Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Notice of decision to amend the current Poisons Standard in relation to animal blood products

13 September 2024

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Contents

Notice of final decision made under Regulation 42ZCZU of the *Therapeutic Goods Regulations 1990*

This document constitutes a notice for the purposes of regulation 42ZCZX of the *Therapeutic Goods Regulations 1990* (the **Regulations**). This notice sets out:

- An amended final decision made by a delegate of the Secretary of the Department of the Health and Aged Care (the **Delegate)** under Regulation 42ZCZU in relation to proposed amendments to the current Poisons Standard which were not referred to an expert advisory committee[1]
- reasons for the decision, and
- the date of effect of the decision.

The amended final decision follows an application to defer the implementation date for the amendment specified in the May 2024 Final Decision with regards to animal blood products to 1 February 2025. In accordance with r 42ZCZX of the Regulations, this notice provides a publication of the Delegate's decision, and the reasons for the decision.

Defined terms

In this notice, the following terms are used in addition to those above:

- the Therapeutic Goods Act 1989 (Cth) (the **Act**)
- the Therapeutic Goods Regulations 1990 (the **Regulations**)
- the Scheduling Policy Framework 2018 (the **SPF**)
- the Scheduling handbook, Guidance for amending the Poisons Standard (the **Handbook**)
- the Therapeutic Goods Administration (the **TGA**)

Note: additional terms are also defined for individual decisions.

[1] Established under sections 52B and 52C of the *Therapeutic Goods Act 1989* (Cth).

Final decision on proposed amendments to the current Poisons Standard

Final decision in relation to animal blood products

Pursuant to r 42ZCZU of the Regulations, the Delegate has made a final decision to amend the current Poisons Standard in relation to animal blood products as follows:[2]

Schedule 4 – New Entry

ANIMAL BLOOD PRODUCTS for veterinary use including:

a) whole blood;

b) blood components including red cells, white cells, platelets, and plasma (including cryoprecipitate); and

c) the following plasma-derived therapeutic proteins; and their equivalent recombinant alternatives:

(i) albumin;

(ii) anticoagulation complex;

(iii) C1 esterase inhibitors;

(iv) clotting factors;

(v) fibrinogen;

(vi) protein C;

(vii) prothrombin complex concentrate (PCC);

(viii) thrombin;

(ix) haemoglobin.

Index – New Entry

ANIMAL BLOOD PRODUCTS

Schedule 4

Implementation date

1 February 2025

[2] Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

Materials considered

In making this decision, the Delegate considered the following material:

- the Delegate's final decision dated 22 May 2024 (the **May 2024 Final Decision**) to amend the current Poisons Standard with regards to animal blood products
- the request to amend the current Poisons Standard with respect to animal blood products as specified in the May 2024 Final Decision but to defer the implementation date
- subsection 52E(1) of *the Therapeutic Goods Act 1989* (Cth) (the **Act**), in particular (a) the risks and benefits of the use of a substance; (b) the purposes for which a substance is to be used and the extent of use of a substance; (c) the toxicity of a substance; (d) the dosage, formulation, labelling, packaging and presentation of a substance; and (f) any other matters considered necessary to protect public health.
- the Scheduling Policy Framework 2018 (the **SPF**), and
- the Scheduling handbook: Guidance for amending the Poisons Standard (the **Handbook**).

Proposal

Currently animal blood products are not captured in the Poisons Standard. In July 2023, the Delegate received a proposal to create a new entry in Schedule 4 of the Poisons Standard for animal blood products for veterinary use.

On 22 May 2024, after due consideration pursuant to the Act and the Regulations, the Delegate made a final decision (the May 2024 Final Decision) to amend the Poisons Standard with regards to animal blood products. The May 2024 Final Decision was to:

- create a new Schedule 4 entry for animal blood products for veterinary use
- this includes capturing whole blood, blood components and plasma-derived therapeutic proteins; and their equivalent recombinant alternatives:

The Delegate decided that the amendments will come into effect on 1 October 2024.

On 14 August 2024, the Delegate received an application to defer the implementation date for the amendments specified in the May 2024 Final Decision with regards to animal blood products to 1 February 2025.

Reasons for the decision (including findings on material questions of fact)

Pursuant to regulation 42ZCZW of the Regulations, I have made a final decision to confirm my decision to amend the Poisons Standard with regards to animal blood products as specified in the May 2024 Final Decision but with a later implementation date of 1 February 2025.

My May 2024 Final Decision agreed with the advice of the Advisory Committee on Chemicals Scheduling (ACCS 37, November 2023). Further, I did not receive reasons for any opposition to the proposal or my interim decision to create a new entry in Schedule 4 for animal blood products (including the implementation date) during the two rounds of public consultation.

In August 2024, an industry stakeholder voiced concerns regarding the implementation date of 1 October 2024 for a new entry in Schedule 4 for animal blood products, after which it sought a deferral of the implementation date. The key issue raised by the stakeholder is products have already been prepared to meet the seasonal demand of blood products supplied throughout the standardised equine foaling season of the southern hemisphere, which starts on 1 August and concludes

31 December each year. The animal blood products are designed to support the immune system of neonatal foals.

The highest volumes for supply, purchase and use of animal blood products are between August and December, and the original implementation date of 1 October 2024 falls in the middle of the peak use period.

The stakeholder provided information that the distribution of animal blood products throughout this foaling season is expected to experience substantial interruptions if the implementation date of the May 2024 Final Decision is not deferred due to the logistical requirements around repacking and relabelling.

In addition, deferring the implementation date to 1 February 2025 would be during a time of low product demand, substantially simplifying the implementation of the new scheduling requirements.

There was no objection to the May 2024 Final Decision to create a new entry in Schedule 4 for animal blood products and only sought to defer the implementation date of that decision. Therefore, I have decided not to refer the matter to an expert advisory committee.

While it is irregular to alter any final decision to amend the Poisons Standard after it has been published, I recognise the consequences to industry of the May 2024 Final Decision and its original implementation date of 1 October 2024 should it be allowed to stand. While there are no changes from the May 2024 Final Decision with regards to the amendments to the entry for animal blood products, the implementation date of 1 October 2024 will be superseded and deferred to **1 February 2025.**

I also encourage all stakeholders affected by scheduling decisions to engage with the public consultations conducted as part of the scheduling of medicines and chemicals. While every effort is made by the decision maker to independently acquire information that inform scheduling decisions, feedback from stakeholders, peak bodies and the wider community is crucial to the decision-making process.

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au