**ATTACHMENT A**

FACT SHEET for Healthcare Professionals

**FORTHCOMING CHANGE TO AUSTRALIA’S DOMESTICALLY PRODUCED INTRAVENOUS IMMUNOGLOBULIN (IVIg).**

**INTRAGAM 10 TO REPLACE INTRAGAM P COMMENCING MARCH 2017**

**What is changing?**

INTRAGAM P, the currently available domestic intravenous immunoglobulin (IVIg) product, will be replaced by INTRAGAM 10, a 10% concentration product.

**What are some of the main similarities and difference between INTRAGAM P and INTRAGAM 10?**

INTRAGAM P and INTRAGAM 10 are both manufactured by CSL Behring from blood and plasma collected by the Australian Red Cross Blood Service (Blood Service) from Australia’s voluntary non-remunerated blood donors. INTRAGAM 10 is manufactured using the same core plasma fractionation process as INTRAGAM P.

INTRAGAM P is a 6% concentration product and INTRAGAM 10 is a 10% concentration product; hence, INTRAGAM 10 will provide lower volume doses for patients compared with the same Ig dose of INTRAGAM P.

INTRAGAM P is currently available in two vial size presentations – 3g (50mL) and 12g (200mL). INTRAGAM 10 will be available in three vial size presentations – 2.5g (25mL), 10g (100mL) and 20g (200mL).

**When will this change occur?**

INTRAGAM 10 will be introduced from 1 March 2017.

Approved Health Providers (dispensers) can commence ordering INTRAGAM 10 from the Blood Service from 20 February 2017 to meet anticipated new patient requirements from 1 March 2017.

**How will this change happen?**

INTRAGAM 10 will be introduced in a two-step process.

1. In all states and territories except NSW:
   1. New patients – From 1 March 2017, new patients with conditions for which domestic IVIg is allocated will be allocated to receive INTRAGAM 10 in BloodSTAR.
   2. Existing patients who are currently authorised to receive INTRAGAM P
      1. From 1 March 2017, existing patients for whom an authorisation request is submitted in BloodSTAR will be allocated to receive INTRAGAM 10 - this includes initial authorisation requests, continuing authorisation requests, requests to change the patient’s dose or requests for an additional dose.
      2. All remaining existing patients will be transitioned to INTRAGAM 10 as national inventories of INTRAGAM P are reduced. Once the transition date for existing authorised patients is known, the National Blood Authority (NBA) will use BloodSTAR to automatically change all existing authorisations for INTRAGAM P to INTRAGAM 10 and automatically update dosing calculations. Any change to products authorised for patients will automatically update BloodNet for dispensers.
2. In NSW only:
   1. New patients – From 1 March 2017, new patients with conditions for which domestic IVIg is allocated will be allocated to receive INTRAGAM 10.
   2. Existing patients who are currently authorised to receive INTRAGAM P will be transitioned to INTRAGAM 10 when national inventories of INTRAGAM P are depleted. If BloodSTAR has not been implemented in NSW by the INTRAGAM 10 transition date, the Blood Service will manage the transition of the NSW patients to INTRAGAM 10 using the existing processes.

**Will INTRAGAM P continue to be available after the transition date?**

No. Upon commencing INTRAGAM 10 manufacture, CSL Behring will cease INTRAGAM P manufacture. Once all existing stocks of INTRAGAM P are utilised, INTRAGAM P will no longer be available. All existing patients previously authorised to receive INTRAGAM P will need to transition to INTRAGAM 10.

**What do I need to do to prepare for this change?**

In preparation for this upcoming change, clinicians are requested to communicate the required product change to their patients who are currently authorised to receive INTRAGAM P and to other relevant parties including their infusion clinic staff, and to ensure that relevant protocols are updated or developed for INTRAGAM 10.

A fact sheet for patients who need to transition from INTRAGAM P to INTRAGAM 10 is provided at **Attachment B**.

**Where can I find more information about INTRAGAM 10 and/or the transition arrangements?**

The following additional information is provided:

* INTRAGAM 10 Product Information and Consumer Medicine Information sheets - see **Attachment C**.
* A high-level comparison of the IVIg products available under the national blood arrangements - see **Attachment D**.

Electronic copies of Product Information sheets, Consumer Medicine Information sheets and other product support materials (e.g., dose and infusion rate tool) are available from the manufacturer’s website:

* CSL Behring - [http://www.cslbehring.com.au/products/product-finder.htm.](http://www.cslbehring.com.au/products/product-finder.htm)

Further queries on the national supply arrangements for Ig can be directed to:

* National Blood Authority: [support@blood.gov.au](mailto:support@blood.gov.au)
* Australian Red Cross Blood Service: by contacting a member of your local Transfusion Medicine team.