Australian Government
Department of Health and Aged Care
Office of the Gene Technology Regulator

What do we mean by Intentional Release?

The Gene Technology Regulator issues licences that allow people to work with genetically modified organisms (GMOs). Most licences issued are for scientific research in laboratories, greenhouses, insectaries and other specialised facilities which have been designed to contain the GMOs. Some work like planting and growing GM crops, clinical trials of a new medicine or vaccine, or commercial sale of a GM medicine cannot be done in a laboratory. Instead, they take place in a range of settings, like growing in a field, being administered in a clinic or hospital, or manufactured in a factory and sold in a chemist or pharmacy. Because these two different types of work involve different contexts, the gene technology laws have two different types of licences to cover them.

Licences for research or other work in special facilities are called a 'dealing not involving release into the environment' (DNIR). The work is contained within a building or other structure rather than outside, or in a hospital, or sold in a store.

Licences for all other work with GMOs are called a 'dealing involving intentional release into the environment' (DIR). The GMOs are *not* contained within a facility. This category includes:

- GM crops grown in a field, either commercially or experimentally
- GM medicines and vaccines tested in a clinical trial
- GM medicines and vaccines for sale in a pharmacy or chemist.

'Dealings' is the legal name for the list of approved activities with a GMO, such as:

- making
- growing
- research
- transport and
- disposal.

The term 'intentional release into the environment' was chosen with GM plants in mind. The term separates research on plants in greenhouses from plants being grown in a field. When the laws were originally written most of the licences were for crops. Now that we are seeing GM therapeutics being developed and commercialised, this term also applies to them even though it doesn't adequately describe the activities.

An **intentional release into the environment of a GM vaccine means** that a patient or trial participant is given a vaccine in a hospital or clinic rather than in a research laboratory. It may also mean they can purchase a GM vaccine at a pharmacy or chemist and bring it to their GP for administration. All of the usual rules for clinical trials apply to a trial of a GM vaccine authorised by a DIR. This includes the requirement for fully informed consent, oversight by a human research ethics committee and individual approval by an appropriate doctor or physician. All of these requirements must be met before anyone can be exposed to a GM vaccine.

Further information:

- Genetically modified organisms in Australia
- How are Genetically modified organisms (GMOs) regulated in Australia