to be sterile; and
- (g) does not contain a substance that;
 - i. is included in the Scheduling Standard; or
 - ii. has the characteristics of a substance that could be included in the Scheduling standard;unless otherwise permitted, in relation to the substance and for the purposes of this item, in an Order; and
- (h) is not derived from a mother substance specified, for the purposes of this item, in an Order.



Schedule 4: Product licensing exemptions

Part 1 Unconditional exemptions

6. A homoeopathic preparation or anthroposophic preparation that is supplied as a starting material to a licensed manufacturer.

Schedule 5: Manufacturing licensing exemptions

Part 1 Exempt manufacturers

4. A complementary healthcare practitioner who is engaged in the manufacture of any complementary medicine

The kind of medicine in respect of which exemption applies:

A preparation to be supplied in the course of the practitioner's business, if:

- (a) *It is manufactured on premises that the practitioner occupies and that he or she is able to close so as to exclude the public; and*

Schedule 5: Manufacturing licensing exemptions

Part 1 Exempt manufacturers

4. A complementary healthcare practitioner who is engaged in the manufacture of any complementary medicine

The kind of medicine in respect of which exemption applies:

- (b) *The practitioner:*
 - i. *Supplies the preparation for administration to a particular person after consulting with that person; and*
 - ii. *Uses his or her own judgement as to the treatment required*



Proposed provisions for essences

- Provisions exist to declare that particular products do not come under the jurisdiction of the regulatory scheme
- This will only occur for products where particular criteria are met

Proposed provisions for essences

- Essence products will need to meet the following conditions
 - Contains a concentration of the mother substance equal to or less than 10mg per litre or per kilogram
 - Mother substance may not be referred to in the Scheduling standard
 - May not be required to be sterile
 - May NOT make therapeutic claims



Questions?



For further information....

www.anztpa.org



Session 2

Discussion of issues:

- **Quality standards, including GMP**
 - **Permitted ingredients**
- **Evidence to support indications and claims**

Session 2

Introduction to issues	10 mins
1. Quality standards including GMP - discussion	30 mins
2. Permitted ingredients - discussion	30 mins
3. Evidence to support indications - discussion	15 mins
How to comment on proposals	5 mins

DEFINITIONS

- Proposed regulatory definitions for homoeopathic and anthroposophic medicines and essences in Draft Medicines Rule
 - pharmacopoeial (manufacture) based definitions
 - recognises valid medicines derived from valid homoeopathic/anthroposophic starting materials
 - recognises anthroposophic medicines distinct from homoeopathic medicines

HOMOEOPATHIC, ANTHROPOSOPHIC MEDICINES

- Manufacture under GMP proposed
 - interpretative Guidelines to be developed
- Product Licence required
 - proposed exemptions for specific preparations for practitioners and certain single preparations
- Permitted ingredients
- Evidence to support indications consistent with risk and paradigm

ESSENCES

- Exemption for certain preparations that make no therapeutic claim
- Need to develop guidance on suitable indications
- Need to determine type and level of evidence to support indications consistent with risk and paradigm

Issue for Discussion: Quality standards, including GMP

- International requirements for compliance with the code of GMP are variable
- Common theme is compliance with the relevant pharmacopoeia
- Appropriate and accountable dilution and succussion is imperative to ensure the preparation of an authentic homoeopathic remedy

Questions for consideration

- What aspects of the current code of Good Manufacturing Practice (GMP) are not applicable to these types of medicines, and why?
 - Quality management
 - Personnel
 - Premises and equipment
 - Cleaning and sanitation
 - Documentation
 - Production

Questions for consideration

- Applicability of current requirements of GMP (continued)
 - Quality control (Micro/QC)
 - Contract manufacture and analysis
 - Non-conforming product handling
 - Self audit
 - Compliance with marketing authorisation
 - Compliance with relevant annexes
- Where do dispensing pharmacies fit in?

Issue for Discussion: Managing Director Order (MDO) for Mother Substances

- Development of a list of homoeopathic and anthroposophic mother substances for inclusion in ‘OTC’ products must include consideration of:
 - The validity of the ingredient in terms of the paradigm
 - Concentration cut-offs for the final preparation
 - Poison scheduling requirements
 - Current eligibility for Listing
 - General concentration cut-off
 - Naming of the ingredients

Questions for consideration

- What references should be used to formulate the content of the list of mother substances?
- What provisions are needed for ‘new’ substances’?
- What mother substances are appropriate for homoeopathic medicines or anthroposophic medicines, but not for combination with non-homoeopathic ingredients?
- How should these ingredients be named?

Issue for Discussion: Evidence to support indications and claims

- This provision is important to support the integrity of the paradigm, and address practitioner and consumer concerns
- Current requirements in the Levels of Evidence Guidelines require reconsideration
- Consideration needs to be given as to how the different approaches to homoeopathy can be addressed in a practical manner

Questions for consideration

- What references could be used to support a principles approach to evidentiary requirements?
- What evidence helps to support combination products?
 - Combination homoeopathic
 - Combination with non-homoeopathic
- How do symptom pictures translate to ‘conventional’ claims?

HOW TO COMMENT ON PROPOSALS

- Instructions on how to comment on the proposals can be found at:

www.anztpa.org/consult/consultdocs1.htm

- Email to consultation@anztpa.org
- Post to ANZTPA consultation
c/- Joint Agency Establishment Group
TGA (PO Box 100, Woden, ACT)
or
Medsafe (PO Box 5013, Wellington)

HOW TO COMMENT ON PROPOSALS

- Please remember to:
 - support your positive/negative concerns with examples/evidence
 - suggest what you think could be a workable alternative, and why
 - consider the overall impact of what you are suggesting



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Regulatory Proposals



**Thankyou for your time
and attention**