

Australian Health Ministers' Advisory Council

Scheduling Policy Framework for Medicines
and Chemicals

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This policy document is to be read in conjunction with the Scheduling Handbook.

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Purpose

The *Scheduling Policy Framework (Scheduling Policy)* sets out the national policy for applying access restrictions on all “poisons”. As defined in the Poisons Standard, poisons include medicines for human therapeutic use, veterinary medicines, agricultural, domestic and industrial chemicals where there is a potential risk to public health and safety.

Poisons are scheduled according to the risk of harm and the level of access control required to protect consumers. State and territory governments are responsible for imposing legislative controls on the supply of poisons. Generally, these controls flow from the schedule in which the poison has been included.

Provisions for the scheduling of medicines and chemicals are set out in the *Therapeutic Goods Act, 1989* (the Act) and associated Regulations. They have been developed to ensure operational effectiveness while supporting the existing high level of scheduling uniformity across states and territories.

Responsibilities & Obligations

The key aspects of the scheduling of medicines and chemicals in Australia include:

- the Australian Health Ministers’ Advisory Council (AHMAC) is responsible for scheduling policy (including this document)
- the Secretary of the Department of Health (in practice his or her delegate/s) is the decision-maker on the scheduling of medicines and chemicals, and other changes to the Poisons Standard
- two Advisory Committees: the Advisory Committee on Medicines Scheduling (ACMS) and the Advisory Committee on Chemicals Scheduling (ACCS) advise the decision-maker/s
- a single Poisons Standard is produced, typically updated three times annually, and is a Commonwealth legislative instrument
- the States and Territories give effect to the Poisons Standard, usually by reference, through the relevant medicines and poisons legislation.

Scheduling Policy

AHMAC has responsibility for the policy principles on scheduling and other poisons regulatory controls, as set out in this document. The Scheduling Handbook provides further guidance for stakeholders and provides details of the processes that underpin the scheduling policy.

The Scheduling Policy allows decision-makers, expert Advisory Committee(s), evaluators and the delegate to judge the best fit for new substances and to facilitate the rescheduling assessment process when an application for rescheduling is received or new knowledge or practice emerges.

An *ad hoc* group will be convened as required to review and provide oversight of the guidance and process for scheduling. The Scheduling Policy and Scheduling Handbook documents are maintained by the Scheduling Secretariat. Any policy considerations arising will be referred to AHMAC for consideration.

Secretary's delegate

The Secretary may make decisions on the scheduling of medicines or chemicals, as well as changes to other parts and appendices of the Poisons Standard. This authority is provided under sections 52D, 52E and 52EAA of the Act.

In practice, persons to whom the Secretary has delegated decision-making responsibility will make the decision. These persons have the appropriate expertise and hold appropriate positions within the Department of Health, or other Government Agencies if required.

When making a decision in relation to the scheduling of a substance the decision-maker may seek advice from the Advisory Committees, relevant State and Territory regulators, and/or any other expert committee, person or entity. The decision-making process will be undertaken in accordance with the relevant sections of the Act, the *Therapeutic Goods Regulations 1990* (the Regulations) and the *Scheduling Policy* and *Scheduling Handbook*.

Advisory Committees

The Advisory Committee on Medicines Scheduling and the Advisory Committee on Chemicals Scheduling are established under sections 52B and 52C of the Act. The membership, functions and procedures for the expert Advisory Committees are set out in the *Regulations* and the *Scheduling Handbook*.

As provided for by Subdivision 3D.2 of Part 6 of the Regulations the Secretary may refer an application or proposal to amend the Poisons Standard to either or both of the Advisory Committee(s). They will provide advice to the Secretary on rescheduling and certain new proposals to amend the Poisons Standard.

Implementation of decisions

The decision made by the Secretary will be incorporated in the Poisons Standard. The Poisons Standard is the cumulative result of scheduling related decisions of the Secretary and is maintained by the Scheduling Secretariat on behalf of the Secretary of the Department.

Decisions to amend the Poisons Standard are recommendations to the states and territories.

States and territories will give effect to these decisions by adoption of the Poisons Standard through their relevant legislation.

To be legally enforceable in any or all jurisdictions, decisions must be incorporated in the Poisons Standard.

Associated Legislation

Part 6-3 of the Act, sections 52AA through 52EC inclusive, sets out the legislative basis for scheduling.

In particular, section 52E sets out the matters to be taken into account when making scheduling decisions.

The legislation is further supported by regulations 42ZCA through 42ZCX inclusive of the Regulations.

The Scheduling Factors

Section 52E of the Act sets out the general factors for scheduling consideration, in order to determine the relevant schedule for a substance, factors specific to each schedule need to be considered. These factors are a critical piece of scheduling policy and are intended to ensure consistency in the application of public health risk consideration when making a scheduling decision. This document sets out the factors for each schedule and the appendices.

Details regarding amendments to Parts 1-3 of the Poisons Standard are included in the *Scheduling Handbook*.

Factors for pharmacy medicines (schedule 2)

- 1. The quality use of the medicine can be achieved by labelling, packaging, and/or provision of other information; however access to advice from a pharmacist should be available to maximise the safe use of the medicine.**

The medicine is for minor ailments or symptoms that can easily be recognised and are unlikely to be confused by the consumer with other more serious diseases or conditions. Treatment can be managed by the consumer without the need for medical intervention. However, the availability of a pharmacist at the point of sale supports the consumer in selecting and using the appropriate medicine.

- 2. The use of the medicine is substantially safe for short term treatment and the potential for harm from inappropriate use is low.**

Suitable for diagnosis and treatment by the consumer in the management of minor ailments.

- 3. The use of the medicine is very unlikely to produce dependency (at either the established therapeutic dose or suprathreshold doses) and the medicine is very unlikely to be misused, abused or illicitly used.**

Medicines which do not meet this factor are not suitable to be classified as Schedule 2 Pharmacy Medicines, irrespective of any other applicable factors.

- 4. The risk profile of the medicine is well defined and the risks can be identified and managed by a consumer through appropriate packaging and labelling, including consultation with a health professional if directed by labelling.**

There is a low and well-characterised incidence of adverse effects; interactions with commonly used substances or food and contra-indications.

- 5. The use of the medicine at established therapeutic dosage levels is not likely to mask the symptoms or delay diagnosis of a serious condition.**

Appropriate labelling and packaging can manage any risks.

Factors for pharmacist only medicines (schedule 3)

- 1. The medicine is substantially safe with pharmacist intervention to ensure the quality use of the medicine. There may be potential for harm if used inappropriately.**

The consumer can identify the ailments or symptoms that may be treated by the medicine but counselling and verification by a pharmacist is required before use. Consumer consultation with a pharmacist is necessary to reinforce and/or expand on aspects of the safe use of the medicine.

- 2. The use of the medicine is not expected to produce dependency at either the established therapeutic dose or at suprathreshold doses. Where risk of misuse, abuse or illicit use is identified, the risk can be minimised through pharmacist-consumer consultation.**
- 3. The risk profile of the medicine is well defined and the risk factors for adverse effects, interactions and contraindications are known, identifiable and manageable by a pharmacist.**
- 4. Where the medicine is intended for recurrent or subsequent treatment of a chronic condition, pharmacist intervention is required to monitor safe use of the medicine following recommendation by a medical practitioner or other authorised prescriber.**

The consumer may not be able to self-monitor the safe ongoing use of the medicine. The condition does not require medical diagnosis or only requires initial medical diagnosis, and the consumer does not require close medical management.

- 5. The use of the medicine at established therapeutic dosage levels may mask the symptoms or delay diagnosis of a serious condition.**

Pharmacist-consumer consultation is required to detect the risk of masking a serious disease or compromising medical management of a disease, and to deal with it appropriately.

Note: Additional controls over access and training for substances in Schedule 3 may be required through inclusion in Appendix M, particularly where the potential for severe and possibly irreversible injury may occur without the user being aware of exposure and/or where the pattern of use of the substance poses a significant risk from direct or indirect public exposure.

Factors for prescription only medicines and prescription animal remedy (schedule 4)

- 1. The ailments or symptoms that the substance is used for require medical, veterinary or dental intervention¹.**

Diagnosis, management or monitoring of the medical condition is such that it requires medical, veterinary or dental intervention before the substance is used.

- 2. The use of the substance requires adjunctive therapy or evaluation or specialised handling for administration.**

Adjunctive therapy could include other medicines, non-pharmacological measures, or specialised medicine delivery devices. Evaluation could include laboratory tests or additional clinical assessments.

For human medicines, a requirement for administration by injection will usually mean medical or dental supervision is required because of the additional risks and complexity of this route of administration.

- 3. The use of the substance at established therapeutic dosage levels may produce dependency but has a moderate propensity for misuse, abuse or illicit use.**

Control of access and duration of therapy by a medical, veterinary or dental practitioner is required.

- 4. The seriousness, severity and frequency of adverse effects are such that monitoring or intervention by a medical, veterinary or dental practitioner is required to minimise the risk of using the substance.**

- 5. The margin of safety between the therapeutic and toxic dose of the substance is such that it requires medical, veterinary or dental intervention to minimise the risk of using the substance.**

- 6. The seriousness or severity and frequency of the interactions of the substance (medicine-medicine, medicine-food, or medicine-disease) are such that monitoring or intervention is required by a medical, veterinary or dental practitioner.**

- 7. The use of the substance has contributed to, or is likely to contribute to, communal harm.**

For example the development of resistant strains of microorganisms. Appropriate use, and/or the decision to continue treatment, requires evaluation by a medical, veterinary or dental practitioner.

- 8. The experience of the use of the substance under normal clinical conditions is limited.**

Unexpected effects of the substance may only become evident after widespread use. Close monitoring of the patient is required by a medical, veterinary or dental practitioner to monitor for unanticipated effects.

¹ For the purposes of the document medical, veterinary or dental intervention is considered to include other authorised prescribers as described in relevant legislation of Australian states and territories.

Factors for label use of “caution” (schedule 5)

1. The substance is non-corrosive and has a low toxicity.

Acute oral toxicity (rat) is between 2000 mg/kg – 5000 mg/kg. Acute dermal LD50 is more than 2000 mg/kg. Acute inhalation LC50 (rat) is more than 3000 mg/m³ (4 hours).

Dermal irritation is slight to moderate. Eye irritation is slight to moderate. Immediate, prolonged or repeated contact with the skin or mucous membranes may cause slight to moderate inflammation. Skin sensitisation is weak or nil.

When non-animal test data are used, validated test results meeting the following GHS categories are taken to meet the factors for this schedule: Acute toxicity Cat 5 (H303); Skin irritation Cat 3 (H316); Eye irritation Cat 2B (H320); Skin sensitisation Cat 1B (H317).

2. The substance has a low health hazard.

The substance presents a low hazard from repeated use and is unlikely to produce irreversible toxicity. There is no other significant toxicity (e.g. respiratory sensitisation, mutagenicity, carcinogenicity, reproductive toxicity etc).

3. The substance is capable of causing only minor adverse effects to humans in normal use.

Specialised equipment should not be necessary for safe use.

4. The likelihood of injury in handling, storage and use can be mitigated through appropriate packaging and simple label warnings.

Adequate packaging and labelling protects the consumer from the known danger(s) of the substance if it is inhaled, taken internally or if it penetrates the skin. Potential harm is reduced through labelling which informs the consumer about the safety measures to apply during handling and use (including safety directions) and child resistant packaging (where appropriate).

5. The substance has a low potential for causing harm.

Potential harm is reduced through the use of appropriate packaging with simple warnings and safety directions on the label.

Factors for label use of “poison” (schedule 6)

1. The substance has a moderate to high toxicity, which may cause death or severe injury (including destruction of living tissue) if inhaled, taken internally, or in contact with skin or eyes.

Acute oral LD50 (rat) is between 50 mg/kg – 2000 mg/kg. Acute dermal toxicity is between 200 mg/kg and 2000 mg/kg. Acute inhalation LC50 (rat) is between 500 mg/m³ and 3000 mg/m³ (4 hours).

Dermal irritation is severe. Eye irritation is severe. Skin sensitisation is moderate to severe.

When non-animal test data are used, validated test results meeting the following GHS categories are taken to meet the factors for this schedule: Acute Toxicity Cat 3 or 4 (H301, H302, H311, H312); Skin irritation Cat 2 (H315); Eye irritation Cat 2A-(H319); Skin sensitisation Cat 1A or Cat 1 (H317).

2. The substance has a moderate health hazard.

The substance presents a moderate hazard from repeated use and moderate risk of producing irreversible toxicity.

3. Reasonably foreseeable harm to users can be reduced through strong label warnings, extensive safety directions and child-resistant packaging (where appropriate).

Adequate packaging and labelling protects the consumer from the known danger(s) of the substance. Potential harm is reduced through labelling which informs the consumer about the safety measures to apply during handling and use (including safety directions) and child resistant packaging.

4. The substance has a moderate potential for causing harm.

Potential harm is reduced through the use of distinctive packaging with strong warnings and safety directions on the label.

Factors for dangerous poisons (schedule 7)

1. The substance has a high to extremely high toxicity.

Acute oral LD50 (rat) is 50 mg/kg or less. Acute dermal LD50 is 200 mg/kg or less. Acute inhalation LC50 (rat) is 500 mg/m³ (4 hours) or less. Dermal irritation is corrosive. Eye irritation is corrosive.

When non-animal test data are used, validated test results meeting the following GHS categories are taken to meet the factors for this schedule: Acute Toxicity Cat 1 or 2 (H300, H301, H310, H311); Corrosive Cat 1A, 1B, 1C (H314); Eye damage Cat 1-(H318).

2. The substance has a high health hazard.

The substance presents a severe hazard from repeated and unprotected use or a significant risk of producing irreversible toxicity, which may involve serious, acute or chronic health risks or even death if it is inhaled, taken internally or penetrates the skin.

3. The dangers of handling the poison are such that special precautions are required in its manufacture, handling or use.

The dangers associated with handling the substance are too hazardous for domestic use or use by untrained persons and warrant restrictions on its availability, possession or use.

4. The substance has a high potential for causing harm at low exposure.

The substance should be available only to specialised or authorised users who have the skills necessary to handle the substance safely. Restrictions on their availability, possession, storage or use may apply.

Note: Additional controls over access and training for substances in Schedule 7 may be required through inclusion in Appendix J, particularly where the potential for severe and possibly irreversible injury may occur without the user being aware of exposure and/or where the pattern of use of the substance poses a significant risk from direct or indirect public exposure.

For Schedules 5, 6 and 7 the following definitions apply:

Eye irritation

Slight	no corneal opacity
Moderate	corneal opacity reversible within 7 days
Severe	corneal opacity not reversible within 7 days
Corrosive	irreversible tissue damage in the eye following application of a test substance to the anterior surface of the eye

Dermal irritation

Slight	weak irritation at 72 hours
Moderate	moderate irritation at 72 hours
Severe	severe irritation at 72 hours
Corrosive	irreversible tissue damage in the skin following application of a test substance

In light of changes to animal testing acceptability and government regulations, alternative test data may be considered for scheduling consideration. The Scheduling Handbook provides additional guidance on acceptable tests for chemicals that may be classified as Schedule 5, 6 or 7.

Factors for controlled drugs (schedule 8)

- 1. The substance is included in Schedule I or II of the United Nations Single Convention on Narcotic Drugs 1961 or in Schedule II or III of the United Nations Convention on Psychotropic Substances 1971.**
- 2. The substance has an established therapeutic value but its use, at established therapeutic dosage levels, is recognised to produce dependency and has a high propensity for misuse, abuse or illicit use.**

The substance has an established therapeutic value but by reason of its novelty or properties carries a substantially increased risk of producing dependency

Factors for prohibited substances (schedule 9)

- 1. The substance is included in either Schedule IV to the United Nations Single Convention on Narcotic Drugs, 1961 or in Schedule I to the United Nations Convention on Psychotropic Substances 1971.**
- 2. The substance has no currently established therapeutic value and is likely to present a high risk of dependency, abuse, misuse or illicit use.**

A high level of control is required through prohibition of manufacture, possession, sale or use to prevent abuse, misuse or diversion into illicit activities.

The benefits of use are substantially outweighed by the risks, and dangers are such as to warrant limiting use to strictly controlled medical and scientific research.

Note: High risk substances which do not have risks of dependency, abuse, misuse or illicit use should be included in Schedule 10.

Factors for substances of such danger to health as to warrant prohibition of sale, supply and use (schedule 10)

- 1. The substance poses such a high public health risk, including potential risk, that its sale, supply and/or use require very strict control, with access generally being prohibited. The potential health risk does not include potential for abuse, diversion into illicit products or other factors which would warrant inclusion in Schedule 9.**
- 2. The substance has a public health risk that substantially outweighs the benefit to the extent that no other Schedule would provide appropriate public access to any proposed or known products. The serious public health risk may be restricted to particular uses.**

The Secretary may establish a cut-off from Schedule 10 where the substance no longer meets the factors for inclusion in this Schedule or in any other Schedule in the Poisons Standard.

Considerations for amending the appendices (Part 5 of the Poisons Standard)

Changes to certain Appendices in Part 5 of the Poisons Standard, in particular Appendices A and B, can only be considered in the context of an application for scheduling or rescheduling of an existing poison.

For amendments to Appendices A and B, where a proposal is clearly and exclusively related to:

- i. human therapeutic use, then the ACMS may be consulted; or
- ii. some other use excluding human therapeutic use, then the ACCS may be consulted; or
- iii. where neither of these situations applies, the ACMS and ACCS may be consulted at a joint meeting prior to any decision.

Where the Appendix may have direct implications for the labelling, storage or supply of a product, an application to vary the specific entry must be made through the relevant product registration authority or scheme (Therapeutic Goods Administration, Australian Pesticides and Veterinary Medicine Authority or National Industrial Chemicals Notification and Assessment Scheme). This includes Appendices D, K and L for therapeutic goods and F, E, and L for all other poisons.

Appendix A – General exemptions

Appendix A provides general exemptions from the controls set out in the Poisons Standard for classes of products where the physical nature of the products, or their use, or other legislative controls applicable to the class of product, mitigate to an acceptable level the public health risk of any substances in that class.

Inclusion of an entry in Appendix A may be made by the Secretary, where classification of representative members from a product or substance class has consistently demonstrated that they do not meet any of the criteria for inclusion in the Schedules.

When considering an entry in Appendix A the Secretary must consider whether making or amending an entry will:

- be generally consistent with the safety profile of members of the proposed class;
- address a regulatory need for a class exemption; and
- provide a public benefit through the class exemption.

Appendix B – Substances considered not to require control by scheduling

Appendix B is a positive list of substances that have been considered to be exempt from scheduling requirements on the basis of information available at the time of the decision not to schedule them.

No direct application can be made for inclusion of a substance in Appendix B and there are no explicit criteria for inclusion in the Appendix. However an application may be made to exclude a substance from scheduling.

An entry in Appendix B may be made by the Secretary following consideration of the application for scheduling, if the substance does not meet the factors for inclusion in the Schedules of the Poisons Standard. In this instance the Secretary may decide that there is a public benefit by adding an entry to Appendix B to record the outcome.

The Secretary may make an entry in Appendix B for a new substance or for clarity and may consult with the appropriate Advisory Committee for a rescheduling application.

Appendix C

Schedule 10 supersedes Appendix C.

Appendix D – Additional controls on possession or supply of poisons included in Schedules 4 or 8

Inclusion of a substance in Appendix D may be considered by the Secretary for any human or veterinary medicine where the assessment of the proposal identifies:

- a specific health risk that may be mitigated by restricting availability through specialist medical practitioners; or
- significant potential for illicit diversion and/or abuse which does not warrant inclusion in Schedule 8 but warrants particular control of possession; or
- a specific high potential for abuse, particular international treaty restrictions on availability or other matters of national public health policy which when weighed against the need for access to the substance, warrants, in addition to inclusion of the substance in Schedule 4 or 8, further restrictions on access, such as authorisation by the Secretary of the Department of Health or some other appropriate State/Territory or Commonwealth authority.

Inclusion of a substance in Appendix D may be made following consultation with the appropriate advisory committee or a joint meeting, and must take into account the implications for professional practice by affected healthcare practitioners and regulatory control by the states and territories.

Appendix E – First aid instructions for poisons

Appendix F – Warning statements and general safety directions for poisons

The requirements under Appendices E and F do not apply to workplace chemicals, industrial, manufacturing, laboratory or dispensary use, these chemicals must meet the requirements under the Globally Harmonised System (GHS).

First aid and safety directions for human medicines are assessed as a component of the registration requirements and are included in the TGA publication *Required Advisory Statements for Medicines Labels*. The same directions for agricultural and veterinary chemicals are included in the APVMA publication *First Aid Instructions and Safety Directions Handbook*. Accordingly these two Appendices do not apply to agricultural and veterinary chemical products and only apply to therapeutic goods that are exempted from the requirements of the Act such as medicines that are compounded by a pharmacist on a prescription for an individual patient.

Appendices E and F include safety and first aid directions required to be included on the label to promote safe use of products available to the public. These directions supplement the directions for use of the product by identifying specific hazards of the product, precautions to be taken, any personal protective equipment to be worn during use of the product and appropriate first aid measures to be taken following any misadventure involving the product.

Entries are based on the assessment of the scheduling proposal and take into account current best-practice in occupational and emergency medicine.

The Secretary may make an entry in these Appendices as part of the scheduling decision for a new substance. An entry or amended entry may also be made in these appendices following a rescheduling application and consultation with the ACCS, ACMS or a Joint meeting.

New or amended entries in these appendices may also be made following a specific application in relation to these Appendices, after consultation with ACCS, ACMS or a Joint meeting.

Appendix G – Dilute preparations

An entry in Appendix G exempts the substance from all requirements of the Poisons Standard when included in a product at a concentration at or below that specified in the Appendix.

The Secretary may make an entry in the Appendix:

- following consultation with one or both Advisory Committees, depending on the scope of the entry; and
- where the assessment of the substance at the proposed maximum concentration does not meet the criteria for inclusion in any Schedule of the Poisons Standard; and
- where the assessment of the undiluted substance does not meet the factors for inclusion in Schedule 8, 9 or 10; and
- there are no other public health concerns in relation to the proposed entry.

Appendix H – Schedule 3 medicines permitted to be advertised

A new or amended entry to Appendix H may be made by the Secretary after taking into account matters set out in the **Guidelines for advertising of substances included in Schedule 3 of the Poisons Standard** (the Guideline).

In principle, schedule 3 substances will be included in Appendix H unless the Secretary determines there are reasons for not permitting the advertising of a particular substance. The Guideline sets out when substances cannot be advertised.

Appendix I – Uniform paint standard

Part 2 Section 7 supersedes Appendix I.

Appendix J – Schedule 7 poisons requiring additional controls on availability and use

A new or amended entry to Appendix J will only be considered if:

1. Significant, or potential to cause, severe and possible irreversible injury may occur without the individual being aware of exposure – whether that is a single or repeated exposure or a low or high dose exposure.
2. Specialised skills and/or equipment are required to mitigate the risks of using the poison.
3. The patterns of use of the poison pose an unacceptable risk resulting from direct or indirect exposure to the public.

The Secretary may make a new entry or vary an existing entry following consultation with the ACCS and will consider the need for any additional State and Territory controls over access, training or possession of the substance, to ensure its safe use.

Appendix K – Medicines required to be labelled with a sedation warning

The Secretary can make a new entry or vary an existing entry on his or her own initiative or following consultation with ACMS. In making a decision to vary an entry or make a new entry in Appendix K the Secretary must consider:

- the potential for sedation in humans exhibited by a medicine in normal use;
- animal or human data demonstrating any impairment of critical motor reflexes and cognitive skills applicable to driving or the operation of machinery;
- the need to warn users of any potential danger of the medication when the user is in control of machinery or an automobile; and
- regulatory implications for the states and territories.

Appendix L – Requirements for dispensing labels for human and veterinary medicines

The Secretary may make a new entry or vary an existing entry on his or her own initiative or following consultation with ACMS for dispensing of human medicines, ACCS for dispensing of veterinary medicines or both if relevant. An amendment to Appendix L may be considered following a proposal for a new or existing medicine where:

- specific labelling needs to be applied for safe use of a medicine when dispensed;
- professional practice standards require specific labelling of the medicine when dispensed.

Appendix M – Additional requirements for Schedule 3 medicines

The Secretary may, in consultation with ACMS, require additional controls or supply requirements for certain Schedule 3 substances to enable them to be provided by a pharmacist. This Appendix is intended to facilitate down scheduling from Schedule 4 to Schedule 3 where, for example, there is community need for access to a medicine but additional controls and oversight, including by the dispensing pharmacist are needed.

The substance and proposed intervention/additional requirement(s) will be listed in the Appendix.

All proposals for inclusion in Appendix M must be referred to ACMS and undergo public consultation.