Australian Government
Department of Health
Office of the Gene Technology Regulator

Licence for dealings involving an intentional release of a GMO into the environment

Licence No.: DIR 182

Licence holder: Janssen-Cilag Pty Ltd

Commercial supply of a genetically modified COVID-19 vaccine

Issued: 19 April 2021

Gene Technology Regulation in Australia

Australia's gene technology regulatory system operates as part of an integrated legislative framework. The *Gene Technology Act 2000* (Cth) and corresponding state and territory legislation form a substantial part of a nationally consistent regulatory system controlling the development and use of genetically modified organisms.

This licence is issued by the Gene Technology Regulator in accordance with the *Gene Technology Act 2000* and, as applicable, Corresponding State law.

The Gene Technology Regulator is required to consult with, and take into account advice from, a range of key stakeholders, including other regulatory authorities, on risks to human health and safety and to the environment in assessing applications for dealings involving the intentional release of genetically modified organisms into the Australian environment.

Other agencies that also regulate genetically modified organisms or GM products include Food Standards Australia New Zealand, Australian Pesticides and Veterinary Medicines Authority, Therapeutic Goods Administration, Australian Industrial Chemicals Introduction Scheme and the Department of Agriculture, Water and the Environment. Dealings conducted under any licence issued by the Regulator may also be subject to regulation by one or more of these agencies. It is recommended that the licence holder consult the relevant agency (or agencies) about their regulatory requirements.

The licence authorises the licence holder and persons covered by the licence to conduct specified dealings with the genetically modified organism(s) listed in Attachment A of this licence.

Further information on licence DIR 182

More information about the decision to issue this licence is contained in the Risk Assessment and Risk Management Plan prepared in connection with the assessment of the application for the licence. This document can be obtained from the Office of the Gene Technology Regulator (OGTR) website or by telephoning the Office on 1800 181 030.

Section 1 Interpretations and Definitions

1. In this licence:

   (a) unless defined otherwise, words and phrases used have the same meaning as they do in the Act and the Gene Technology Regulations 2001 (the Regulations);

   (b) words denoting a gender include any other gender;

   (c) words in the singular include the plural and words in the plural include the singular;

   (d) words denoting persons include a partnership and a body whether corporate or otherwise;

   (e) references to any statute or other legislation (whether primary or subordinate) are a reference to a statute or other legislation of the Commonwealth of Australia as amended or replaced from time to time and equivalent provisions, if any, in corresponding State law, unless the contrary intention appears;

   (f) where any word or phrase is given a defined meaning, any other part of speech or other grammatical form in respect of that word has a corresponding meaning;

   (g) specific conditions prevail over standard conditions to the extent of any inconsistency.

2. In this licence:

'**Act**' means the *Gene Technology Act 2000* (Cth) or the corresponding State legislation under which this licence is issued.

'**Annual Report**' means a written report provided to the Regulator by the end of September each year containing all the information required by this licence to be provided in the Annual Report.

'ARTG' means the Australian Register of Therapeutic Goods maintained in accordance with the *Therapeutic Goods Act 1989*.

'**GM**' means genetically modified.

'**GMO**' means the genetically modified organism that is the subject of the dealings authorised by this licence.

'NLRD' is a Notifiable low risk dealing. Dealings conducted as an NLRD must be assessed by an institutional biosafety committee (IBC) before commencement and must comply with the requirements of the Gene Technology Regulations 2001.

'**OGTR**' means the Office of the Gene Technology Regulator.

'**Regulator**' means the Gene Technology Regulator.

Section 2 Licence conditions and obligations

3. This licence remains in force until it is suspended, cancelled or surrendered. No dealings with the GMO are authorised during any period of suspension.

4. The licence holder is Janssen-Cilag Pty Ltd.

5. Any person, including the licence holder, may conduct any authorised dealing(s) with the GMO.

6. The dealings authorised by this licence are:

   (a) import of the GMOs;

   (b) transport of the GMOs;

   (c) disposal of the GMOs;

   and the possession (including storage) and supply of the GMOs for the purposes of, or in the course, of any of these dealings.

Note: Use of the GMO for therapeutic purposes is not covered by the Gene Technology Act 2000 *and therefore this licence is not required to authorise such use. The GMOs are also subject to regulation by other federal and state departments and agencies, including the Therapeutic Goods Administration and the Department of Agriculture, Water and the Environment. These other departments and agencies may impose further requirements for, or limitations on, the use of the GMO or these dealings.*

7. This licence does not apply to dealings with the GMOs conducted as a Notifiable Low Risk Dealing (NLRD) or pursuant to another authorisation issued under the Act.

Note: Dealings conducted as an NLRD must be assessed by an Institutional Biosafety Committee (IBC) before commencement and must comply with the requirements of the Regulations.

8. Dealings with the GMO authorised by this licence may be conducted in all areas of Australia.

9. The licence authorises dealings with the GMO described in **Attachment A**.

2.1 Obligations of the Licence Holder

10. The licence holder must immediately notify the Regulator if any of its contact details change.

Note: Please address correspondence to OGTR.M&C@health.gov.au

Prior to issuing a licence, the Regulator considers suitability of the applicant to hold a licence. The following conditions address ongoing suitability of the licence holder.

11. The licence holder must, at all times, remain an accredited organisation in accordance with the Act and must comply with its instrument of accreditation.

12. The licence holder must:

    (a) inform the Regulator immediately in writing, of:

        i. any relevant conviction of the licence holder; and

        ii. any revocation or suspension of a licence or permit held by the licence holder under a law of the Australian Government, a State or a foreign country, being a law relating to the health and safety of people or the environment; and

        iii. any event or circumstances that would affect the capacity of the holder of this licence to meet the conditions in it; and

    (b) provide any information related to the licence holder's ongoing suitability to hold a licence, if requested, within the stipulated timeframe.

13. The licence holder must inform any person covered by this licence, to whom a particular condition of the licence applies, of the following:

    (a) the particular condition (including any variations of it); and

    (b) the cancellation or suspension of the licence; and

    (c) the surrender of the licence.

2.2 Provision of new information to the Regulator

Licence conditions are based on the risk assessment and risk management plan developed in relation to the application using information available at the time of assessment. The following condition requires that any new information that may affect the risk assessment is communicated to the Regulator.

14. The licence holder must inform the Regulator if the licence holder becomes aware of:

(a) additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence; or

(b) any contraventions of the licence by a person covered by the licence; or

(c) any unintended effects of the dealings authorised by the licence.

Note: The Act requires, for the purposes of the above condition, that:

(a) the licence holder will be taken to have become aware of additional information of a kind mentioned in paragraph 14 if he or she was reckless as to whether such information existed; and

(b) the licence holder will be taken to have become aware of contraventions, or unintended effects, of a kind mentioned in paragraph 14, if he or she was reckless as to whether such contraventions had occurred, or such unintended effects existed.

Note: Contraventions of the licence may occur through the action or inaction of a person.

15. If the licence holder is required to inform the Regulator under condition 14, the Regulator must be informed without delay.

Note: An example of informing without delay is contact made at the time of the incident via the OGTR free call phone number 1800 181 030, which provides emergency numbers for incidents that occur out of business hours.

16. If at any time the Regulator requests the licence holder to collect and provide information about any matter to do with the progress of the dealings authorised by this licence, including but not confined to:

(a) additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence, whether or not the licence holder has provided information to the Regulator under condition 14(a);

(b) any contraventions of the licence by a person covered by the licence, whether or not the licence holder has provided information to the Regulator under condition 14(b);

(c) any unintended effects of the dealings authorised by the licence, whether or not the licence holder has provided information to the Regulator under condition 14(c);

(d) research, including by way of survey, to verify predictions of the risk assessment, or for any purpose related to risks to the health and safety of people, or to the environment;

(e) scientific literature and reports in respect of the GMO authorised by this licence, for a nominated period;

(f) details of any refusals of applications for licences or permits (however described) to deal with the GMO made pursuant to the regulatory laws of a foreign country;

and the request is reasonable, having regard to consistency with the Act and relevance to its purpose, then the licence holder must collect the information and provide it to the Regulator at a time and in the manner requested by the Regulator.

Note: The Regulator may invite the licence holder to make a submission on the reasonability of a request by the Regulator to collect and provide information relevant to the progress of the dealings with the GMO.

2.3 Obligations of persons covered by the licence

17. If a person is authorised by this licence to deal with the GMOs and a particular condition of this licence applies to the dealing by that person, the person must allow the Regulator, or a person

authorised by the Regulator, to enter premises where the dealing is being undertaken, for the purposes of auditing or monitoring the dealing.

Section 3 Reporting and Documentation Requirements

3.1 Notification of Authorisation by the Therapeutic Goods Administration

18. If the GMOs are included on the ARTG, the licence holder must notify the Regulator in writing within 14 days of registration.

19. The licence holder must notify the Regulator in writing of any subsequent amendments to the conditions of the ARTG registration involving the pattern of usage, handling, storage, transport or disposal of the GMOs, within 14 days of the change occurring.

3.2 Annual Report

20. The licence holder must provide an Annual Report to the Regulator by the end of September each year covering the previous 1 July to 30 June financial year. An Annual Report must include:

    (a) information about any adverse impacts, unintended effects, or new information relating to risks, to human health and safety or the environment caused by the GMOs or material from the GMOs;

    (b) information about the numbers of GM vaccine doses imported and distributed to each State and Territory.

3.3 Testing methodology

21. At least 14 days prior to conducting any dealings with the GMO, the licence holder must provide to the Regulator a written methodology to reliably detect the GMO, or the presence of the genetic modifications described in **Attachment A** in a recipient organism or environmental sample. The detection method(s) must be capable of identifying, to the satisfaction of the Regulator, the GMO described in **Attachment A**.

Note: Please address correspondence to OGTR.M&C@health.gov.au

ATTACHMENT A

DIR No: 182

Full Title: Commercial supply of a genetically modified COVID-19 vaccine

Organisation Details

Postal address: Janssen-Cilag Pty Ltd
1-5 Khartoum Rd
Macquarie Park NSW 2113

Phone No: 1800 226 334

Accreditation No: Accr 237

GMO Description

GMOs covered by this licence

The GM vaccine contains a human adenovirus (HAdV) vaccine vector which is derived from human adenovirus serotype 26 (HAdV-D26). The HAdV-D26 vaccine vector was produced by deleting E1 and and a large portion of the E3 region from the HAdV-D26 genome and by replacing the E4 region open reading frame *orf6* gene with the equivalent gene from human adenovirus 5 (HAdV-C5) into the same locus. This results in a replication defective HAdV-D26 vaccine vector. In addition, a construct containing a human cytomegalovirus (CMV) promoter with tetracycline operator sites (TetO), a synthetic transgene containing a modified sequence based on SARS-CoV-2, and a Simian virus 40 (SV40) polyadenylation signal was then inserted into the E1 locus of the HAdV-D26 vaccine vector to boost induction of an immune response.

Parent Organism

Common Name: Adenovirus

Scientific Name: *Human adenovirus 26*

Modified traits

Category: Vaccine – altered antigen expression
Vaccine – replication incompetent

Description: The GMO consists of a recombinant, replication defective virus which produces a modified SARS-CoV-2 spike protein. The altered genes and associated regulatory elements are listed in Table 1.

Table 1: Genetic and regulatory elements responsible for conferring the modified traits:

Source, identity, nature of modification	Modified trait
Deletion of E1 gene	Renders virus unable to multiply (replication incompetent)
Deletion of a large portion of the E3 region	Increases immune response to virus and virus production during manufacture
Partial substitution of E4 gene with equivalent gene from HAdV-5	Improves virus yield during manufacture
Insertion in the E1 locus:	

Source, identity, nature of modification	Modified trait
• Gene based on SARS-CoV-2 spike protein	Expresses modified spike protein into the host cells
• CMV promoter	Provides high level of expression in cells
• TetO sites	Represses antigen expression when propagated in cell lines that stably express the tetracycline repressor protein
• Polyadenylation signal	Terminates protein expression

Purpose of the dealings with the GMO

The purpose of the dealings is commercial supply of the GM COVID-19 vaccine for use as human vaccine Australia-wide to provide protection against COVID-19. The permitted dealings under this licence are import, transport, storage and disposal of the GM vaccines.