Therapeutic Goods (Poisons Standard) (COVID-19 Vaccine—Moderna) (Elasomeran) Labelling Exemption 2022

I, John Skerritt, as the appropriate authority, grant the following labelling exemption.

Dated 3 August 2022

Adjunct Professor John Skerritt
Deputy Secretary
Health Products Regulation Group
Department of Health and Aged Care

Contents

1 Name

This instrument is the *Therapeutic Goods (Poisons Standard) (COVID-19 Vaccine—Moderna) (Elasomeran) Labelling Exemption 2022*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	The day after this instrument is made.	4 August 2022

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This labelling exemption is granted under section 1.5.5 of Part 2 of the current Poisons Standard.

4 Definitions

Note 1: A number of expressions used in this labelling exemption are defined in subsection 3(1) of the Act, including the following:

(a) current Poisons Standard;

(b) Register;

(c) registered goods.

Note 2: A number of expressions used in this labelling exemption are defined in section 1 of Part 1 of the current Poisons Standard, including the following:

(a) appropriate authority.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

specified products means registered goods that are vaccines, and that:

(a) contain elasomeran as the only active ingredient; and

(b) have an indication accepted in relation to their inclusion in the Register that relates to the prevention of coronavirus disease 2019 (COVID-19); and

(c) are manufactured, imported or supplied by Moderna Australia Pty Ltd.

5 Exemption

The specified products are exempt from the labelling requirements in:

(a) section 1.3(1)(a) of Part 2 of the current Poisons Standard; and

(b) section 1.3(1)(c) of Part 2 of the current Poisons Standard; and

(c) section 1.3(1)(k) of Part 2 of the current Poisons Standard; and

(d) section 1.4(1)(a) of Part 2 of the current Poisons Standard.

Note 1: Under section 1.1(1) of Part 2 of the current Poisons Standard, a scheduled substance or preparation must not be supplied unless labelled in accordance with section 1 of Part 2 of the current Poisons Standard.

Note 2: Section 5 of this instrument exempts the specified products from the following labelling requirements in section 1 of Part 2 of the current Poisons Standard:

(a) labelling of the primary pack and immediate container with signal words, as required by section 1.3(1)(a);

(b) labelling of the primary pack and immediate container with the cautionary statement 'KEEP OUT OF REACH OF CHILDREN', as required by section 1.3(1)(c);

(c) labelling of the primary pack and immediate container with the approved name and a statement of the quantity, proportion or strength, as required by sections 1.3(1)(k) and 1.4(1)(a).

6 Repeals

Each instrument that is specified in Schedule 1 is repealed as set out in the applicable items in that Schedule.

Schedule 1—Repeals

Note: See section 6.

Therapeutic Goods (Poisons Standard) (COVID-19 Vaccine—Moderna) Labelling Exemption 2021

1 The whole of the instrument

Repeal the instrument.