

INFORMATION SHEET

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Special provisions for medicines and veterinary medicines

Introduction

One of the recommendations of the Royal Commission on Genetic Engineering was that the processing of applications for the release of low risk medicines which contain new organisms should be streamlined. Under the NOOM Bill amendments to the HSNO Act this was done. Low risk animal and human medicines can now be considered by rapid assessment, thereby reducing both the time and cost involved. Also the restrictions on the use and storage of medicines and veterinary medicines will be simplified, as the duplication of controls between HSNO and the medicines and ACVM Acts will be eliminated.

The Act allows for rapid assessment of qualifying organisms, and allows delegation of decision making to particular Chief Executives.

What is a qualifying organism?

A qualifying organism is a new organism that is:

- contained in a medicine or veterinary medicine or
- is a medicine or veterinary medicine

Qualifying organisms can be genetically modified organisms (GMO's) or non-GMO's that are new to New Zealand.

A qualifying organism may be approved for rapid assessment if meets low risk criteria. A low risk qualifying organism is one where, when the dose and route of administration is taken into account, it is highly improbable that there will be significant adverse effects on people or on valued species. It is appropriate to consider the methods by which the medicine is administered as this has a very large bearing on how risks might arise. Highly improbable has been defined by the Authority as "*Almost certainly not occurring but cannot be totally ruled out*". An example of an organism that is highly improbable to cause adverse effect is the intramuscular injection of a vaccine that is imported and distributed in sealed single dose ampoules.

A significant adverse effect has been defined by the Authority as "*Measurable long term damage to local plant and animal communities, ... medium term individual ecosystem damage*". An example of an organism that does not cause significant adverse effects is Orochol©, as it cannot cause disease, and would not pose

any risks additional to the ones already posed by cholera-toxin producing bacteria already present in the environment.

The Authority has determined that all approvals for these medicines and veterinary medicines will be reviewed if there is a change in the way they are administered.

Who makes the decisions?

Decisions by rapid assessment on qualifying organisms must be made ten days after the application is received. The decision can be made by the Chief Executive of ERMA, by the Chief Executive responsible for the Medicines Act or the Chief Executive responsible for the Agricultural Compounds and Veterinary Medicines Act.

At this stage the only delegation that has been made is to the Chief Executive of ERMA New Zealand.

What is in the decision?

An approval of a qualifying organism is a release approval. The Act allows for controls on the distribution, method of administration (eg injection or topical application), on the people allowed to administer the medicine, and controls on who may receive the medicine. There may also be controls on the storage and disposal of the qualifying organism, as the Act specifically does not limit the types of controls that may be used.

Further information or feedback

For further information on Qualifying Organisms, or to provide any feedback or comment on the new initiatives described above, just contact us at ERMA New Zealand, or visit the website at **www.ermanz.govt.nz**.

ERMA New Zealand publishes information sheets on a range of topics to provide background information on current issue or proposals being dealt with by the Authority. All publications may be viewed and downloaded from our website at www.ermanz.govt.nz or may be requested by contacting ERMA New Zealand, P O Box 131, Wellington. Ph +64 4 916 2426 Fax +64 4 914 0433 Email info@ermanz.govt.nz