

# 5 Assessment of GMO Medicines

## 5.1 Summary

At present, medicines that are or contain a GMO require assessment and approval under both the Medicines and HSNO Acts. The Royal Commission on Genetic Modification recommended that imported medicines and pharmaco foods (see below) that include live GMOs be approved for use by Medsafe<sup>5</sup> without additional approval from ERMA.

In response, the Government directed officials to report on options to reduce duplication and streamline the approval processes under the Medicines Act and the HSNO Act for medicines. It noted that the recommendation was consistent with the precedent set for finished-dose forms of medicines, which are exempt from the hazardous substances part of the HSNO Act. The Government's response also included consideration of GMO medicines *developed* in New Zealand as well as those *imported* into New Zealand.

Four options have been identified for reducing duplication and streamlining approval processes for all medicines that are or contain new organisms (including GMOs). The options are:

- **Option 1:** retain approval under both the Medicines and HSNO Acts, but clarify the respective roles of Medsafe and ERMA;
- **Option 2:** approval under the Medicines Act only;
- **Option 3:** approval under the Medicines Act, with a environmental risk assessment of the medicine provided by ERMA; or
- **Option 4:** approval under the HSNO Act, with safety, quality and efficacy assessment of the medicine provided by Medsafe.

A similar situation arises with veterinary medicines that are assessed under the ACVM Act and the HSNO Act. Whether or not similar options should be considered in that situation is also discussed.

## 5.2 Medicines that are or contain GMOs

Currently medicines that are or contain GMOs and are administered to humans by conventional mechanisms – such as pills, capsules and injections for a therapeutic purpose – are considered to be medicines and require assessment by Medsafe and approval by the Minister of Health under the Medicines Act before they can be legally distributed in New Zealand. There are currently no GMO medicines available in New Zealand. GMO medicines are available overseas, including the cholera vaccine Orachol Berna.

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<sup>5</sup> The New Zealand Medicines and Medical Devices Safety Authority. Medsafe is a business unit of the Ministry of Health and is responsible for the regulation of therapeutic products in New Zealand.

Medsafe uses international standards of safety, quality and efficacy to assess whether the risk–benefit profile of a medicine supports its use in humans. Medsafe’s assessment is conducted from the perspective of individual human health benefit and risk. Other than for products such as vaccines, public health risk or benefit is not routinely built into Medsafe’s evaluation.

In addition to Medsafe’s assessment, live GMOs in medicines must also be assessed and approved by ERMA for risks to people, communities and the environment as required by the HSNO Act.

Medsafe assesses applications after obtaining input from an expert group. No public participation is required. In contrast, ERMA has a mandatory obligation to call for public submissions on applications for release and, if requested, to conduct a public hearing.

It should also be noted that new medicines containing GMOs are likely to consist of vaccines and medicines for the treatment of severe medical conditions that have limited alternative treatment options. The compliance costs of a full environmental assessment may result in these products not being available in New Zealand. Similarly, neither the HSNO Act nor the Medicines Act can provide complete control over the release of medications containing GMOs into the New Zealand environment. Travellers, for example, may enter the country freely after exposure to these medicines when overseas.

## 5.2.1 Medicines containing organisms other than GMOs

This section gives consideration to exempting from the HSNO Act medicines that are or contain *any* live new organism, not just GMOs, because this wider category of medicines gives rise to the same issues as GMO medicines. However, the only new medicines likely to be affected in the immediate future are GMO medicines. This is because the non-GMO organism in a medicine probably will also not be a new organism, and so would not require a HSNO approval.

## 5.2.2 Finished-dose form medicines

Medsafe generally assesses a medicine when it is ready for clinical trial on humans or commercialisation (when it is ready for release). The issue of duplication therefore only arises with *finished-dose form medicines* that are or contain new organisms and that are ready for clinical trial or commercialisation. These are medicines approved under sections 20, 23 and 30 of the Medicines Act.

The development and testing in containment of medicines that are or contain new organisms should remain within the ambit of the HSNO Act. Accordingly, if medicines that are or contain new organisms were to be exempt from the HSNO Act or subject to a streamlined approval process, the only applications that would be relevant would be ones to *release* such medicines. This would include both applications to ‘import for release’ and to ‘release from containment’.

The Medicines Act provides for exemptions from Medsafe evaluation for medicines that are administered to a particular patient. These exemptions are not covered by this discussion because such medicines should remain within both the HSNO and Medicines Acts.

### 5.2.3 Development of a single trans-Tasman therapeutic agency

Options to reduce duplication and streamline approval processes for medicines that are or contain new organisms need to be co-ordinated with the policy work to develop a single trans-Tasman therapeutics agency. The Ministry of Health is leading this work for New Zealand.

### 5.2.4 Pharmaco foods

Pharmaco foods are excluded from this discussion. ‘Pharmaco food’ is a new term not in common currency. Without a clear and agreed definition it is not possible to include these products in any regulatory change. This does not mean that pharmaco foods would be unregulated if they become available. Live pharmaco foods involved in the treatment or prevention of disease would be considered a new organism and would be covered by the HSNO Act. Those considered a food would also be regulated by the Australia New Zealand Food Authority and the Australia New Zealand Food Standards Council, and those considered a medicine would be covered under the Medicines Act.

## 5.3 The options

Four options have been identified to reduce duplication and streamline approval processes under the Medicines Act and HSNO Act.

- **Option 1:** Retain approval under both the Medicines and HSNO Acts, but clarify the respective roles of Medsafe and ERMA.
- **Option 2:** Approval under the Medicines Act only – amend the HSNO Act to stipulate that new organism medicines that are the subject of an application for release into the environment are not included in the Act (an environmental risk assessment could be done by Medsafe as part of a Medicines Act approval).
- **Option 3:** Approval under the Medicines Act, with environmental risk assessment by ERMA – amend the HSNO Act as above so that new organism medicines are assessed and approved under the Medicines Act, but the assessment would include an environmental risk assessment provided by ERMA. ERMA could apply the same risk assessment to new organism medicines as it would to all new organisms, or it could apply a streamlined assessment that, for example, excluded public participation or allowed for submissions but no public hearing.
- **Option 4:** Approval under the HSNO Act, with safety, quality and efficacy assessment by Medsafe – amend the Medicines Act to exempt new organism medicines so that new organism medicines are assessed and approved under the HSNO Act, but the assessment would include a safety, quality and efficacy assessment of the medicine provided by Medsafe. Medsafe could apply the same safety, quality and efficacy assessment to new organism medicines as it does to all medicines.

All of the options would require amendments to both the Medicines Act and the HSNO Act.

### 5.3.1 Discussion of the options

The options outlined above aim to reduce duplication and streamline approval processes while ensuring that an appropriate environmental risk assessment framework is applied. They are assessed against the following questions:

- Does the option reduce duplication?
- Does the option streamline processes?
- Does the option ensure an appropriate environmental risk assessment is done?
- Does the option provide for appropriate public participation?

We note that there is a tension between the first two bullet points (which are aimed at reducing compliance costs) and the second two bullet points (which focus on robust risk assessment processes).

#### **Option 1: Retain approval under both the HSNO and Medicines Acts but clarify the roles of ERMA and Medsafe**

Option 1 requires clarifying the roles of Medsafe and ERMA. It could be made clear that Medsafe assesses the medicine for safety, quality and efficacy to the individual, while ERMA assesses the environmental effects. Clarification would also be required regarding public health assessments, as Medsafe's public health assessment is limited to the perspective of the individual with the disease and their immediate contacts, whereas the assessment conducted by ERMA is broader.

To further reduce duplication, amendments could be made to the HSNO Act and Medicines Act to establish a process whereby approval from Medsafe is required before an application is considered by ERMA. ERMA could then use Medsafe's assessment of safety, quality and efficacy to assess benefits to human health in its risk assessment.

Option 1 would reduce duplication and ensure that an appropriate environmental risk assessment was undertaken, including provision for public participation. However, two approvals would still be required. It is likely that compliance costs would be reduced only marginally, if at all.

#### **Option 2: Approval under the Medicines Act only**

Option 2 would require amending the HSNO Act so that ERMA does not assess and approve applications to release new organism medicines. The assessment and approval process would remain solely within the Medicines Act. This option would reduce duplication and streamline the application process. Unless stipulated, there would be no public comment on applications sent to Medsafe for assessment and approval by the Minister of Health. There would need to be assurances that an environmental risk assessment would be undertaken that is appropriate for New Zealand and consistent with international best practice and obligations. This option may also require amendment to the Medicines Act.

A recommendation to require all medicines containing a new organism to be assessed only by Medsafe means that these products may be subject to a limited environmental risk assessment. There are no internationally agreed guidelines for assessing the adverse ecological effects of a live organism medicine, so these would need to be developed nationally. It would be necessary to conduct further public consultation to determine whether the dataset developed for assessing the adverse ecological effects of live organism medicines is sufficient to satisfy the expectations of New Zealand consumers with respect to managing the general release of new organisms (particularly GMOs) contained in medicines.

In the absence of any international guidelines, a dataset could be developed based on the HSNO Act. Depending on the extent to which this dataset mirrored the HSNO Act, it may result in medicines that are or contain new organisms undergoing a similarly rigorous risk assessment as currently provided for in the HSNO Act (with or without public participation provisions). This could have implications for compliance costs. It would also require that Medsafe staff be suitably qualified, which could raise administrative inefficiencies; that is, two bodies (ERMA and Medsafe) would need to have environmental expertise.

### **Option 3: Approval under the Medicines Act, with environmental risk assessment by ERMA**

Under Option 3 the environmental risk assessment would be provided to Medsafe by ERMA. Attention would need to be given to:

- the breadth of the environmental risk assessment conducted by ERMA (for example, focusing on natural resource or ecological impacts only, or including public health aspects)
- the extent to which the public participation process laid down in the HSNO Act is followed (for example, ranging from full submissions and hearings on the environmental risk assessment to consultation with key stakeholders)
- how much weight should be given to ERMA's assessment (for example, whether or not ERMA might have the ability to decline approval based on the environmental risk assessment).

Option 3 would reduce duplication and, depending on the approach, ensure that a comprehensive or streamlined environmental risk assessment was undertaken, including a broad public health assessment. Although only one formal application would be lodged under the Medicines Act, depending on the extent of the HSNO assessment required, it may not meaningfully streamline the application process. An advantage of Option 3 (and Option 4) is that there would be consistency between the environmental risk assessments for approvals for the development, field testing and release of the new organism medicine.

### **Option 4: Approval under the HSNO Act; with safety, quality and efficacy assessment by Medsafe**

Option 4 is the reverse of Option 3, in that new organism medicine applications would be lodged with and approved by ERMA and not Medsafe. Medsafe would provide ERMA with an assessment of the medicine's safety, quality and efficacy. All non-new organism medicines would continue to be assessed by Medsafe and approved by the Minister of Health.

As with Option 3, Option 4 could be implemented in more than one way. For example, Medsafe could have the right to veto applications based on its assessment of safety, quality and efficacy of the medicine.

Option 4 would reduce duplication and ensure that a robust environmental risk assessment was undertaken, including a broad public health assessment. Although only one formal application would be lodged under the HSNO Act, depending on the extent of the HSNO assessment conducted, it may not meaningfully streamline the application process nor reduce compliance costs.

- 5a Do you think medicines that are or contain new organisms (including GMOs) should be subject to a streamlined approval process for release? Why?**
- 5b If yes, which of the options described above do you prefer? Are there any alternatives that you can think of that reduce compliance costs but also adequately consider environmental issues and public consultation?**
- 5c Do you think that conducting an environmental risk assessment that does not include some of the areas currently covered in the HSNO Act (e.g. economic or cultural considerations) would be an appropriate way of streamlining the approval process for these medicines? Why?**
- 5d Options 3 and 4 above propose to streamline the process by requiring only one formal application to the lead agency. Do you have a preference for which agency should lead the approval process: Medsafe or ERMA? Why?**
- 5e What level of public participation and consultation should there be in the approval process for new organism medicines?**

## 5.4 What about veterinary medicines?

The Royal Commission did not make any recommendation about animal remedies that are or contain new organisms. However, under current legislation such animal remedies are also subject to a dual assessment and approval process. The ACVM Group of MAF Food is provided with regulatory powers under the Agricultural Compounds and Veterinary Medicines (ACVM) Act and performs the same regulatory function for animal remedies as Medsafe does for human medicines, including their assessment for safety, quality and efficacy.

Therefore, the four options described above for human medicines that are or contain new organisms are also relevant to animal remedies that are or contain new organisms.

Veterinarians can and do use human medicines to treat animals. However, in practice the use of human medicines for that purpose is small, and given that most medicines that are or contain new organisms will be designed to target only human illnesses and conditions, it is likely that these future medications will have limited utility in animals. That said, consideration would have to be given to the relevance of human remedies used for the treatment of animals, particularly if those animals entered the human food chain.

- 5f Do you think veterinary medicines that are or contain new organisms (including GMOs) should also be subject to a streamlined approval process for release? Why? If not, why not?**
- 5g If yes, which of the options described above do you prefer? Are there any alternatives that you can think of that reduce compliance costs but also adequately consider environmental issues and public consultation?**
- 5h Do you think that conducting an environmental risk assessment that omits some of the areas currently covered in the HSNO Act (e.g. economic or cultural considerations) would be an appropriate way of streamlining the approval process for these veterinary medicines? Why?**
- 5i Options 3 and 4 above propose streamlining the process by requiring only one formal application to the lead agency. Do you have a preference for which agency should lead the approval process: ACVM Group or ERMA? Why?**
- 5j What level of public participation and consultation should there be in the approval process for such veterinary medicines?**
- 5k Do you believe that human new organism medicines that have veterinary applications should be restricted to use in humans only?**