Medicines and Poisons Act 2019

Factsheet – current as at September 2021

Emergency orders, emerging risk declarations, recall orders and public warnings

The Act allows the chief executive (or delegate) to make the following:

- an emergency order;
- an emerging risk declaration;
- a recall order; and
- a public warning.

What is an emergency order?

The Act allows the chief executive (or delegate) to make an *emergency order* to take immediate action to manage the risk of significant harm or illness, or in emergency situations where powers are needed to effectively manage that risk.

The chief executive may make an emergency order authorising a person to carry out a regulated activity with a regulated substance in relation to any of the following events:

- a biosecurity event for which a biosecurity emergency order applies under the *Biosecurity Act 2014*;
- a disaster situation under the *Disaster Management Act 2003*;
- a declared public health emergency under the *Public Health Act 2005*;
- an emergency under the *Public Safety Preservation Act 1986*;
- another event, at a State or local level, that poses a health risk, including an event that has the potential to cause human disease through exposure to infection, such as an outbreak of a communicable disease.

The Act prescribes what an emergency order must contain. An emergency order is in force for no longer than three (3) months and must be published on the department's website.

What is an emerging risk declaration?

The Act allows the chief executive (or delegate) to make an *emerging risk declaration* if there is a belief that an unscheduled substance or device used to apply or administer a substance poses a risk of injury or illness. For example, this may apply to a sports supplement containing substances that have new evidence of harm to human health.

The policy intent of the emerging risk declaration powers is to enable the chief executive to prevent substances that may pose a risk of injury or illness from entering the marketplace until their safety can be determined or an alternative means of regulating the unsafe substance is implemented.

The chief executive may make an emerging risk declaration in relation to a substance that is not a regulated substance if the chief executive believes:

- the substance is being made, sold or used in the State, including by using a device; and
- there is an urgent need to regulate, or further regulate, the substance under the Act because of a health risk.

An emerging risk declaration is a declaration made by the chief executive declaring one (1) or more of the following in relation to a substance that is not a regulated substance:

- the substance must not be made, sold or used in the State;
- the substance may be used only in a particular device or in a particular way;
- a particular device must not be used with the substance;
- the substance must be disposed of in a particular way.

Relevantly, the chief executive may not make an emerging risk declaration in relation to a medical device under the Therapeutic Goods Act 1989 (Cth).

The emerging risk declaration may state conditions that apply to carrying out an activity with the substance, including conditions about using devices, if the chief executive is satisfied the conditions are reasonably necessary to prevent or minimise a health risk.

The Act prescribes:

- what an emerging risk declaration must contain;
- how long it remains in force; and
- that an emerging risk declaration may be renewed.

An emerging risk declaration is in force for no longer than three (3) months and must be published on the department's website.

Failure to comply with an emerging risk declaration can attract a significant penalty.

What is a recall order?

A recall order may be made if the chief executive (or delegate) considers a product containing a regulated substance poses a health risk.

The chief executive may make a recall order that:

- is directed to a stated person (the *responsible person*) who the chief executive believes is responsible for the manufacture, possession or supply of the product; and
- requires the responsible person to recall the product from manufacture, possession or supply.

A recall order may be made by the chief executive if there is a risk of harm to persons or animals because of labelling, packaging, efficacy or other safety issues. For example, this

may apply to hair dyes causing extreme skin and scalp irritation due to incorrect formulation with a scheduled substance.

Before making a recall order, the chief executive must give the responsible person for the proposed recall order a notice which specifies several prescribed matters.

Recall orders may be applied to substances or devices that are subject to an emerging risk declaration. To minimise overlap of powers, a recall order is not made if the substance is regulated under the powers of another Act or Commonwealth law, for example the Therapeutic Goods Act 1989 (Cth), and those powers have been exercised, for example, by the Therapeutic Goods Administration.

If the chief executive makes an emerging risk declaration or a recall order, manufacturers, wholesalers and retailers must comply with the requirements of the order. This may include, for example:

- stopping the manufacture or supply;
- recalling substances from end users;
- destroying substances;
- re-labelling or re-packaging products,

and other measures to protect the public from harm. There may also be a requirement to publish warnings about the product.

Failure to comply with a recall order can attract a significant penalty.

What is a public warning?

The Minister, chief executive or chief health officer may make a public statement (a public warning) identifying, and giving warnings or information about, any of the following matters:

- contraventions of the Act that have resulted in notification action being taken and the persons who committed the contraventions;
- practices regulated under a relevant law that are unlawful;
- offences committed against a relevant law and the persons who committed the offences.

Associated guidance documents

- Nil

Further information

For further information, contact the Healthcare Approvals and Regulation Unit:

- Email: HARU@health.qld.gov.au