Queensland Government
Department of Health

Approval no: C-FILE-21962-029

Approved alternative way (to complying with the Poisons Standard, Part 2) of labelling a package containing a medicine (labelling exemption)

Medicines and Poisons (Medicines) Regulation 2021 - section 237

I, Gregory Perry, Director, Medicines Approvals and Regulation Unit and delegate of the Chief Executive, Queensland Health, do hereby approve the following alternative way of labelling a package containing a medicine.

The Alternative Way

In Queensland, the products in Table 1 which are labelled as an unscheduled product and include the signal heading “For Animal Use Only” and include wording that they are “to be used by, or under the supervision, of a registered veterinary surgeon” can be supplied by Plasvacc Pty Ltd as a Schedule 4 medicine.

Table 1: Products to which label exemption applies:

APVMA Product / Permit Number	Schedule	Details: Descriptor, Form, Strength, Pack size/Use
APVMA Product Number 56329	S4	**Caniplas Fresh Frozen Canine Plasma** Form: Liquid, frozen Active Constituent: 10 g/L Canine Gamma Globulins Pack Size: 100 mL, 200 mL Indications: May aid in the treatment of various conditions in dogs in which the administration of fresh frozen plasma would be considered desirable, e.g. Severe pancreatitis, Parvovirus enteritis, coagulopathies, hypoproteinaemia, major tissue trauma or surgery, and disseminated intravascular coagulation (DIC).
APVMA Permit Number PER14792	S4	**Caniplas E Canine Immunoglobulin to Endotoxin** Form: Liquid, frozen Active Constituent: Minimum 5 µg/mL Canine Immunoglobulin to *Escherichia coli* J5 Lipopolysaccharide Pack Size: 100 mL Indications: For the improvement of survival rates in dogs with canine parvoviral gastroenteritis when used as an adjunct to traditional therapy. An aid in the treatment of dogs with endotoxaemia. Conditions that may result in endotoxaemia include enteritis, sepsis, pneumonia, trauma, burns and pyometra.

APVMA Product Number 81359	S4	**CaniPRBC Canine Packed Red Blood Cells** Form: Liquid, refrigerated Active Constituent: Canine erythrocytes (RBC) 40-60 mL/100 mL Pack Size: 350 mL Indications: As an aid in the treatment of acute anaemia in dogs.
APVMA Product Number 60275	S4	**UniPRBC Canine Packed Red Blood Cells** Form: Liquid, refrigerated Active Constituent: Canine erythrocytes (RBC) ≥ 50 mL/100 mL Pack Size: 250 mL Indications: May assist in the treatment of clinically significant anaemia with symptomatic deficit of oxygen carrying capacity, and replacement of traumatic or surgical blood loss in dogs.
APVMA Product Number 55771	S4	**Equiplas Equine Gamma Globulins** Form: Liquid, frozen Active Constituent: 22 g/L Equine Gamma Globulins Pack Size: 1 litre Indications: Failure of Passive Transfer, when there is Hypogammaglobulinaemia and other conditions where it is desirable to increase the gamma globulin level in the blood of foals.
APVMA Permit Number PER14506	S4	**Equiplas R Equine Gamma Globulins** Form: Liquid, frozen Active Constituent: Equine gamma globulins containing specific antibodies to Virulence Associated Protein A of *Rhodococcus equi* at a concentration at least equivalent to a standard reference plasma when measured by ELISA as having a relative potency of 1.0. Pack Size: 1 litre Indications: For use as an aid in preventing *Rhodococcus equi* infection and in increasing the gamma globulin level of foals.
APVMA Permit Number PER12891	S4	**Equiplas E Equine Immunoglobulin to Endotoxin** Form: Liquid, frozen Active Constituent: Minimum 5 µg/mL Equine Immunoglobulin to *Escherichia coli* J5 Lipopolysaccharide Pack Size: 1 litre Indications: For the improvement of survival rates in foals with failure of passive transfer (i.e. inadequate colostrum suckled or absorbed) and as an aid in the treatment of horses with endotoxaemia. Conditions that may result in endotoxaemia include: colitis, sepsis, gastrointestinal lesions, pleuropneumonia, retained placenta, pyometra and peritonitis.

APVMA Permit Number PER13801	S4	**Camelplas Camelid Gamma Globulins** Form: Liquid, frozen Active Constituent: 15 g/L Camelid Gamma Globulins Pack Size: 300 mL Indications: Failure of Passive Transfer, when there is Hypogammaglobulinaemia and other conditions where it is desirable to increase the gamma globulin level in the blood of camelid neonates.

Conditions of approval

1. The medicines in Table 1 must only be supplied by wholesale to a licensed medicine wholesaler or to a registered veterinary surgeon for administration by a veterinary surgeon or under the supervision of a veterinary surgeon.

2. Supply must be in compliance with all other obligations relating to supply in the *Medicines and Poisons (Medicines) Regulation 2021*.

3. This approval is effective from 01 February 2025.

4. This approval expires on 01 February 2026 or until existing stock of the products in Table 1 without labelling that complies with the Poisons Standard are exhausted, whichever is the earlier.

Approved at Brisbane this 11 day of November 2024 by Greg Perry
Delegate of the Chief Executive
Healthcare Approvals and Regulation Unit
Queensland Health
Certification number: C-FILE-21962-029