



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration



Plain English Guide
to the
proposed medicines scheduling provisions of
the draft Australia New Zealand
Therapeutic Products Regulatory Scheme
(Administration and Interpretation) Rule 2006

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1. INTRODUCTION

On 10 December 2003 the Australian and New Zealand Governments signed an agreement to establish a joint scheme for the regulation of therapeutic products in the two countries (the Treaty). The joint regulatory scheme will be administered in both countries by a single, bi-national authority, the Australia New Zealand Therapeutic Products Authority (the Authority). The Authority will replace the Therapeutic Goods Administration (TGA) in Australia and the Medicines and Medical Devices Safety Authority (Medsafe) in New Zealand and will be accountable to both the Australian and New Zealand Governments.

The Therapeutic Products Ministerial Council has the power to determine Rules which provide for a framework for the classification of therapeutic products to enable a system or systems of access controls for therapeutic products to be applied in Australia and New Zealand (Article 9(1) (r) of the Treaty).

It is envisaged that in almost all cases Australian jurisdictions and New Zealand will adopt-by-reference the scheduling decisions of the Authority.

This document describes the joint regulatory scheme for the scheduling of medicines in Australia and New Zealand, as contained in the draft Australia New Zealand Therapeutic Products Regulatory Scheme (Administration and Interpretation) Rule 2006.

2. BACKGROUND

The Galbally Review

The National Competition Policy *Review of Drugs, Poisons and Controlled Substances Legislation* (the ‘Galbally Review’) Final Report (2001) made several recommendations to revise arrangements for the scheduling of medicines and poisons. Relevant recommendations have been taken into account in the development of the joint regulatory scheme. One of the key recommendations of the Galbally Review was to disband the National Drugs and Poisons Schedule Committee (NDPSC) and replace it with two separate committees – the Medicines Scheduling Committee (MSC) and the Poisons Scheduling Committee.

3. NEW SCHEDULING ARRANGEMENTS

The proposed scheduling model has been developed in consultation with the National Coordinating Committee on Therapeutic Goods¹ (NCCTG), the Australian Department of Agriculture, Fisheries and Forestry (DAFF) and Medsafe. This model is consistent with the recommendations of the Galbally Review.

Under this model two expert advisory scheduling committees will be established, one for medicines and the other for poisons (Australia only). Please note that under the new scheduling arrangements the New Zealand Medicines Classification Committee (MCC) will also be disbanded. The MSC is expected to include expertise from both Australia and New Zealand and make recommendations to the Authority on access to medicines for implementation in both countries. The Authority’s scheduling decisions will be communicated to stakeholders via an electronic register, the *Standard for the Uniform Scheduling of Medicines and Poisons* (the Scheduling Standard).

¹ The NCCTG, which includes New Zealand membership, currently has responsibility for overarching policy guidance and protocols for scheduling in Australia.

As the arrangements for the scheduling of poisons will be an Australian-only function, it is anticipated that the relevant provisions will be subject to a separate consultation process at a later date.

It was considered important in the interests of ensuring ongoing consistency and cohesiveness in the decision-making process between the two committees that the Authority maintain:

- a single scheduling policy framework;
- a single secretariat to support both scheduling committees; and
- a single Scheduling Standard.

It is proposed the scheduling policy framework will be developed and maintained by the NCCTG. It is expected to contain the details and factors describing the criteria for the inclusion of a substance within a particular schedule, which will be adopted by the Authority. The Authority's scheduling decisions will be included in the Scheduling Standard and given effect through New Zealand and Australian State and Territory legislation. A separate consultation on the proposed scheduling policy framework and the Scheduling Standard is expected to occur in the first quarter of 2007.

4. SCHEDULING OF MEDICINES UNDER THE AUTHORITY

The Australian and New Zealand Governments have agreed to establish a harmonised model for the scheduling of medicines for Australia and New Zealand. The medicines scheduling provisions are set out in the Administration and Interpretation Rule.

Expert Committee

The Administration and Interpretation Rule will establish the MSC as an expert advisory committee to primarily provide advice to the Authority on the scheduling of substances (ie therapeutic product ingredients) in Australia and New Zealand. The Administration and Interpretation Rule also prescribes the functions and constitution of the MSC. It requires the recommendations of the MSC to be made public and this may be through the publication of its minutes on the Authority's website.

Membership of the Medicines Scheduling Committee

The MSC will comprise at least 12 but not more than 16 members. The Authority, New Zealand (as represented by the New Zealand Ministry for Health) and the Australian States/Territories will each be able to nominate one expert member.

The nominated members will be required to be qualified in one of more of the following areas:

- Expertise in the regulation of medicines in Australia or New Zealand;
- Toxicology;
- Pharmacy (as a practicing community pharmacist);
- Medical practice (as a practicing medical practitioner); or
- Clinical pharmacology.

The MSC will also include:

- One member with expertise in therapeutic product Industry issues; and
- One member with expertise in consumer issues.

The membership of the MSC is expected to include the widest possible range of the above expertise. Following the identification of these 12 committee members, the Authority will determine whether there is a lack of coverage in any of the required areas of professional expertise. Where this is the case, the Authority will nominate relevant experts. Authority officials, members of the Australian or New Zealand Governments, industry stakeholders, healthcare practitioner groups and consumer groups may be asked to assist in the identification of suitable candidates for membership.

Members of the MSC will be appointed by the Ministerial Council with appointment decisions based on recommendations from the Authority. The Chair must be a person nominated to that office by the Authority and will also be appointed by the Ministerial Council. Please note that members of the MSC will have equal voting rights. In the case of a tied vote, the Chair will have the deciding vote.

Scheduling procedures and adoption of scheduling decisions

It is proposed that the Scheduling Standard will be maintained as an electronic register published on the Authority's website. It will continue to include decisions relating to the scheduling of poisons which will apply only in Australia.

The Authority will make the medicine scheduling decisions (in terms of the entry in the Scheduling Standard) which will be a scheduling recommendation to New Zealand and to the Australian States and Territories who will give it legal effect.

New Zealand has proposed only to recognise recommendations for scheduling for substances for human therapeutic use included in Schedules 2, 3 and 4 of the Scheduling Standard. The *New Zealand Misuse of Drugs Act 1975* will continue to apply and product labelling in New Zealand will need to reflect the requirements of this legislation as well as relevant ANZTPA labelling requirements.

The New Zealand-specific legislation will deal with situations where the schedule entries in New Zealand and Australia are not harmonised at the commencement of the Authority, or where New Zealand has on public health grounds actively decided not to adopt recommendations from the Scheduling Standard. It is proposed that New Zealand will publish a list of these scheduling departures in the New Zealand Gazette on the Ministry of Health website.

As the NCCTG is a cross jurisdictional committee that interacts with the Authority and has responsibility for coordination of the legislative and administrative controls on therapeutic products at the local level, it is proposed that this committee should provide overarching policy guidance on matters relating to scheduling. The policy framework for scheduling will include criteria that the Authority, the MSC and other expert advisory committees will use to determine the appropriate schedule of a substance.

It is expected that the NCCTG will continue to operate as a standing sub-committee of the Australian Health Ministers' Advisory Council (AHMAC). The New Zealand Ministry of Health will continue to be a member of each of these Committees. Additionally, the New Zealand Health Minister is a member of the Australian Health Ministers' Conference.

Scheduling of new substances

The Authority will make initial decisions on the scheduling of a new substance (ie a substance on which a scheduling decision has not already been made). This will take place during the evaluation and approval processes that occur prior to a product licence being issued. The Authority may also schedule a new substance on its own initiative. Before making a scheduling decision, the Authority will seek advice from the expert advisory committee considering the product licence application and may seek advice from the MSC or another expert advisory committee.

The Authority's decision-maker will also be required to comply with the scheduling policy framework developed by the NCCTG in making scheduling decisions for new substances.

If the Authority considers for any reason that it is necessary to vary the framework, the matter will be referred through the MSC to the NCCTG for confirmation.

Public consultation of the scheduling of a new substance being considered for a product licence will not routinely occur, unless the Authority considers that it would be in the public interest to do so. In these circumstances the scheduling proposal would be referred to the MSC (see below).

Rescheduling

The Authority will refer all rescheduling proposals to the MSC for advice and must have regard to this advice before making a decision on rescheduling. The Authority may also initiate a review of a scheduling decision where this is deemed to be in the interests of public health and safety. In determining whether a review is warranted the Authority may take into account any proposals received from the MSC or the public.

Public Consultation

All scheduling matters to be considered by the MSC will be subject to public consultation. The public consultation procedures include publishing a notice in the Authority Gazette detailing each scheduling proposal to be considered by the MSC (other than information considered to be commercial-in-confidence) and inviting public submissions. Any public submissions received will be published on the Authority's website.

Notification of decisions

The Authority as soon as practicable after a scheduling decision is made must publish on its website the decision and the reasons for the decision. It also is required to notify the applicant (and those persons who made public submissions) that they may provide a further submission for reconsideration of the decision.

Reconsideration of decisions

Reconsideration of a scheduling decision can be made on the grounds of a relevant matter which the Authority must take into account when scheduling a substance (section 10.09 of the Administration and Interpretation Rule) or if the NCCTG scheduling policy framework was incorrectly applied.

The submission for reconsideration must be made within 20 working days after the decision is published on the Authority's website. Submissions for reconsideration and the grounds for the reconsideration must be published on the Authority's website. Additionally, the Authority may refer the request for reconsideration to the MSC for advice. The Authority must have regard to advice provided by the MSC, and in reconsidering the scheduling decision either confirm the decision, vary the decision or set aside the decision and make a new decision in place of the decision.

As soon as possible after reconsidering a scheduling decision, the Authority must notify the person who requested the review of the result and reasons and publish them on the Authority's website.

It is expected that the merits of the scheduling decisions of the Authority will be reviewable in Australia and New Zealand on the basis of an error of law by the courts in each country.

Urgent Scheduling

The Administration and Interpretation Rule includes provisions for urgent scheduling where the Authority is satisfied that it would be in the interest of public health and safety to urgently schedule/reschedule a medicine. Under these circumstances, the Authority may make a scheduling decision without public consultation. The Authority must reconsider the scheduling decision as soon as practicable after making the decision and invite public submissions.

Amendments to the Scheduling Standard

Before amending the Scheduling Standard, the Authority will be required to publish a notice in the Authority Gazette advising of the amendment together with the date of effect. The electronic Scheduling Standard would be updated as the date of effect falls due.

Costs

The costs associated with the scheduling of medicines will be recovered. A separate consultation paper on the fees and charges under the ANZTPA (May 2006) included a proposal relating to the recovery of costs associated with scheduling related activities.

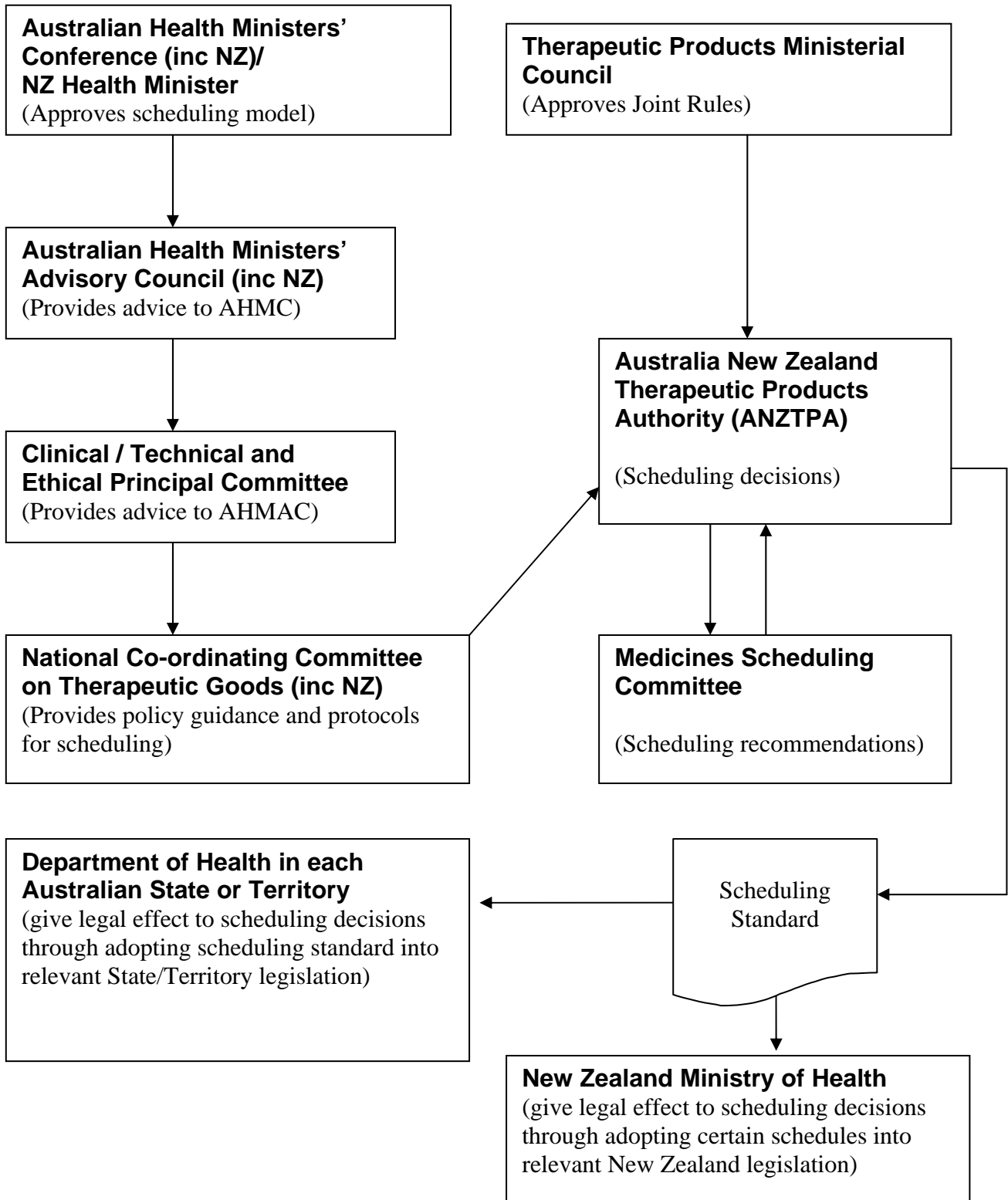
Proposed transitional arrangements

It is proposed that decisions made at the last NDPSC meeting before the joint regulatory scheme commences which have been completed but not yet come into effect will carry over into the new legislation as scheduling decisions with the same date of effect.

Initial medicine scheduling decisions made at the last NDPSC meeting before the joint regulatory scheme commences which have not been completed before the new legislation comes into effect, are expected to be completed by the MSC .

Scheduling decisions made by the New Zealand MCC, which come into effect after the release of the Scheduling Standard and differ from the entries in that standard, will be published in the New Zealand Gazette as required by the New Zealand legislation. The date of effect of these MCC decisions will carry over unchanged into the new legislation. The MSC would review New Zealand departures ("non-harmonised" entries) from the Scheduling Standard as part of its ongoing work program.

Key Bodies in the Scheduling of Medicines



Note: The New Zealand Minister of Health is a member of the Australian Health Ministers' Conference and the Director-General of the New Zealand Ministry of Health is a member of the Australian Health Ministers' Advisory Council. The New Zealand Ministry of Health is a member of the National Coordinating Committee on Therapeutic Goods. The Therapeutic Products Ministerial Council includes the Australian Health Minister and the New Zealand Minister of Health.