**ATTACHMENT D**

**Comparison of Intravenous Immunoglobulin Products available under National Blood Supply Arrangements from 1 March 2017\***

\* INTRAGAM 10 will be introduced from March 2017 and will eventually replace INTRAGAM P.

Further details about the domestic IVIg product transition can be found at <https://www.blood.gov.au/document/announcement-forthcoming-domestic-ivig-product-transition-pdf>

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| **DESCRIPTION** | **INTRAGAM P** | **INTRAGAM 10** | **FLEBOGAMMA 5% DIF** | **FLEBOGAMMA 10% DIF** | **PRIVIGEN 10%** |
| Presentation | Solution; 3g (50mL),  12g (200mL) vials | Solution; 2.5g (25mL), 10g (100mL), 20g (200mL) vials | Solution; 0.5g (10mL),  2.5g (50mL), 5g  (100mL), 10g (200mL),  20g (400mL) vials | Solution; 5g (50mL), 10g (100mL), 20g (200mL) vials | Solution; 5g (50mL),10g  (100mL), 20g (200mL),  40g (400mL) vials |
| Concentration | 6% | 10% | 5% | 10% | 10% |
| Source Plasma | Australian volunteer non- remunerated donors | Australian volunteer non- remunerated donors | USA and European remunerated and non- remunerated Qualified Only donors (QSEAL certified) | USA and European remunerated and non- remunerated Qualified Only donors (QSEAL certified) | European and USA remunerated and non- remunerated donors |
| Plasma Testing | Hepatitis B surface antigen; antibodies to HIV 1/2 and hepatitis C; nucleic acid testing for hepatitis B, hepatitis C and HIV-1. | Hepatitis B surface antigen; antibodies to HIV 1/2 and hepatitis C; nucleic acid testing for hepatitis B, hepatitis C and HIV-1. | Hepatitis B surface antigen; antibodies to HIV 1/2 and hepatitis C; nucleic acid testing for hepatitis A, hepatitis B, hepatitis C, HIV and parvovirus B19 | Hepatitis B surface antigen; antibodies to HIV 1/2 and hepatitis C; nucleic acid testing for hepatitis A, hepatitis B, hepatitis C, HIV and parvovirus B19 | Hepatitis B surface antigen; antibodies to HIV 1/2 and hepatitis C; nucleic acid testing for hepatitis A, hepatitis B, hepatitis C, HIV-1 and parvovirus B19 |
| Manufacturer | CSL Behring, Broadmeadows, Australia | CSL Behring, Broadmeadows, Australia | Instituto Grifols, S.A. Can Guasch, 2 - Parets del Vallès  08150 Barcelona - Spain | Instituto Grifols, S.A. Can Guasch, 2 - Parets del Vallès  08150 Barcelona - Spain | CSL Behring, Broadmeadows, Australia  CSL Behring AG, Wankdorfstrasse 10, CH–3000 Bern 22, Switzerland |
| Distributor | Australian Red Cross Blood Service | | | | |
| Manufacturing  Process | Chromatographic fractionation | Chromatographic fractionation | Cold alcohol fractionation, polyethylene glycol precipitation, ion exchange chromatography and low pH treatment | Cold alcohol fractionation, polyethylene glycol precipitation, ion exchange chromatography and low pH treatment | Cold ethanol fractionation, octanoic acid fractionation, depth filtration, anion exchange chromatography |
| Viral Safety | Two dedicated steps:  • Pasteurisation (60°C for 10 hours)  • Incubation at low pH | Three dedicated steps:  • Pasteurisation (60°C for 10 hours)  • Incubation at low pH  • Nanofiltration  (20nm) | Three dedicated steps:  • Pasteurisation  • Solvent detergent treatment  • Two sequential nanofiltrations  (35nm and 20nm) | Three dedicated steps:  • Pasteurisation  • Solvent detergent treatment  • Two sequential nanofiltrations  (35nm and 20nm) | Three steps to optimise pathogen safety.  Two dedicated steps:  • Incubation at pH 4  • 20nm nanofiltration  Third step contributes to virus reduction capacity:  • Depth filtration |
| Stabiliser 1 | Maltose 2 | Glycine (non-essential amino acid) | Sorbitol 3a | Sorbitol 3b | Proline (non-essential amino acid) |
| Storage  Conditions | Refrigerate at 2-8°C for up to 2 years. Do not freeze.  Once removed from refrigeration, store below 25°C and use within 3 months.  Protect from light. | Refrigerate at 2-8°C for up to 2 years. Do not freeze.  Once removed from refrigeration, store below 25°C and use within 3 months.  Protect from light. | Store below 30°C for up to 2 years. Do not freeze.  Protect from light. | Store below 30°C for up to 2 years. Do not freeze.  Protect from light. | Store below 25°C for up to 3 years. Do not freeze.  Protect from light. |
| Need for  Reconstitution | No | No | No | No | No |
| Dosage and  Administration | For intravenous use only, see approved Product Information for rate of infusion | | | | |
| Relative IgG  subclass content | IgG1 61%  IgG2 36%  IgG3 3%  IgG4 1% | IgG1 47.6-56.2%  IgG2, 41.5-49.5%  IgG3, 1.3-1.6%  IgG4 0.9-1.3% | IgG1 66.6%  IgG2 28.5%  IgG3 2.7%  IgG4 2.2% | IgG1 66.6%  IgG2 27.9%  IgG3 3.0%  IgG4 2.5% | IgG1 67.8%  IgG2 28.7%  IgG3 2.3%  IgG4 1.2% |
| IgA level 4 | < 0.025mg/mL | <0.025 mg/mL | <0.05 mg/mL | <0.1 mg/mL | ≤ 0.025 mg/mL |
| Precautions and  Adverse Reactions 5 | See approved Product Information. Note that different IVIg products have different infusion rates and some adverse reactions may be infusion rate dependent | | | | |
|  | The information contained in the above table has been provided and approved by CSL Behring Australia and Grifols Australia.  The Australian Red Cross Blood Service makes no warranties in relation to the products, FLEBOGAMMA 5% DIF, FLEBOGAMMA 10% DIF, PRIVIGEN 10%, INTRAGAM P and INTRAGAM 10, nor the information provided about these products.  Notes:  1. Although the majority of renal adverse events have occurred with sucrose containing IVIg products, caution is advised during administration of any IVIg product.  2. The maltose present in INTRAGAM P may interfere with some blood glucose measurements, resulting in the overestimation of blood glucose results. If this glucose measurement is used to guide treatment, hypoglycaemia may occur. (Reference: INTRAGAM P Product Information).  3. a. Patients with rare hereditary problems of fructose intolerance should not take this medicine. Special precautions should be taken with babies and young children because this fructose intolerance may not yet be diagnosed and may be fatal. (Reference: FLEBOGAMMA 5% DIF Product Information)  b. Patients with rare hereditary problems of fructose intolerance should not take this medicine. Babies and young children should not receive FLEBOGAMMA 10% DIF because this fructose intolerance may not yet be diagnosed and may be fatal. (Reference: FLEBOGAMMA 10% DIF Product Information).  4. In IgA deficient patients, product with the lowest IgA level should be selected.  5. Infusion of IVIg may lead to a relative increase in blood viscosity. Patients should be adequately hydrated prior to commencement of the infusion. IVIg should NOT be infused rapidly to patients at increased risk of thromboembolic and renal adverse events, particularly when using higher concentration IVIg products. | | | | |