The supply of plasma-derived medicinal products in the future of Europe

Second edition

23-24 April 2024 Rome, Italy

CENTRO NAZIONALE SANGUE

PLASMA ITALIA
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with the patronage of
Ministero della Salute

Australian Red Cross Lifeblood®

Australian experience on PDMPs contingency

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Disclosure

Nil disclosures

Australian governments fund Australian Red Cross Lifeblood for the provision of blood, blood products and services to the Australian community

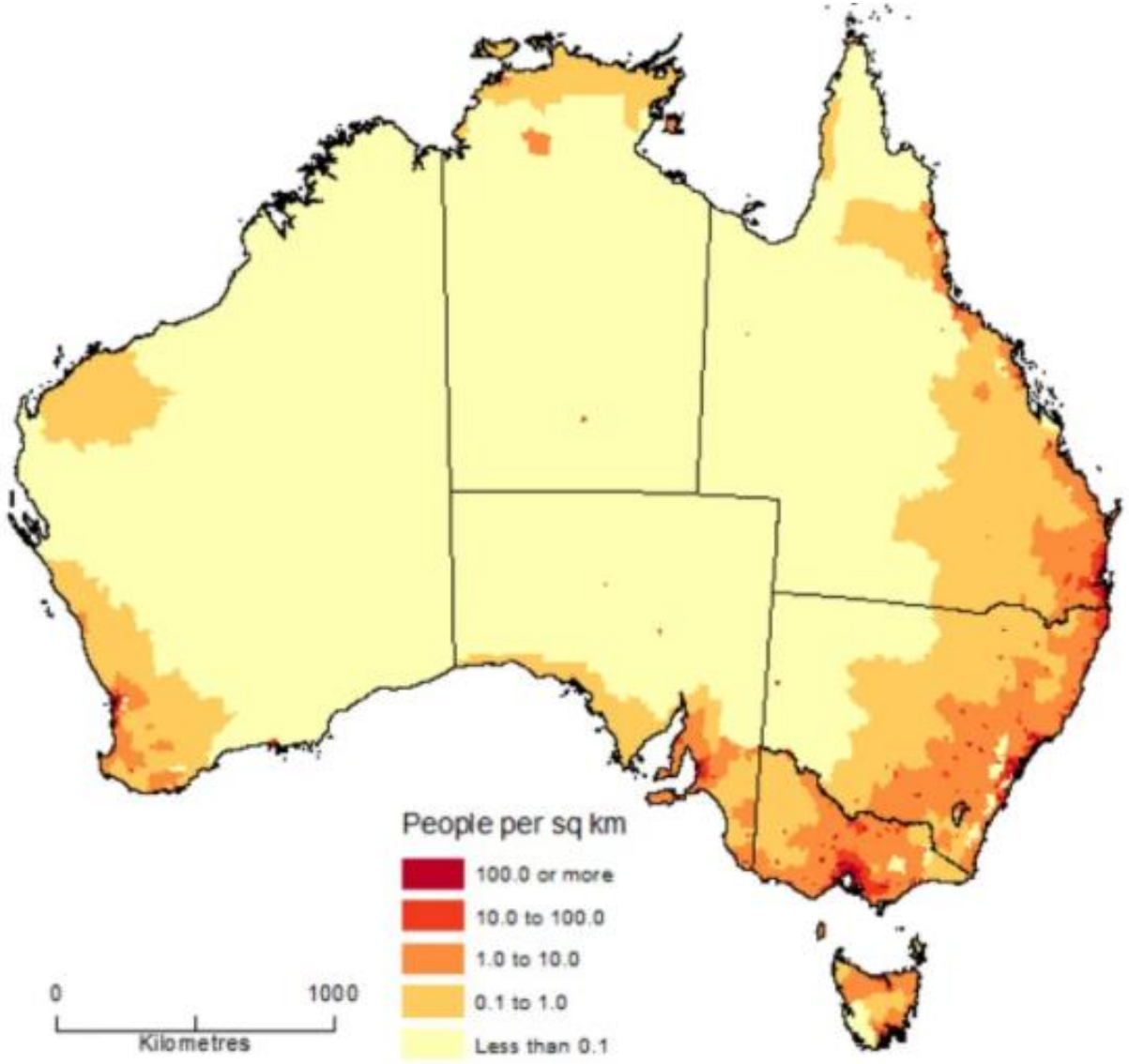
Acknowledgement of Country

We acknowledge and pay our respects to the past, present and future Traditional Custodians and Elders of this land and the continuation of cultural, spiritual and educational practices of Aboriginal and Torres Strait Islander peoples.

Australia

- Australia is the 6th biggest county in the world – 7.7 million km^2
- 26 million people

- Lifeblood is funded by all Australian Governments
- Blood donation is voluntary and non-remunerated
- Blood and blood products are provided to Australian patients at no cost

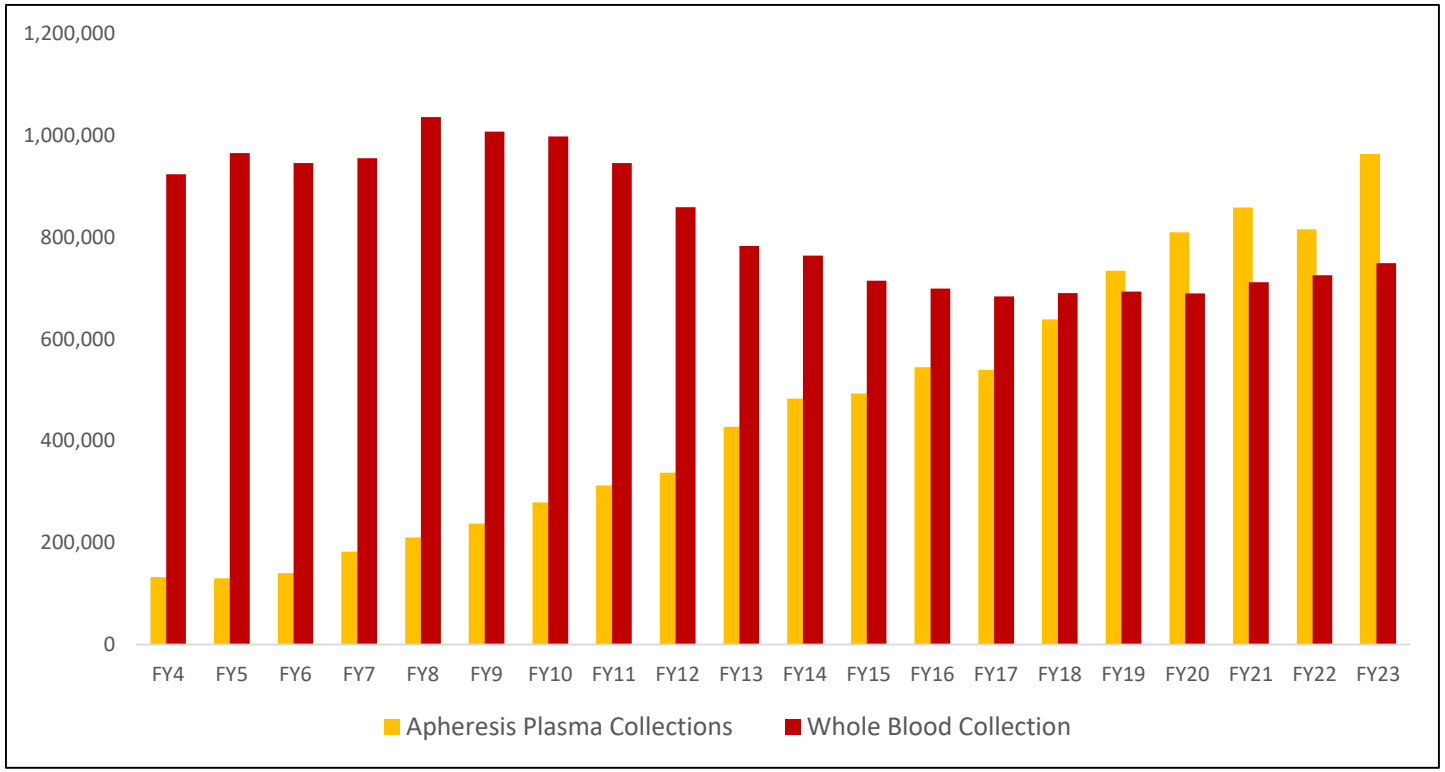


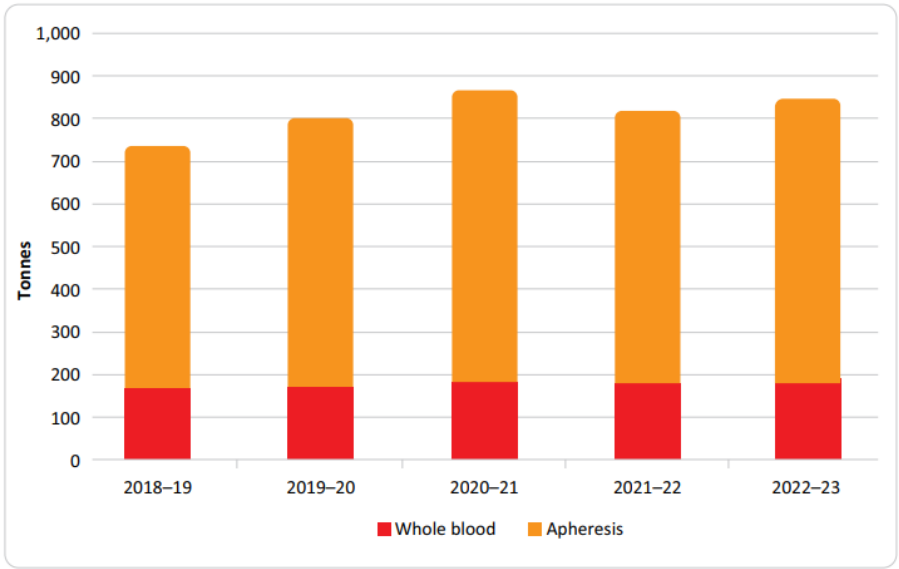
Donor Centres

- 102 donor centres, mobiles and pop-up centres
- 592,000 active and registered donors
- 1.6 million individual donations of blood, plasma and platelets

Changing mix of donations

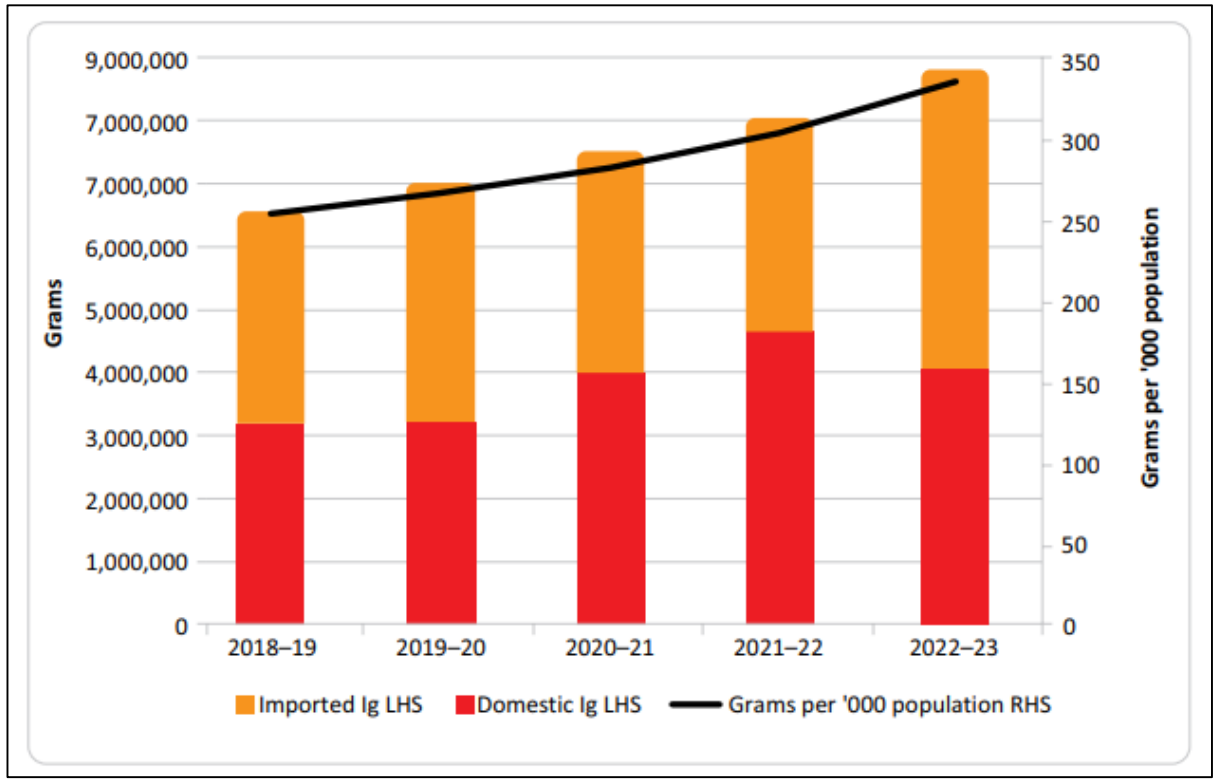
- 2018/19 was the first year that plasma donations outnumbered whole blood.
- Expect trend to continue (and widen)





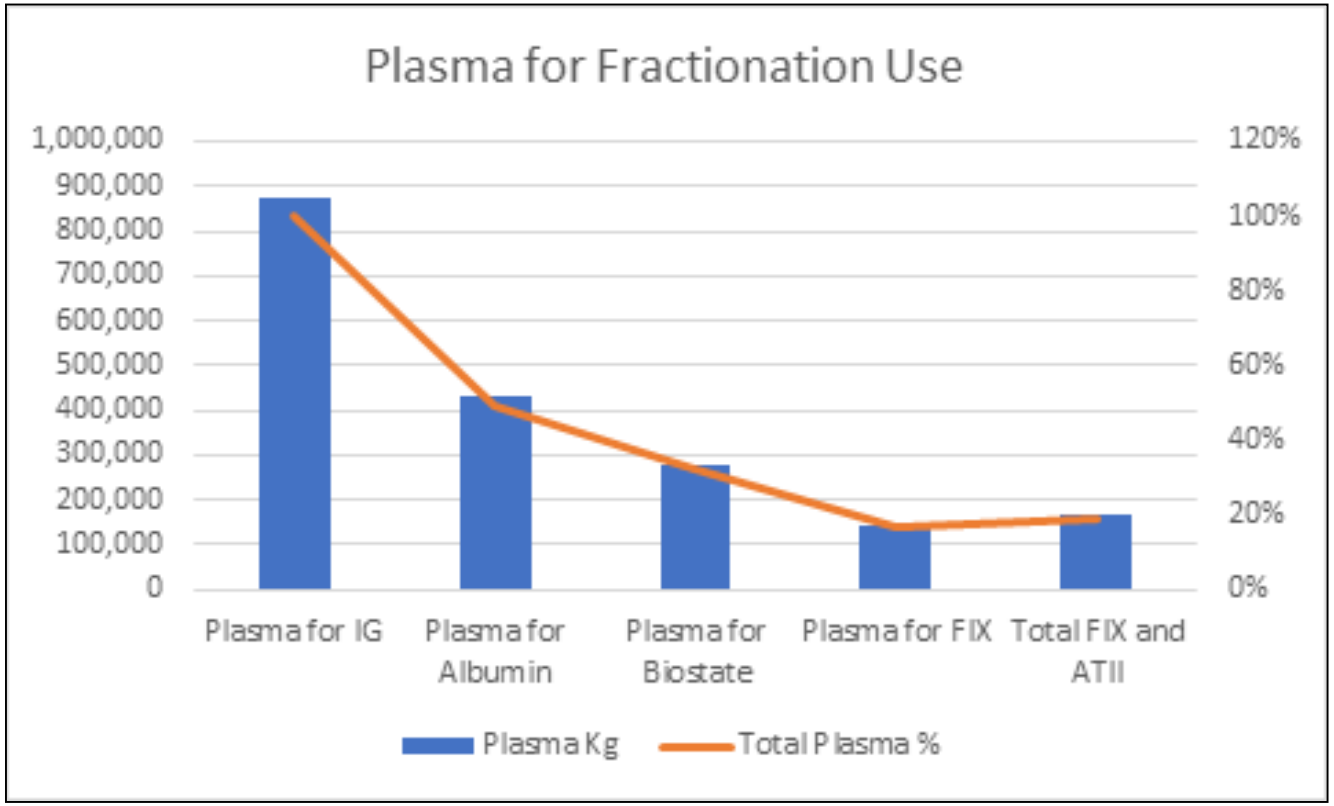
Source of plasma for fractionation

Demand for Ig is increasing



- Australia was 100% self-sufficient for Ig in 2003/04. Since that time, imported Ig has supplemented supply to ensure clinical demand could be met.
- Demand for Ig was increasing at a rate >10% per annum up until 2017/18. Since 2018/19 the demand for Ig has slowed with annual increases between 6.7-7.4% per annum – impact of revised clinical guidelines.
- In 2023 46.8% of Ig was produced in Australia and 53.2% was imported.

Plasma for Ig is our plasma driver



Australia has toll fractionation of domestically sourced plasma.
There is manufacturing capacity to increase production of non-Ig plasma-derived medicinal products if required.

National Blood Authority

The NBA manages and coordinates arrangements for the supply of blood, blood products and blood services on behalf of all Australian governments in accordance with the National Blood Agreement.

The primary objectives of the National Blood Agreement are:

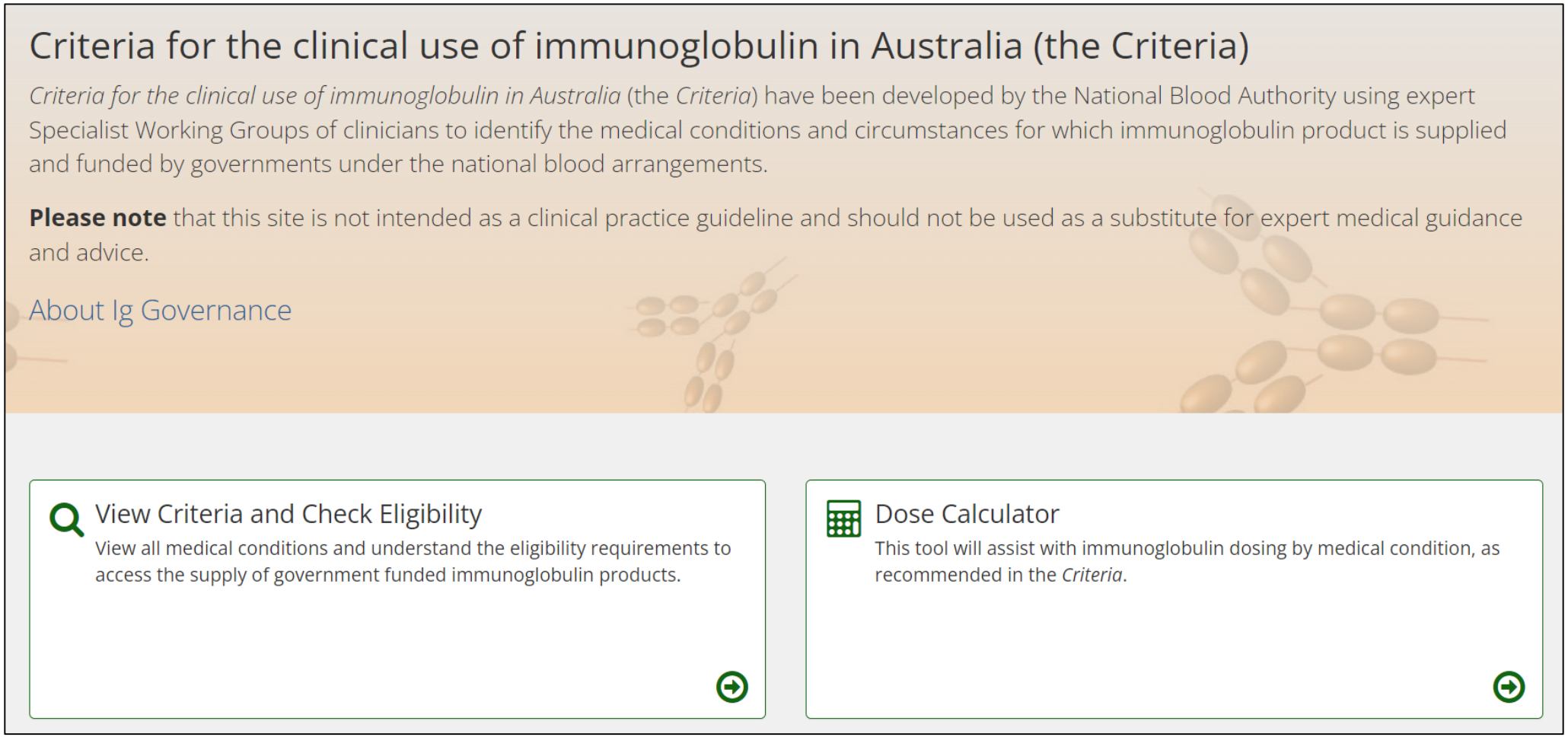
- To provide an adequate, safe, secure and affordable supply of blood products, blood-related products and blood related services in Australia; and
- To promote the safe, high-quality management and use of blood products, blood related products and blood related services in Australia

A secure supply of safe and affordable blood products – key considerations

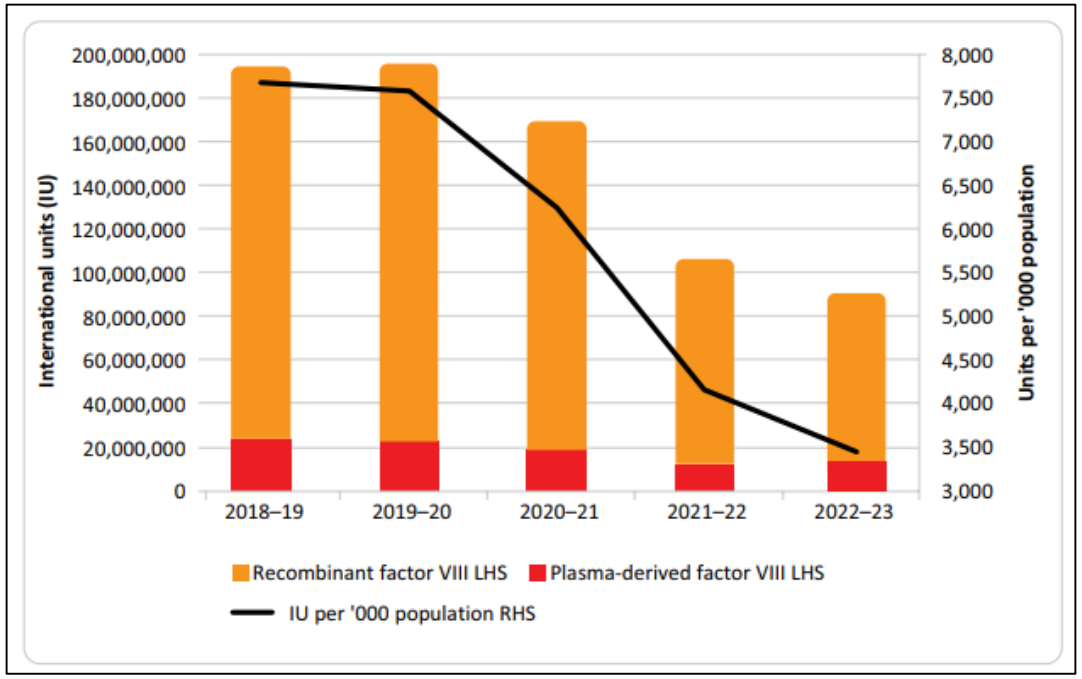
1. What is the clinical demand – is it appropriate, what alternates are there?
2. How much does it cost to supply – is it affordable and cost-justified?
3. Is there good performance across the sector – strategies to drive performance improvements, benchmarking, wastage?

4. How do we manage a supply or demand failure so that an adverse impact on patients is minimised? **Contingency planning.**

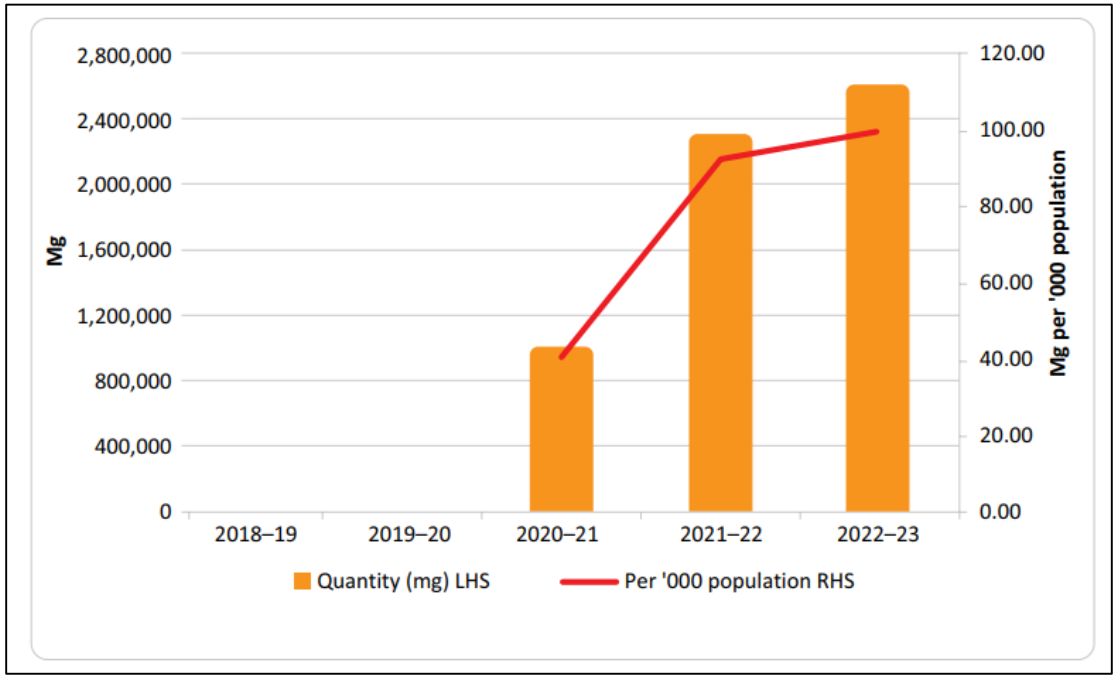
Clinical demand - appropriate use of PDMPs



Alternatives to blood products



Factor VIII products issued per 1,000 pop



Emicizumab (Hemlibra) issued per 1,000 pop

The demand for Factor VIII products has reduced significantly since the introduction of Hemlibra, a monoclonal product used to treat FVIII deficiency.

National mitigation strategies to prevent shortages of blood and PDMPs

The NBA works with suppliers and other stakeholders to improve the preparedness of the sector and to **help prevent the activation of the National Blood Supply Contingency Plan.** Strategies have been put in place to limit both the likelihood of a supply or demand failure and to minimise the impact if there is such a failure.

- Risk management plans are included in supply contracts
- Co-operation in supplier contingency planning – agreed domestic stock levels and batch volumes, to balance risk and commercial capabilities
- Product reserves and contingent supply arrangements

- Promotion of best practice use of blood and blood products

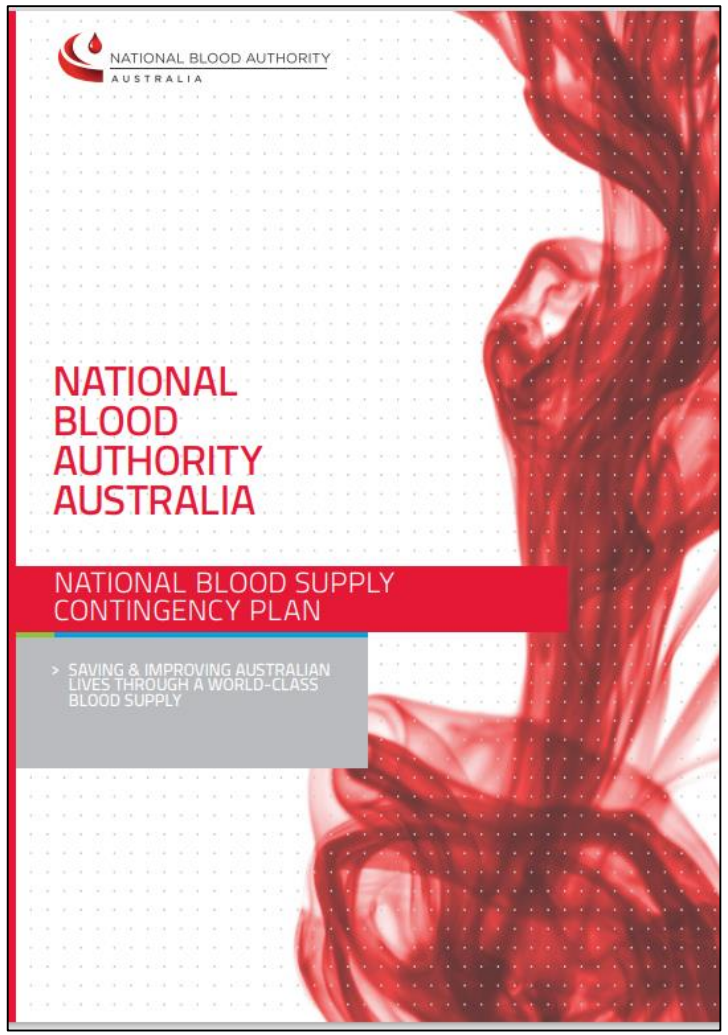
- Focus on inventory management and minimising wastage and reporting

Supplier mitigation arrangements

Suppliers are required to have a range of business continuity supply arrangements:

- Robust risk management supply and disaster recovery arrangements
- Requirements for holding of required levels of in-country reserves
- Multiple supplier arrangements
- Notification and reporting processes to identify impending risks
- Intensive product management mechanisms
- Commitment from suppliers to accord preferred customer status to supply for Australia
- Requirements for products to have a specified minimum level of shelf-life at time of supply in Australia

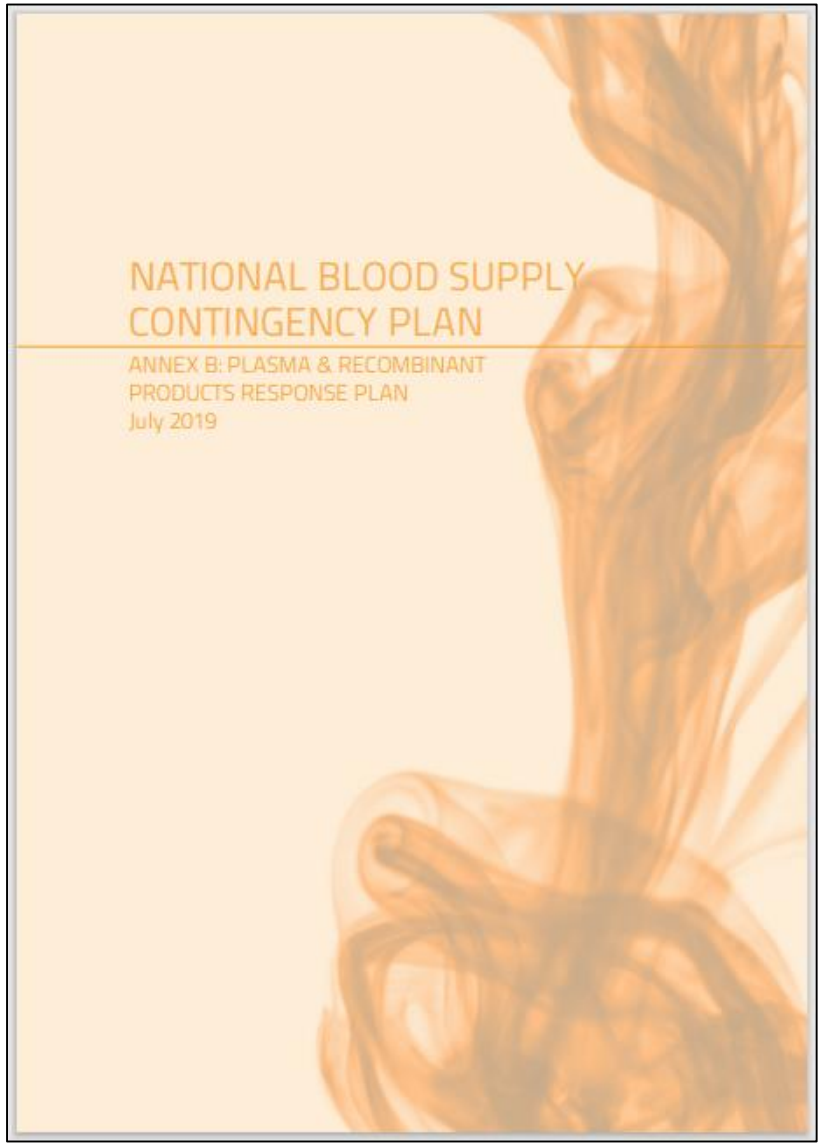
National blood supply contingency plan



Aim is to:

- Provide an overarching framework for a rapid and co-ordinated response by the NBA and other key stakeholders, to manage the consequences of a demand surge or a supply failure at a state/territory or national level
- Ensure appropriate preparation, mitigation and planning for the impact of a blood crisis
- Define the roles and responsibilities of key stakeholders
- Outline the modes of communication
- Facilitate national decisions for an appropriate response

NBSCP – plasma and recombinant products



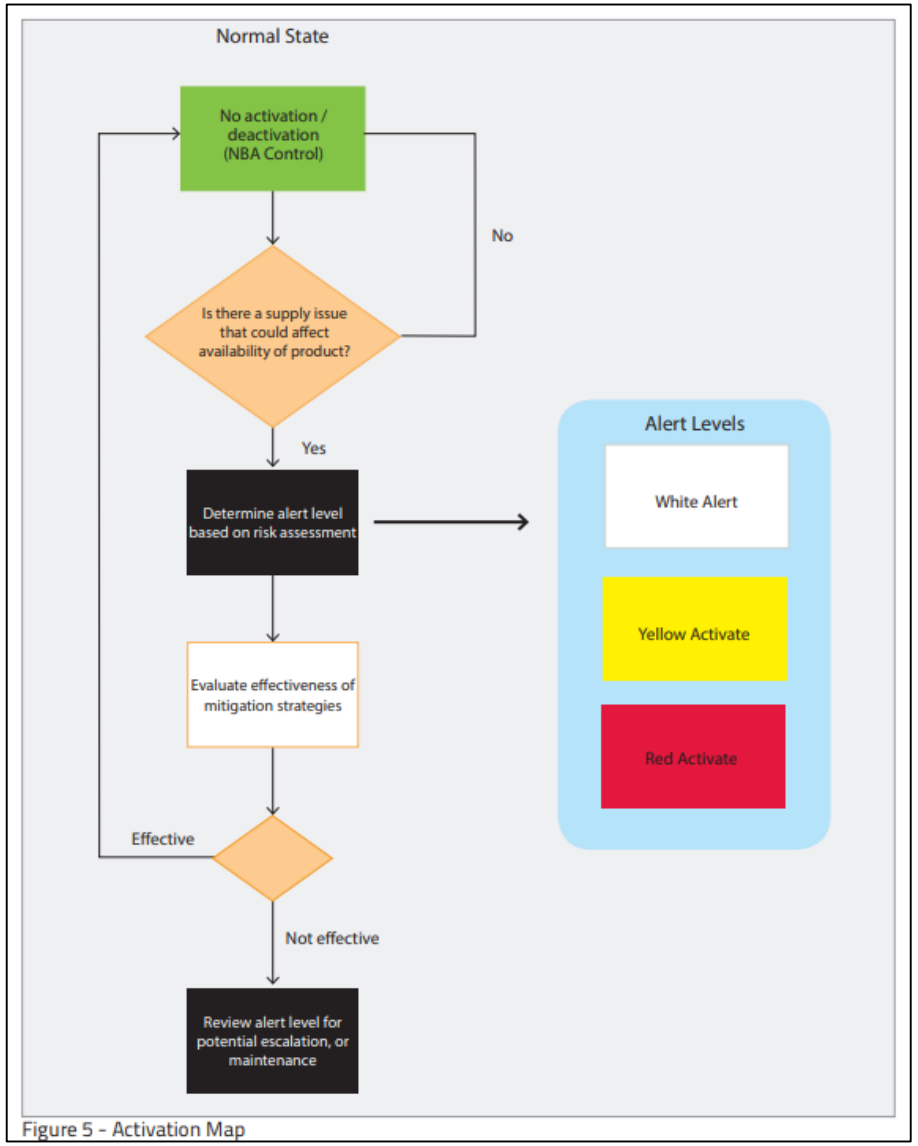


Figure 5 - Activation Map

White alert

Table 1: Alert Levels – Definition, Potential Actions and Desired Outcomes

Alert Level (Indicative Control)	Alert Level Definition	Potential Actions	Desired Outcomes
WHITE ALERT	The NBA General Manager will determine that a national shortage of a plasma or recombinant product has occurred, or is likely to occur **and/or** A shortage is recorded from inventory (sourced through BloodNet), the National Inventory Template and commercial supplier inventory reports indicating that current stock levels will not meet future demand (this may be opinion based by the NBA) **and/or** The product in stock or work in progress may be at a known or potentially high risk of 'failure.	▪ If impact is plasma focused, benefit may be from: » Blood Service calls for more donors » Increase the number of donations collected into packs suitable for production » Extend shifts in the processing department to increase production » Extend the opening times of static clinics for (the collection of donations) » Extend opening times of mobile sessions (for the collection of whole blood donations). ▪ Health service organisations confirm their inventory levels when requested, to the NBA and minimise the use of product where appropriate, and without adversely impacting on patient outcomes ▪ Access commercial suppliers contractual arrangements including Intensive Product Management (IPM) and reserves including (but not limited to) In Country Reserves (ICR), minimum product inventory (MPI) and CSL Behring National Reserve (NR). ▪ Alert health service organisations to focus on optimising product inventory management. For example, emphasise the importance that hospitals/laboratories keep track of the status of the orders so that the same order is not requested twice for the same patient at times of change of shift etc. ▪ Increase monitoring and movement of the national product stock ensuring wastage is kept to a minimum.	To increase collection and production to build stock levels while meeting demand for emergency services and other clinical requirements.

Aim is to **increase collection and production to build stock levels** while meeting demand for clinical requirements:

- Lifeblood actions
- Hospitals /labs check inventory levels
- Access commercial supplier contractual arrangements
- Keep stock wastage to a minimum

Yellow alert

Alert Level (Indicative Control)	Alert Level Definition	Potential Actions	Desired Outcomes
YELLOW ACTIVATE	Actions in WHITE ALERT phase have not rectified the situation allowing for the plan to be deactivated **and/or** Inventory (sourced through BloodNet), National Inventory Template and commercial supplier inventory reports indicating current stock levels will continue to not meet future demand (this may be opinion based by the NBA) **and/or** The product in stock or work in progress may be at a known or potentially high risk of 'failure'.	▪ If not already utilised under IPM, access remaining commercial supplier reserves/measures including committed global stock (CGS), contractual Australian preferred customer status and alternative product supply requirements. ▪ Decrease non-urgent product use in consultation with Jurisdictions / AHPPC as applicable. ▪ Recommendations from the AHPPC / NBA are put in place at either jurisdictional or national level so that available products can be redirected to meet life threatening and/or other agreed priorities based on appropriate clinical assessment. ▪ Prioritise surgery to minimise affected product use in consultation with Jurisdictions/AHPPC and to explore clinical options for reducing affected product use. ▪ NBA / OHP will inform Jurisdictions that affected products should be issued with an intention of reducing use in non-urgent situations. ▪ At this point all requests for affected products from the hospital should be authorised by a named senior clinician within the health service organisation. ▪ Work with commercial suppliers and TGA to import alternative products ▪ Extend the shelf life of affected products if the TGA approves.	Decrease non-urgent product use so that available products can be redirected to meet life threatening and/or other agreed priorities based on appropriate clinical assessment. Consider prioritising surgery to minimise product if applicable.

Aim is to **decrease non-urgent product** use so that available products can be redirected to meet life-threatening and /or other agreed priorities based on appropriate clinical assessment.

- Access commercial supplier reserves
- Consider prioritising surgery to minimise product if applicable.
- Authorisation of product by a senior clinician
- Potential extension of product shelf-life (if regulator approves)

Red alert

Alert Level (Indicative Control)	Alert Level Definition	Potential Actions	Desired Outcomes
RED ACTIVATE	Actions from WHITE ALERT and YELLOW ACTIVATE have not rectified the situation; **and/or** Inventory (sourced through BloodNet), National Inventory Template and commercial supplier inventory reports indicates stocking levels will continue to not meet future demand (this may be opinion based by the NBA) **and/or** The product in stock or work in progress may be at a known or potentially high risk of 'failure'.	▪ Actions as described for Yellow Alert. ▪ Close the NBSCP Operations Centre and NBA transition to a support role under the Commonwealth Office of Health Protection and AHPPC incident management arrangements. ▪ Implement AHPPC national policies for prioritisation of affected product use. ▪ Affected product use triaged for life threatening and other clinical AHPPC recommendations and actions dependant on the situation. ▪ Restrictions imposed on affected product use in elective surgery. ▪ NBA support and replicate OHP communication and messaging using NBSCP communication arrangements. ▪ At this point all requests for affected products in the hospital are to be made via a named senior Clinician or treating physician. This will facilitate communication between the requestor and OHP / NBA / Blood Service or other relative medical advisory body. ▪ At this point, the NBA or if a Health NIR is in place, the OHP, will take responsibility for facilitating the discussion and request for affected products between the treating clinician and the relevant product supplier Blood Service or relevant medical advisory body such as AHDCO. This will ensure that hospitals/laboratories can keep track of the status of the orders so that the same order is not requested twice for the same patient at times of change of shift etc. ▪ Hospitals will be required to track closely the fate of each unit/vial/bottle of affected products delivered to them. Information may be requested on each unit/vial/bottle of affected products at regular intervals so that, if the product is not used, it can be retrieved and delivered to an alternative location for use. This will ensure that wastage of affected product is kept to a minimum and the most urgent cases are supported.	Affected product use in elective surgery is restricted and procedures are compliant with jurisdictional emergency arrangements. If chronic, national consistency in triage of medical and surgical blood use.

Affected product use in elective surgery is **restricted** and procedures are compliant with jurisdictional emergency arrangements.

If chronic, national consistency in **triage of medical and surgical blood use.**

Track fate of all product.

De-activate

Alert Level (Indicative Control)	Alert Level Definition	Potential Actions	Desired Outcomes
DE-ACTIVATE	Affected products nationally have returned to a pre-WHITE alert level that is acceptable and the incident that led to the shortage has been resolved to the satisfaction of the NBA	• NBSCP improved for possible future crises and if possible new measures as recommended by AHPPC are introduced to decrease the likelihood or impact of a similar situation.	Evaluation of the activation for areas of improvement and possible adoption of any new measures as recommended by AHPPC.

Evaluation of the activation for areas of improvement and possible adoption of any new measures as recommended by government.

Take home messages

- A broad range of strategies should be implemented ***to limit the likelihood of a supply or demand failure*** and, ***to minimise the impact*** if there is such a failure.

- Contingency planning and emergency preparedness are fundamental in ensuring an adequate, safe, secure and affordable supply of blood products. This requires:
  - A clearly defined plan with triggers that define ***when*** and ***what*** actions are to be taken for different scenarios.
  - Key stakeholder collaboration - roles, responsibilities and communication channels need to be defined for each key stakeholder and agreed.
  - Access to required data which is routinely collected and monitored.
  - Regular testing and training, which may involve desk-based reviews or practical exercises.

Thank you

The information in this presentation was sourced from:

- National Blood Authority website: https://blood.gov.au
- National Blood Authority
- Lifeblood annual reports