Operations Biochemistry – Forms	
Procedure	Forms - Label Checklist
Written	s22
Authorised	s22
Date issued	7/3/2013
Revision #	5

Label Evaluation

Compliance with Therapeutic Goods Order number 69 – General requirements for labels for medicines

Product name	CSL Rh(D) IMMUNOGLOBULIN VF (human) 250 IU injection vial		
AUSTR	76643	LIMS #	1608003191

Analyst

Result	Pass ☐ Fail ☒
Analyst comments	The letter height for "Prescription only medicine" does not comply with the Standard for the Uniform Scheduling of Medicines and Poisons: Part 2.7.1(a) or 3(1)(b)(ii) The letter height for "Australian Red Cross" does not comply with 3(1)(b)(ii) This applies to both the container and primary packaging
Name	s22
Date	30 November 2016

Test manager

Result	Pass ☐ Fail ☒ If fail, is there S14 exemption? Yes ○ No ◉
Test manager comments	As above.
Name	s22
Date	

About the product

Is it a recombinant product? ☐ Yes ☑ No

Is it a biological prescription medicine? ☑ Yes ☐ No

Is it in a small container (capacity ≤ 20 mL)? ☑ Yes ☐ No

Is the product scheduled in the *Standard for the Uniform Scheduling of Medicines and Poisons*? ☑ Yes – Schedule 4
☐ No – Not scheduled

SUSMP - Standard for the Uniform Scheduling of Medicines and Poisons

Schedule 4 'Prescription only medicine'

- Many biotechnology products are Schedule 4 – check the list (link to SUSMP on TGA intranet)
- Immunoglobulins for human parenteral use are Schedule 4 **except** when separately specified in these Schedules

Not scheduled – Appendix A (General exemptions)

- Human blood products including - whole blood, blood components including red cells, white cells, platelets and plasma (including cryoprecipitate, the following plasma-derived therapeutic proteins **and their equivalent recombinant alternatives**: albumin; anticoagulation complex; C1 esterase inhibitors; clotting factors; fibrinogen; protein C

Is it an Injectable ☑ Yes ☐ No If yes then

Is it for single or multi-use dose	☑ single use dose	☐ multi-use dose
Is it a small or large volume injection?	☑ small volume(≤ 100mL)	☐ large volume (>100 mL)
Is the volume of the container greater than 1mL?	☑ yes	☐ no

Container: means an article that immediately covers the goods, and includes an ampoule, blister pack, bottle, sachet, dial dispenser pack, strip pack, syringe, tube, vessel, vial, wrapper or other similar article

Primary pack: means the complete pack in which the goods, or the goods and their container, are to be supplied to consumers

Main label: Where there are two or more labels, the label where the product name is most conspicuous. Where the product name is equally conspicuous on two or more labels, each of these is a main label

Small container: the goods are enclosed in a container which has a capacity of 20 mL or less

Small volume injection: means an injection having a volume of less than or equal to 100 mL

Large volume injection: means an injection having a volume of greater than 100 mL

Medicament for injection: means a substance in a container to which a sterile diluent is added to prepare an injection

Relevant sections of TGO69

Use this section to identify which sections of the form to use by ticking the appropriate boxes.

- ☑ **3(1) General labels**
- ☑ **3(2) Particulars to be included on a label**
- ☑ **3(3) Particulars to be included on a MAIN label**
- 3(4) Preparations for ophthalmic use
- ☑ 3(5) Injections other than large volume injections (**small vol. injections**, ≤ 100 mL)
- 3(6) Large volume injections (> 100 mL)
- 3(7) Dialysis concentrates
- 3(8) Peritoneal dialysis solutions
- 3(9) Preparations for use on skin or mucous membranes
- ☑ **3(10) Biological products (biological prescription medicines)**
- ☑ 3(11) Small containers (capacity of ≤ 20 mL)
- 3(12) Individually wrapped goods
- 3(13) Strip, blister and dial dispenser packs
- ☑ 3(14) Directions for use
- 3(15) Homeopathic preparations
- 3(16) Formulations containing both homeopathic and non-homeopathic ingredients
- 3(17) Plastic ampoules
- 3(18) Composite packs *eg, a vial containing a powder for reconstitution and an ampoule containing a diluent*
- ☑ **4 - Expression of quantity or proportion of active ingredient in medicines**
- ☑ **5 - Expression of potency in biological products**
- ☑ 6 - Expression of activity of radionuclides in radiopharmaceutical preparations
- ☑ **7 – Permitted statements of storage conditions**

3 – Label requirements

The name of all active ingredients and excipients must use terminology consistent with the ***Australian Approved Names List*** *(AAN)* **[*use the ingredients list in eBS*]**

Containers and the **primary packs** must each bear labels which comply with the following requirements:

3(1) General

Containers and primary packs MUST each bear labels which are clearly visible and must be written;

Primary pack (eg box)	Container (eg vial)	Section 3(1) is compulsory	
Pass	Pass	(a)	in the English language
Pass	Pass	(b)	in durable and legible characters and;
Pass	**n/a**	(b) (i)	the ARTG number is at least 1 mm in height or greater *[refer to 3(2)(n)]*
Fail	Fail	(b) (ii)	all other letter heights are at least 1.5 mm or greater
S4	S4	(c)	in a metric unit of measurement.
n/a (IU)	n/a (IU)	(c) (i)	For active ingredients whose quantity is expressed in metric units; ☐ 1 microgram to 999 micrograms must be expressed in terms of micrograms ☐ 1000 micrograms must be expressed as 1000 micrograms or 1 milligram ☐ 1 milligram up to 999 milligrams must be expressed in terms of milligrams ☐ 1000 milligrams must be expressed as 1000 milligrams or 1 gram ☐ 1 gram up to 999 grams must be expressed as grams **But** - where the medicine is one of a series of strengths containing the same active ingredient in the same dosage form, the label may state the quantity of active ingredient in terms of the highest or lowest metric unit, eg 0.5 mg, 1.0 mg and 5.0 mg rather than 500 µg, 1.0mg, 5.0 mg.

3(2) Particulars to be included on a label

Subject to qualifications in subclauses listed below, the labels MUST include;

3(6) – large volume injections

3(11) – small containers

3(12) – individually wrapped goods

3(13) – strip, blister and dial dispenser packs

3(14) – directions for use

3(17) – plastic ampoules

Primary pack (eg box)	**Container (eg vial)**	Section 3(2) is compulsory ***Note:*** *for products in a small container (≤ 20mL capacity)* **use** the column for **primary pack** in section **3(2)** *(strike out column for container)* and use the column for **container** in section **3(11)**	
Pass	n/a	(a)	The product name
Pass	n/a	(b)	The name(s) of all the active ingredients in the goods
Pass	n/a	(c)	The quantity or proportion of all active ingredients in the goods in accordance with **clause 4 - Expression of quantity or proportion of active ingredient in medicines** [page 15 of this document]
n/a (S4)	n/a	(d)	***Note – not applicable to products in Schedule 4 of the SUSMP*** Where the medicine contains any ingredient referred to in column 1 of the First Schedule as an excipient (page 37-40 in TGO 69) **and**: (i) a *condition*, if any, stated in column 2 of the First Schedule applies in relation to such an ingredient; **and** (ii) the medicine is intended to be administered via any one or more of the *routes referred to in column 4* of the First Schedule; **and** (iii) the medicine is *not included in Schedule 4 or Schedule 8* of the Poisons Standard Then – a statement **mus**t be included on the primary pack indicating the goods contain these ingredients. See page 16 of TGO69 for more details.
Pass	n/a	(e)	The name of the dosage form e.g. Injection, powder for
n/a	n/a	(f)	The quantity of the goods (except for medicines for injection)
Pass	n/a	(g)	Warning statements, where these apply to the medicines *[see page 18 of this document for additional information on warning statements]*
Pass	n/a	(h)	The batch number of the goods preceded by the batch number prefix
Pass	n/a	(i)	The expiry date of the goods preceded by the expiry date prefix

Pass	n/a	(j)	The storage conditions applicable to the goods in accordance with *clause 7 – Permitted statements of storage conditions*
Pass	n/a	(k)	Directions for use of the goods – [if there is not sufficient space, **refer to 3(14)**]
Pass	n/a	(l)	The name and address of the sponsor or supplier of the goods
n/a (S4)	n/a	(m)	A statement of the purpose or purposes for which it is intended that the goods be used, **except**; (i) where the goods are specified in Schedule 4 or Schedule 8 of the Poisons Standard (ii) where the goods are a dispensing pack supplied solely to a complementary healthcare practitioner and include on the label the words 'For Practitioner Dispensing Only'
Pass	n/a	(n)	Where the goods are included in the Australian Register of Therapeutic Goods, the registration or listing number is to be: (i) on the label; **or** (ii) on a securely affixed label adjacent to the main label; **or** (iii) if the container is enclosed in a primary pack, on the primary pack label

3(3) Particulars to be included on a main label

Subject to qualifications in subclauses listed below, the **MAIN LABEL** must include;

3(6) – large volume injections

3(11) – small containers

3(12) – individually wrapped goods

3(13) – strip, blister and dial dispenser packs

3(17) – plastic ampoules

Primary pack (eg box)	**Container (eg vial)**	Section 3(3) is compulsory	
Pass	Pass	3(2)(a)	The product name
Pass	Pass	3(2)(b)	The name of all active ingredients in the goods
Pass	Pass	3(2)(c)	The quantity or proportion of all active ingredients in the goods in accordance with clause 4 - Expression of quantity or proportion of active ingredient in medicines
Pass	Pass	3(2)(e)	The name of the dosage form
n/a (Inj)	n/a (Inj)	3(2)(f)	The quantity of the goods (except for medicines for injection)

Pass	**n/a**	3(2)(n)	Where the goods are included in the ARTG, the number to be; (i) on the label; **or** (ii) on a securely affixed label adjacent to the main label; **or** (iii) if the container is enclosed in a primary pack, on the primary pack label

3(4) Preparations for ophthalmic use

Where the goods are a preparation for ophthalmic use, the label on the container and on the primary pack, or where subclause 3(11) - *Small containers*, applies, on the primary pack only , must include, in addition to the requirements of subclauses 3(2) and 3(3):

Primary pack (eg box)	**Container (eg vial)**	Is this for ophthalmic use? ☐ yes ☒ no	
		3(4)(a)	The name of any antimicrobial preservative in the goods
		3(4)(b)	Where the goods, other than an ophthalmic ointment, do not contain an antimicrobial preservative, the words 'contains no antimicrobial preservative. Use once only and discard residue' or a statement to that effect

3(5) Injections other than large volume injections

(that is – small volume injections – 100 mL and smaller)

In addition to requirements in 3(2) *(general label issues)*, and 3(3) *(main label issues)* where the goods are **an injection** or a **medicament for injection** other than a large volume injection:

Primary pack (eg box)	**Container (eg vial)**	Is this a small volume injection (≤ 100 mL)? ☑ yes ☐ no	
Pass	Pass	(a) (a)(i)	The main label on the container and on the primary pack of the goods must include: (i) the approved route(s) of administration, such as 'intravenous', 'intramuscular', or 'subcutaneous' or other phrase, word or abbreviation denoting the approved route(s) of administration; **and** *Note –'infusion' is not listed in routes of administration table but appears in code tables in eBS*
n/a	n/a	(a)(ii)	where the goods are a medicament for injection, the words 'for injection' **must** appear in or adjacent to the product name;
n/a	n/a	(a)(iii)	Where the goods are an injection which consists of a solution or a suspension in an oil, the label must include the word 'oily' in or adjacent to the product name

Pass	n/a *n/a if small container*	(b) (b)(i)	The label(s) on the container and primary pack [or, where subclause 3(11) – *Small containers* (capacity less than 20 mL) applies, on the primary pack only] of the goods must include: The name (from AAN list) and quantity of each excipient in the goods, expressed : For single dose injections – as the quantity of that excipient in the stated volume of injection in the container For a medicament for injection – as the quantity of that excipient in the container Where the injection is intended for multidose use – as the quantity of that excipient in one mL of the injection or as the quantity in a suitable dose volume where the stated volume is less than 1 mL
Pass	n/a *n/a if small container*	(b) (b)(ii)	The label(s) on the container and primary pack [or, where subclause 3(11) – *Small containers* (capacity less than 20 mL) applies, on the primary pack only] of the goods must include: Where the goods are supplied in a container with **potential** for multidose use, such as a **vial** or **pre-filled syringe**, and an antimicrobial preservative is not included in the goods, the words '*Use in one patient on one occasion only. Contains no antimicrobial preservative*' or a statement to that effect.
n/a n/a	n/a n/a *n/a if small container*	(c) (c)(i) (c)(ii)	The label on the container and on the primary pack of goods which consist of a concentrated solution for injection, [or, where subclause 3(11) – *Small containers* (capacity less than 20 mL) applies, the label on the primary pack only] must include: A direction not to administer the solution undiluted; **and** A direction to dilute the solution with the specified diluent by the appropriate factor or to the appropriate volume before use
n/a	n/a	(d)	The label on the container and on the primary pack of goods which are an injection containing a radio-contrast agent, must include a statement of the equivalent amount of iodine in terms of mg of iodine per mL

3(6) Large volume injections

Return to pevious View

Large volume injections are required to comply with subclause 3(2) *(general label issues)*, and 3(3) *(main label issues)* subject to the following qualifications:

Primary pack (eg box)	Container (eg vial)	Is this a large volume injection (> 100 mL)? ☐ yes ☒ no	
		(a)	In cases where there is no proprietary name of the goods, the product name must include the name of the active ingredient(s) and the name of the dosage form, or where there are more than three active ingredients belonging to the same class of substances, such as amino acids, carbohydrates or electrolytes, the name of the class of substances (see supplementary note 8 , page 47 TGO69) and the name of the dosage form

		(b)	In cases where the goods are intended for electrolyte replacement or nutritional therapy or are intended for use as a radio-contrast agent or as a plasma volume expander or replacement, the product name must include a statement of the proportions of dissolved, emulsified or suspended active ingredient in the goods in terms of percentages;
		(c)	In cases where the goods contain an active ingredient which is not intended for electrolyte replacement or nutritional therapy and is not intended for use as a radio-contrast agent or as a plasma volume expander or replacement, the product name must include a statement of the proportion of that active ingredient expressed in terms of weight (or potency if appropriate) in the stated volume of injection in the container;
		(d)	**And** in addition to these requirements, the label on the container and on the primary pack of goods which are large volume injections must include: The names and quantities of all excipients in the stated volume of injection in the container
		(e)	Where one or more active ingredients are amino acids and/or protein, a statement in grams of the total amount of nitrogen in the stated volume of injection in the container
		(f)	Where the goods are intended for use as an energy source, a statement in kilojoules of the energy equivalent of the stated volume of injection in the container
		(g)	Where the goods are intended for use as a radio-contrast agent, a statement of the equivalent amount of iodine in terms of milligrams of iodine per mL
		(h)	The osmolality
		(i)	A statement specifying whether the injection is 'hypotonic' or 'hypertonic' or 'isotonic'
		(j)	The pH range of the injection
		(k)	The words 'single use' or 'single dose'

3(7) Dialysis concentrates

Yes ☐ No ☒

Refer to page 20 and 21 of TGO69 for further guidance on dialysis concentrates

3(8) Peritoneal dialysis solutions

Yes ☐ No ☒

Refer to page 21 of TGO69 for further guidance on peritoneal dialysis solutions

3(9) Preparations for use on skin or mucous membranes Yes ☐ No ☒

In addition to the requirements referred to in subclauses 3(2) *(general label issues)*, and 3(3) *(main label issues)*,

		3(9)	The label of goods which are preparations for use on skin and mucous membranes, but not intended for ophthalmic use, must include the name of any antimicrobial preservative in the goods

3(10) Biological products

In addition to the requirements referred to in subclauses 3(2) *(general label issues)*, 3(3) *(main label issues)*, and 3(5) *(injections other than large volumes)*, the label of goods which are biological products must include:

Primary pack (eg box)	Container (eg vial)	Is this a biological prescription medicine? ☑ yes ☐ no	
n/a	n/a	(a)	The name and proportion of any antimicrobial preservative in the goods
n/a	n/a	(b)	The name of any adjuvant in the goods
n/a n/a	n/a n/a	(c)	For viral vaccines produced in animal cells or cell cultures (i) the name of the cell culture substrate or the name of the source animal, as specified in the Australian Approved Names List*(AAN) and the name of the tissue used in the manufacture of the goods; **and** (ii) the name of any residual antibiotic present in the goods;
n/a	n/a	(d)	For antisera, the name of the animal in which the goods have been prepared, as specified in the Australian Approved Names List (AAN)
n/a	n/a	(e)	For monoclonal antibodies, the name of the origin of the hybridoma cell line, as specified Australian Approved Names List (AAN), used in the preparation of the goods
n/a	n/a	(f)	For **recombinant products**, the name of the biological source as defined by the biotechnology product descriptors(see page 16) as specified in the Australian Approved Names List (AAN) **– must be placed immediately after the active ingredient name**
Pass	Pass	(g)	For other biological products, the name of the animal or organism, as specified in the Australian Approved Names List (AAN), from which the goods have been prepared
n/a n/a	n/a n/a	(h)	For live vaccines: (i) a statement of the recommended route(s) of administration such as 'intravenous', 'intramuscular', 'subcutaneous', 'oral' or other phrase, word or abbreviation denoting the recommended route(s) of administration (ii) where the contents of the container are intended to be used on one occasion only, the words 'single use' or 'single dose'
Pass	Pass		**** Australian Approved Names List (AAN) – use the ingredients list in eBS***

3(11) Small containers

Return to previous view

- Where the goods are enclosed in a container which has a capacity of **20 mL and less than 20 mL**; **and**
- The container is enclosed in a primary pack; **and**
- There are included in a label on the **PRIMARY PACK** the particulars referred to in 3(2) *(general label issues)*, 3(3) *(main label issues)* and where applicable, subclause 3(4) *(ophthalmic use)* and 3(5) *(small volume injections)*

Then, in relation to the label on the **CONTAINER**, it shall be sufficient compliance to have only;

Primary pack (eg box)	Container (eg vial)	Is this in a small container (≤ 20 mL capacity)? ☑ yes ☐ no	
n/a	Pass	3(2)(a)	The product name
n/a	Pass	3(2)(b)	The name(s) of all the active ingredients in the goods
n/a	Pass	3(2)(c)	The quantity or proportion of all active ingredients in the goods in accordance with clause 4 - Expression of quantity or proportion of active ingredient in medicines
n/a	Pass	3(2)(e)	The name of the dosage form
n/a	n/a (Inj)	3(2)(f)	The quantity of the goods (except for medicines for injection)
n/a	Pass	3(2)(h)	The batch number of the goods preceded by the batch number prefix
n/a	n/a	3(2)(i)	For **viral vaccines only** - expiry date of the goods preceded by the batch number prefix

Note: Where it is not practicable to set out these particulars in full on a label on the container, the particulars in 3(2)(a), 3(2)(b) and 3(2)(c) may be abbreviated provided it is unambiguous

3(12) Individually wrapped goods

Return to previous view

Primary pack (eg box)	Container (eg vial)		Are these individually wrapped goods? ☐ yes ☒ no
n/a		(a)	Where: (i) the goods consist of individual dosage units such as tablets, capsules, pastilles, cachets, lozenges, pessaries, suppositories or single doses of powder; **and** (ii) each such dosage unit is individually wrapped in an unsealed protective cover; **and** (iii) each such dosage unit is, after being so wrapped, enclosed in a primary pack; **and** (iv) the primary pack is labelled with the particulars according to 3(2) *(general label issues)*, 3(3) *(main label issues)* **Then** it is sufficient compliance for the *wrapper* to contain **only**; 3(2)(a) - The product name 3(2)(b) - The name(s) of all the active ingredients in the goods 3(2)(c) - The quantity or proportion of all active ingredients in the goods in accordance with clause 4 - Expression of quantity or proportion of active ingredient in medicines
n/a		(b)	Where : (i) the goods consist of individual dosage units such as tablets, capsules, pastilles, cachets, lozenges, pessaries, single doses of powder or single doses of a liquid or a patch; **and** (ii) each such single dose or patch is sealed into an individual sachet or individual blister; **and** (iii) one or more than one sealed enclosed unit is enclosed in a primary pack; **and** (iv) the outside of the primary pack is labelled with the particulars according to 3(2) *(general label issues)*, 3(3) *(main label issues)* **Then** in relation to the label on each individual sachet or blister, it shall be sufficient compliance for the *individual sachet or blister* to contain **only;** 3(2)(a) - The product name 3(2)(b) - The name(s) of all the active ingredients in the goods 3(2)(c) - The quantity or proportion of all active ingredients in the goods in accordance with clause 4 - Expression of quantity or proportion of active ingredient in medicines 3(2)(h) - The batch number of the goods preceded by the batch number prefix 3(2)(i) – The expiry date of the goods preceded by the expiry date prefix **and** the name or registered trademark of the sponsor or supplier of the goods
		(c)	Where the goods consist of dry loose herbs, refer to page 23 of TGO69 for further guidance

3(13) Strip, blister and dial dispenser packs

Return to previous view

Primary pack (eg box)	Container (eg vial)		Is this container a strip, blister or dial dispenser pack? ☐ yes ☒ no
n/a		(a)	Where: (i) the goods consist of individual dosage units such as tablets, capsules, pastilles, cachets, lozenges, pessaries, suppositories or single doses of powder; **and** (ii) two or more of the dosage units are individually enclosed in a strip blister or dial dispenser pack such that the dosage units can only be extracted individually; **and** (iii) the container is enclosed in a primary pack; **and** (iv) the primary pack is labelled with the particulars according to 3(2) *(general label issues)*, 3(3) *(main label issues)* **Then** in relation to the label on the container, it shall be sufficient compliance for *that strip blister/dial dispenser pack* to have only: 3(2)(a) - The product name 3(2)(b) - The name(s) of all the active ingredients in the goods 3(2)(c) - The quantity or proportion of all active ingredients in the goods in accordance with clause 4 - Expression of quantity or proportion of active ingredient in medicines 3(2)(h) - The batch number of the goods preceded by the batch number prefix 3(2)(i) – The expiry date of the goods preceded by the expiry date prefix **and** the name or registered trademark of the sponsor or supplier of the goods
n/a		(b)	Where in the case of a container described in 3(13)(a)(ii) – two or more dosage units individually enclosed in a strip blister/dial dispenser pack, where an individual segment containing the dosage unit can be readily detached, the particulars referred to in subclauses3(2)(a) - *The product name*, 3(2)(b) - *The name(s) of all the active ingredients in the goods,* 3(2)(c) - *The quantity or proportion of all active ingredients* must appear once in relation to every two dosage units enclosed in the container.

3(14) Directions for use

Return to previous view ☑ Yes ☐ No ☐ n/a

Where there is insufficient space on the label of the container or on the primary pack to include directions for use, it shall be sufficient compliance with subclause 3(2)(k) if there is included on a label on that container or primary pack, a statement that those directions for use are set out on a leaflet inserted in the primary pack provided that such a leaflet is in fact inserted.

3(15) Homeopathic preparations

See page 19 of TGO 69 for further guidance ☐ Yes ☐ No ☐ n/a

3(16) Formulations containing both homeopathic and non-homeopathic ingredients

See page 25 of TGO69 for further guidance ☐ Yes ☐ No ☒ n/a

3(17) Plastic ampoules

Return to previous view

Primary pack (eg box)	Container (eg vial)		Is the container a plastic ampoule? ☐ yes ☒ no
n/a		(a)	Where the medicine is presented in a **plastic ampoule**, the label on the container may be formed by way of **embossing**
n/a		(b)	Where the nominal volume of the medicine in the **plastic ampoule** is between **5 mL and 20 mL** inclusive, the label on the container must be in accordance with subclause 3(11) – *small containers*, and must include a statement of the approved route(s) of administration such as 'intravenous', 'intramuscular', 'subcutaneous', 'inhalation' or other phrase, word or abbreviation denoting the approved route(s) of administration and a warning statement where the incorrect route of administration may be hazardous
n/a		(c)	Where the nominal volume of the medicine in the plastic ampoule is greater than 20 mL, the label on the container must meet the requirements of subclauses 3(2) *(general label issues)*, 3(3) *(main label issues)* and any other subclause relevant to the route of administration, including a warning statement where the incorrect route of administration may be hazardous
n/a		(d)	Where the nominal volume of the medicine in the plastic ampoule is **less than 5 mL** and two or more ampoules are attached to a connecting strip in such a way **that the seal is broken** when an ampoule is detached, it will be sufficient for compliance with subclause 3(2) *(general label issues)*, 3(3) *(main label issues)* if there is: *On the label of each ampoule*; Product name, strength expressed as the amount of active in the nominal volume, approved route of administration *On the label on the connecting strip;* name of the active ingredient, batch number and name or registered trade mark of the sponsor and a warning statement where the incorrect route of administration may be hazardous
n/a		(e)	Where the nominal volume of the medicine in plastic ampoule is **less than 5 mL** and two or more ampoules are attached to a connecting strip in such a way that individual ampoules can be detached **without breaking the seal**, it will sufficient for compliance with subclause 3(2) *(general label issues)*, 3(3) *(main label issues)* if there is: *On the label of each ampoule*; Product name, strength expressed as the amount of active in the nominal volume, the batch number and approved route of administration *On the label on the connecting strip;* name of the active ingredient, and the name or registered trade mark of the sponsor and a warning statement where the incorrect route of administration may be hazardous

3(18) Composite packs

Primary pack (eg box)	Container (eg vial)	Is this a composite pack? ☐ yes ☒ no	
	n/a		Where a primary pack contains more than one kind of item, **such as a vial containing a powder for reconstitution and an ampoule containing a diluent**, which have different expiry dates, the expiry date included in the label on the *primary pack* shall be the expiry date indicating the shorter shelf life

4 – Expression of quantity or proportion of active ingredient in medicines

How should the quantity of active ingredient be expressed?

The quantity or proportion of an active ingredient to be included on a label as required by subclause **3(2)(c)** must;

☐ 4(1)	for a discrete dosage unit	as the quantity of the active ingredient in the dosage unit
☐ 4(7)(a)	where the preparation is a **medicament for injection**	as the nominal quantity of the active ingredient in the container
☐ 4(7)(b)i	(i) where the injection is intended for **multidose use** and the volume in the container is **1 mL or greater**	as the quantity of the active ingredient in 1 mL of the injection
☐ 4(7)(b)ii	(ii) where the injection is intended for **multidose use** and the volume in the container is **less than 1 mL**	as the quantity of the active ingredient in a suitable dose volume of the injection
☑ 4(7)(c)	where the injection is a **small volume** (100 mL and less) injection and is usually intended for administration as a **single dose**	As the quantity of active ingredient in the stated volume of the injection in the container *In justified cases the strength may also be incorporated in the product name as a percentage (w/v) or (v/v) or another concentration term, but not including the quantity of active ingredient per mL*
☐ 4(7)(e)	Where the preparation is a large volume (>100 ml) injection containing an active ingredient which is not intended for electrolyte replacement or nutritional therapy or as a plasma expander	As the weight of the active ingredient in the stated volume of injection in the container

5 – Expression of potency in biological products

5 - Potency in biological products

Primary pack (eg box)	Container (eg vial)		Is this a biological prescription medicine? ☑ yes ☐ no
n/a	n/a	5(1)(a)	The potency of liquid biological products or biological products which are required to be prepared before use must be included on labels and must be expressed as potency units or weight of active ingredient per dose or per unit volume which contains the recommended dose
Pass	Pass	5(1 (b)	The potency unit to be used must be the International Unit (IU) established by the World Health Organisation
n/a	n/a	5(2)	The potency of probiotic biological products must be included on labels and must be expressed as the number of each probiotic organism per dose unit

What are the biotechnology descriptors?

bhk	Produced from genetically engineered **b**aby **h**amster **ki**dney cells
rbe	Produced from **b**acteria (**E**. *coli)* genetically modified by **r**ecombinant DNA technology
rch	Produced from genetically engineered **C**hinese **h**amster ovary cells
rmc	Produced from genetically engineered and transformed **m**ouse **c**ells
rys	Produced by fermentation using **y**east, ***S****accharomyces cerevisiae* containing a **r**ecombinant plasmid
ghu	Gene activated human
hmr	Hybridoma Mouse Rat - produced from mouse-rat hybrid hybridoma cells
rbc	Recombinant Bacteria Corynebacterium diphtheriae. Produced from the bacteria (C. diphtheriae)
rhu	Produced by recombinant DNA technology in human cells
ryp	Recombinant Yeast Pichia
rpc	Recombinant plant carrot

7 – Permitted statements of storage conditions

How should the storage condition be stated?

Permitted statements of storage conditions

For the purposes of subclause 3(2): the following statements of storage conditions are permitted

☑ 7(1)(a)		
	(i)	☐ 'Store below –18°C (Deep freeze)'
	(ii)	☐ 'Store below –5°C (Freeze)'
	(iii)	☐ 'Store below 8°C (Refrigerate)'
	(iv)	☑ 'Store at 2°C to 8°C (Refrigerate. Do not freeze)'
	(v)	☐ 'Store below 25°C'
	(vi)	☐ 'Store below 30°C'
☐ 7(1)(b)		If none of the statements of storage conditions included in the above subclauses are applicable, the sponsor MUST apply to the secretary for permission to use an alternative statement; **and**
☐ 7(1)(c)		A statement of storage conditions specifying a maximum temperature in excess of 30°C may be permitted on application to the Secretary, subject to the review of data to establish the stability of the goods at the higher temperature.

Warning statements

According to the Standard for the Uniform Scheduling of Medicines and Poisons

Part 2.7.1 The **primary pack** and **immediate container** of a **Schedule 4 medicine for human use** must be labelled as follows:

(a) with the signal words relating to the Schedule in which the poison is included and the purpose for which it is to be used,

'**PRESCRIPTION ONLY MEDICINE**' for human use, written:

(i) on the first line or lines of the main label; and

(ii) in bold-face sanserif capital letters of uniform thickness; and

(iii) in letters at least half the height of the largest letter or numeral on the label but need not be large than 6mm on labels for packages having a nominal capacity of 2 litres or less

(iv) with nothing else written on that line *(except in case there is a Class label as specified in the Australian Code for the Transport of Dangerous Goods by Road and Rail)*

(c) with the cautionary statement – '**KEEP OUT OF REACH OF CHILDREN'** written:

(i) on a separate line or lines immediately below the signal words 'PRESCRIPTION ONLY MEDICINE'

(ii) in bold-face sanserif capital letters of uniform thickness; and

(iii) in letters at least four tenths the height of the letters used for the signal words; and

(iv) with no other statement written on that line *(except in case there is a Class label as specified in the Australian Code for the Transport of Dangerous Goods by Road and Rail)*