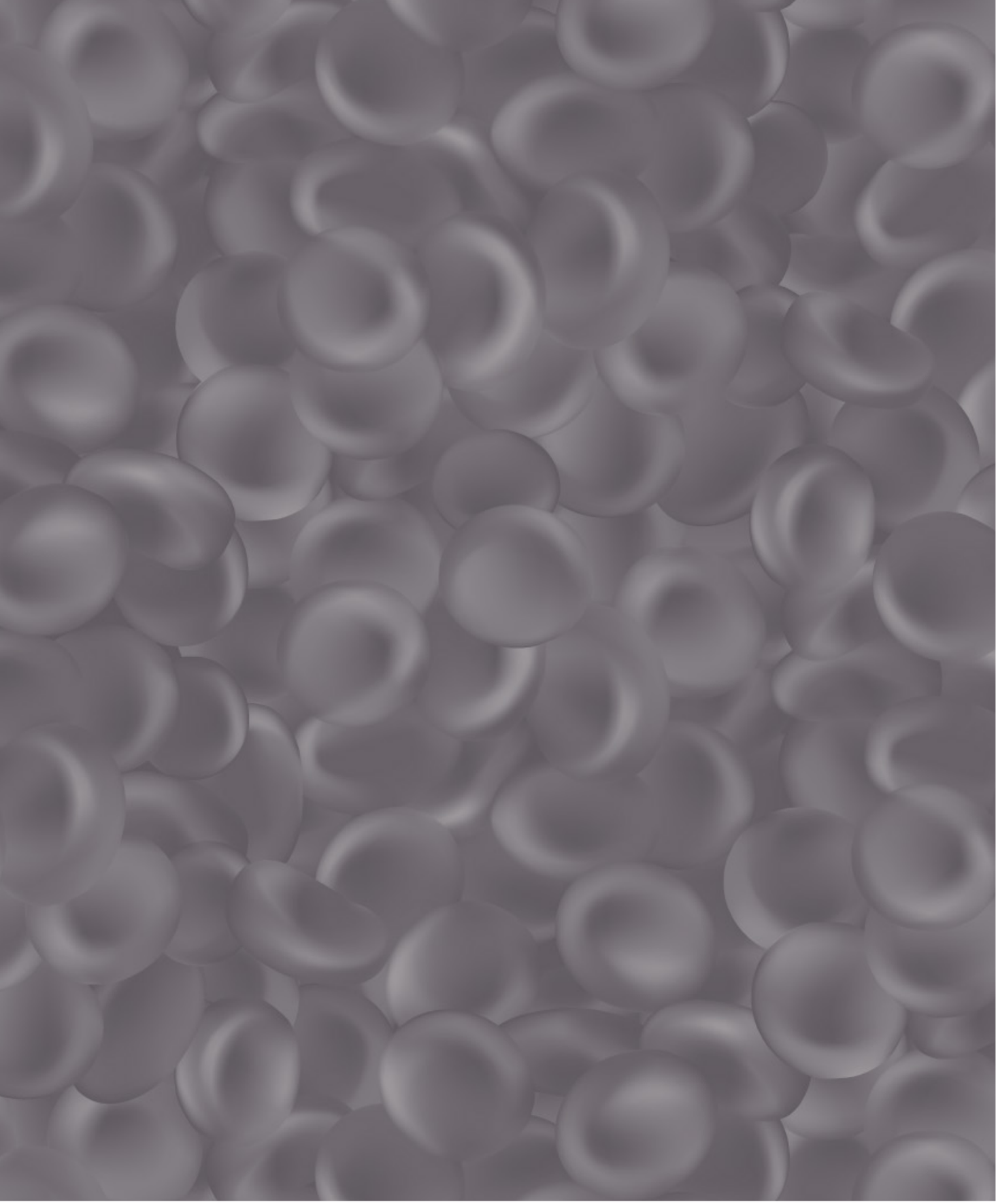

Annex B: Plasma Products Response

National Blood Authority Australia

Australian Health Ministers' Conference

National Blood Supply Contingency Plan (NBSCP)

Version 1

Annex B: Plasma-derived and recombinant product response plan

As endorsed by AHMC in April 2008

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Acronyms and abbreviations

AHMAC	Australian Health Ministers' Advisory Council
AHMC	Australian Health Ministers' Conference
AHP	approved health provider
AHPC	Australian Health Protection Committee
CTEPC	Clinical, Technical and Ethical Principal Committee
DoHA	Department of Health and Ageing
EBMT	emergency blood management team
IPM	intensive product management
JBC	Jurisdictional Blood Committee
NBA	National Blood Authority
NBSCP	National Blood Supply Contingency Plan
NIR	National Incident Room
OHP	Office of Health Protection
SAS	Special Access Scheme
TG Act	*Therapeutic Goods Act 1989*
TGA	Therapeutic Goods Administration

Introduction 1

1.1 Background

The National Blood Authority (NBA) developed a National Blood Supply Contingency Plan (NBSCP) to facilitate and coordinate a rapid national response in the event of a domestic threat or disaster that affects the provision of safe and adequate blood supply in Australia. The NBA and other relevant stakeholders are all affected by this plan.

The NBSCP establishes the context in which the NBSCP and this annex have been developed and will operate. It also outlines the crisis planning, preparation and mitigation of a crisis, response framework and recovery arrangements for a crisis affecting the supply of blood and blood products. As part of the framework, the NBA has prepared two annexes to support the response to a range of risks identified as part of the NBSCP. New annexes will be developed through consultation from time to time.

1.2 Purpose

The purpose of this annex is to implement the NBSCP in response to a supply crisis for plasma-derived and recombinant products.

1.3 Phases of plasma-derived and recombinant product response

The plasma-derived and recombinant products escalation process is comprised of four operational phases, in line with the framework established under the NBSCP. The four phases are:

- white alert
- yellow activate
- red activate
- green deactivate.

For each of these phases, this annex details the:

- definition of each phase, including the triggers that may activate a move between phases
- desired outcome from any actions taken
- roles and responsibilities of the key stakeholders, including some of the types of actions that may be taken.

2 Plasma-derived and recombinant products phase — definitions and desired outcomes

To meet clinical demand of plasma-derived and recombinant products in the event of a crisis, there is an escalation and a de-escalation process to guide the blood sector's response. Table 1 provides a definition and the desired outcome of each phase in this process, and Figure 1 shows a flowchart of the activation map.

Table 1 Escalation process for plasma-derived and recombinant products

Phases	Red Blood Cell Definition	Desired outcome
WHITE ALERT	Invoked when: ▪ product(s) are under IPM and are assessed as having high risk of supply failure ▪ there is a crisis that indicates that future demand with not be met with current supply practices.	To increase available product in order to meet the majority of demand requirements. Public health impact is ascertained.
YELLOW ACTIVATE	Invoked when: ▪ the NBA mitigation strategies are not sufficient to deactivate the plan ▪ strategies outside the NBA remit are required.	To increase product levels available to meet life-threatening demand requirements.
RED ACTIVATE	Measures beyond the authority of JBC are required to address the situation.	The available product is prioritised so they are used efficiently to meet life-threatening requirements.
DE-ACTIVATE	Plasma-derived and recombinant products have returned to a pre-white alert IPM assessment of 'low' or 'medium' on a national level.	The NBSCP is improved for possible future crises and, if possible, measures are introduced to decrease the likelihood or impact of a similar situation.

IPM = intensive product management; JBC = Jurisdictional Blood Committee; NBA = National Blood Authority; NBSCP = National Blood Supply Contingency Plan

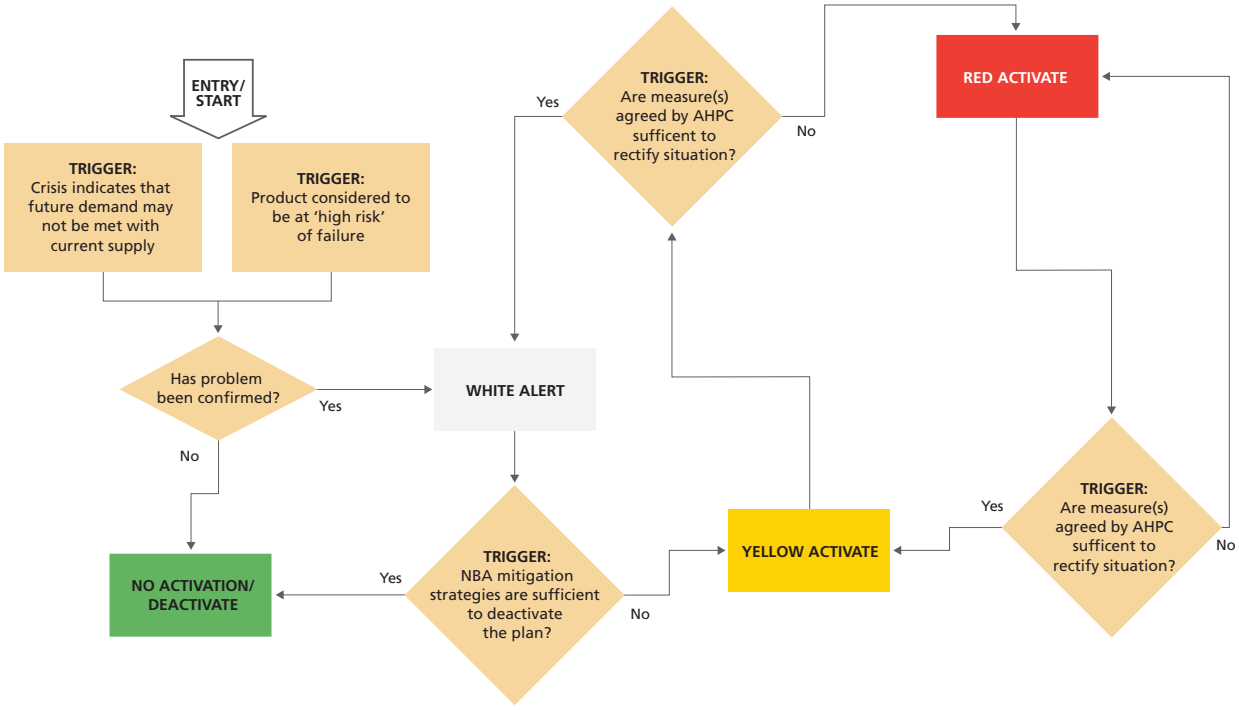

Figure 1 Activation map of the escalation process

AHPC= Australian Health Protection Committe; NBA= National Blood Authority

Actions to be taken — roles and responsibilities 3

Outlined in this chapter are the roles and responsibilities of the key stakeholders involved in the management of plasma-derived and recombinant products during each operational phase. These are high-level descriptions of their responsibilities and other roles may be required depending on the nature of the incident.

3.1 National Blood Authority (NBA)

WHITE ALERT	▪ confirms situation is real and activates NBSCP ▪ notifies key stakeholders (JBC, OHP, TGA), suppliers, DoHA, relevant product-user groups and colleges ▪ considers using reserve stocks ▪ implements mitigation strategies with suppliers and the clinical community ▪ works with supplier to rectify the situation ▪ considers plasma replacement planning ▪ if relevant, collects and confirms information on: – supply levels and buffers – production information (e.g. timing and yield) – future plasma-derived collection – demand trends and future weekly demand requirements.
YELLOW ACTIVATE	Continues activities from white alert plus: ▪ confirms escalation of NBSCP to stakeholders ▪ appoints Supplier Liaison Officers ▪ provides advice on options to JBC ▪ implements JBC agreed measures ▪ informs stakeholders of JBC decisions ▪ undertakes media activities, such as the provision of information and data to relevant bodies (DoHA and suppliers) in accordance with agreed media protocol ▪ begins planning for possible movement to red activation ▪ evaluates the impact on plasma collection requirements.
RED ACTIVATE	Continues activities from white alert and yellow activate, plus: ▪ prepares advice for AHPC, AHMAC and AHMC ▪ responds to AHPC, AHMAC and AHMC recommendations and communicates with stakeholders ▪ works with TGA and suppliers on possible importation options.
DE-ACTIVATE	▪ informs stakeholders of deactivation ▪ manages and conducts debriefing session ▪ collects information to support improvements ▪ revises plan, if necessary ▪ provides advice to JBC on new mitigation strategies that could be implemented, if appropriate.

3.2 Suppliers

WHITE ALERT	▪ provides relevant data, facts and inventory information to NBA ▪ manages supply to AHPs in accordance with agreed mitigation strategies (reserves and alternatives supplies) or IPM processes.
YELLOW ACTIVATE	Continues activities from white alert plus: ▪ appoints NBA Liaison Officer ▪ works with NBA to implement agreed JBC actions ▪ works with NBA on media activities in accordance with agreed media protocol.
RED ACTIVATE	Continues activities from white alert and yellow activate, plus: ▪ works with NBA to implement any government decisions ▪ works with NBA/TGA on possible importation options ▪ assists with the distribution of any imported products.
DE-ACTIVATE	▪ participates in briefing to improve the NBSCP and decrease the likelihood of future activation of the plan (or both).

3.3 Jurisdictional Blood Committee (JBC) and health departments

WHITE ALERT	▪ provides information on situation to NBA ▪ coordinates communication with AHPs.
YELLOW ACTIVATE	Continues activities from white alert plus: ▪ considers and agrees to actions outside NBA remit ▪ encourages responsible product use throughout hospitals and with other AHPs (if it is not agreed as an ARCBS responsibility) ▪ if required, responds to media activities in accordance with agreed media protocol.
RED ACTIVATE	Continues activities from white alert and yellow activate, plus: ▪ works with the NBA and TGA on importation of alternative products, if available ▪ works with the NBA on establishing a mechanism for alternative products to be distributed ▪ communicates changes in clinical practice to AHPs.
DE-ACTIVATE	▪ considers policy and funding options for additional mitigation strategies, if appropriate ▪ informs AHPs of deactivation.

3.4 Institutions and clinicians

WHITE ALERT	▪ reviews and modifies emergency blood management arrangements, including clinical practice ▪ places EBMT on alert ▪ provides inventory and stock holdings to suppliers, as required.
YELLOW ACTIVATE	Continues activities from white alert plus: ▪ implements emergency blood management arrangements ▪ considers amending the treatment program to minimise product use.
RED ACTIVATE	Continues activities from white alert and yellow activate, plus: ▪ manages the clinical use of the mix of products introduced to rectify situation ▪ implements national strategies agreed by AHPC and AHMC on alternative clinical measures.
DE-ACTIVATE	▪ participates in briefing, if appropriate.

3.5 Department of Health and Ageing (DoHA)

WHITE ALERT	▪ Blood policy area briefs departmental executive and communications area of situation ▪ provides briefing to the Minister ▪ coordinates national media advice on supply level ▪ coordinates jurisdictional analysis of public health impact.
YELLOW ACTIVATE	Continues activities from white alert plus: ▪ manages media requirements in accordance with agreed media protocol ▪ Blood policy area briefs departmental executive and Minister ▪ considers budgetary matters ▪ OHP advises the AHPC for information.
RED ACTIVATE	Continues activities from white alert and yellow activate, plus: ▪ OHP considers activating the NIR and AHPC ▪ communicates AHPC, AHMAC and AHMC decisions to NBA ▪ OHP provides advice in conjunction with NBA to AHMC ▪ manages policy and budget matters associated with agreed actions.
DE-ACTIVATE	▪ participates in briefing ▪ advises departmental executive and Minister of outcomes.

3.6 Therapeutic Goods Administration (TGA)

WHITE ALERT	▪ monitors situation and works with NBA and ARCBS as necessary ▪ supports NBA in analysis of initial information.
YELLOW ACTIVATE	Continues activities from white alert plus: ▪ provides critical information on regulatory matters to the NBA and suppliers ▪ processes actions, such as SAS requests ▪ undertakes media activities, if required, in accordance with agreed media protocol.
RED ACTIVATE	Continues activities from white alert and yellow activate, plus: ▪ works with the NBA on options to import nonregistered products under section 19a of the TG Act.
DE-ACTIVATE	▪ participates in briefing, if appropriate.

3.7 Clinical, Technical and Ethical Principal Committee (CTEPC)

WHITE ALERT	Nil
YELLOW ACTIVATE	Nil
RED ACTIVATE	▪ if required, recommends to AHMAC alternative clinical measures and restrictions in product use.
DE-ACTIVATE	▪ participates in briefing if appropriate.

3.8 Australian Health Protection Committee (AHPC) and Australian Health Ministers' Advisory Council (AHMAC)

WHITE ALERT	Nil
YELLOW ACTIVATE	Nil
RED ACTIVATE	▪ recommends to AHMC alternative clinical measures and restrictions in product use ▪ advises jurisdictions and NBA of recommendations.
DE-ACTIVATE	▪ participates in briefing if appropriate.

3.9 Australian Health Ministers' Conference (AHMC)

WHITE ALERT	Nil
YELLOW ACTIVATE	Nil
RED ACTIVATE	▪ considers and endorses AHPC, AHMAC and CTPEC decisions ▪ outcomes are communicated by the secretariat to stakeholders ▪ coordinates and undertakes all media activities.
DE-ACTIVATE	