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16th November 2022

PLEASE CIRCULATE AS REQUIRED

Dear Colleagues

Transition of New Zealand's Plasma Products – Starting Mid-2023

Our plasma product manufacturer, CSL Behring, has been investing in new facilities at their Broadmeadows site in Victoria. The new facilities will provide expanded capacity for processing the growing annual domestic plasma collections in both New Zealand and Australia.

Under this transition the manufacturing process for five of New Zealand's domestic plasma products will change. The products will continue to be manufactured in Australia from New Zealand plasma but will be manufactured using CSL Behring's global manufacturing processes. As per the current products, the transitioned products will comply with the Therapeutic Goods Administration's safety and efficacy requirements and will go through Medsafe's New Medicines Approval process.

Why the change?

Just like now, these five products will continue to be made in Australia from New Zealand plasma. They will be manufactured to the same robust quality and safety standards and be just as effective. But moving to CSL Behring's global manufacturing processes means there will be other benefits too. These include:

- Our products being manufactured in CSL's new 'state of the art' facilities.
- Being able to take advantage of any new plasma products or processes that result from CSL's global investment in research and development.
- Receiving products that, due to the manufacturing process, are identical to the commercial alternative. In the event of a supply or other issue, the commercial back-up will be available to ensure product consistency for patients.
- The manufacture of additional plasma products for New Zealand if required.
- The opportunity to share in the efficiencies that come from being part of the standardised, global process.

What to expect and when

The transitioned products, and their anticipated availability to Blood Banks and NZBS sites, appear below. Their trade names reflect their manufacturing process, while the 'NZ' denotes that the product is manufactured from plasma collected in New Zealand by New Zealand Blood Service (NZBS).

Current product	Transitioned product			Expected supply date[1]
	Trade name	Presentations	Shelf life and storage conditions	
INTRAGAM P (6% intravenous immunoglobulin)	**PRIVIGEN NZ** (10% intravenous immunoglobulin manufactured using the PRIVIGEN process)	200mL, 20g 100mL, 10g 50mL, 5g	36 months Store below 25°C. Do not freeze. Protect from light.	Q3 2023
EVOGAM (16% subcutaneous immunoglobulin)	**HIZENTRA NZ** (20% subcutaneous immunoglobulin manufactured using the HIZENTRA process)	20mL, 4g 10ml, 2g	30 months Store below 25°C. Do not freeze. Protect from light.	Q3 2023 (4g) Q3 2024 (2g)
ALBUMEX 20 (20% albumin)	**ALBUREX 20 NZ** (20% albumin manufactured using the ALBUREX process)	100mL, 20g	36 months Store below 25°C Do not freeze. Protect from light.	Q4 2023
ALBUMEX 4 (4% albumin)	**ALBUREX 5 NZ** (5% albumin manufactured using the ALBUREX process)	500mL, 25g	36 months Store below 25°C. Do not freeze. Protect from light.	Q3 2024
PROTHROMBINEX-VF *(prothrombin complex concentrate containing clotting factors II, IX and X)*	**BERIPLEX NZ** *(prothrombin complex containing clotting factors II, VII, IX and X manufactured using the BERIPLEX process)*	500IU FIX	36 months Store below 25°C. Do not freeze. Protect from light.	Q4 2024

The following changes will also be made because of the transition:

Product	Status	Expected change date
Biostate	1000IU – retained **500IU - retired**	500IU – retired in Q4 2024
Commercial ATIII (Human Antithrombin III Concentrate)	New product	Available from Q3 2023
Thrombotrol-VF	Retired	Q4 2023
Commercial IVIg (10% intravenous immunoglobulin) Gamunex 10g – Grifols Australia Pty Ltd	New product – single presentation (Indicated for those patients who do not tolerate Privigen or Privigen NZ)	Available from Q3 2023

[1] Q1 – January – March, Q2 April – June, Q3 July – September, Q4 – October - December

NZBS will be both convening and working with existing clinical advisory groups to ensure that the appropriate commercial IVIg and commercial ATIII products are selected for implementation. This consultation will occur in the latter part of 2022 and into 2023.

In addition to the above changes to our plasma product portfolio, NZBS will continue to supplement its immunoglobulin portfolio with commercial CSL Behring product.

Current product	Status	Presentations available
Privigen (commercial 10% intravenous immunoglobulin product from renumerated donors)	Retained	200mL, 20g 100mL, 10g 50mL, 5g
Hizentra (commercial 16% subcutaneous immunoglobulin product from renumerated donors)	Retained	20ml, 4g

Ensuring a safe transition

Planning is now well progressed to ensure the safe and seamless implementation of the outlined plasma product portfolio changes. This work will continue in consultation with CSL Behring.

This letter is designed to provide early notification of the product transitions. NZBS, through our Transfusion Nurse Specialist team, will work collaboratively to ensure that the necessary hospital protocols and system changes are implemented in time for each of the product transition. CSL Behring is currently developing product support materials that will become available from 2023. These will provide detailed information about the transitioned products to support this process.

A reminder about adverse event reporting

We would like to take this opportunity to remind you of the importance of reporting all fractionated product adverse events to your local Blood Bank or Transfusion Nurse Specialist. To make a valid comparison of adverse event rates between old and new products, we strongly encourage you to actively report all adverse events occurring with current product before the changeover happens. This includes those that occur during home treatment. A reporting form can be obtained from your Blood Bank.

Please direct any queries to plasmaproductschange@nzblood.co.nz

Thank you for your support in ensuring a safe and effective move to these transitioned products.

Yours faithfully

DR SARAH MORLEY
Chief Medical Officer