Written Submission by the South Australian IVIG User Group Regarding the Review of Australia's Plasma Fractionation Arrangements

The key points which have been raised on previous occasions by the South Australian IVIg Users Committee are:

1. That Australia should strive to maintain self sufficiency in the provision of plasma products.
2. That the safety, quality and efficacy of plasma products can only be maintained by retaining an on shore plasma fractionation facility.

1. **Demand trends for plasma products (intravenous immunoglobulin)**
   It has been anticipated that the demands will rise for plasma products in the areas of transplantation and autoimmune disease. This demand is in addition to the steady increase in demands in the areas of immunodeficiency and neurology. The increase is of the order of 10% per year. However, prediction of the exact demand trends is extremely difficult as it is likely that there will be a role for intravenous immunoglobulin found outside current indications in the future. A tendering process would tend to lock in supply and would limit the ability to vary supply according to demand. Difficulty may be encountered given limited ability to predict demand.

2. **Regulatory requirements**. If there is substantial off shore fractionation, the opportunities for close monitoring of quality of products would be restricted. At present safety and quality requirements of intravenous immunoglobulin preparation are of a higher standard.

2.2 There is no requirement for measurement of antibody levels against various pathogens in the preparation. In addition, there are no ongoing audits of efficacy of intravenous immunoglobulin preparations. In the future where ever the plasma fractionation takes place, it is recommended that efficacy requirements be expanded.

The committee has concern regarding self sufficiency if there is substantial off shore fractionation. The arrangement between the fractionators and ARBS will have to be reviewed. The following concerns will have to be addressed before substantial plasma fractionation off shore takes place.

1) Prioritisation of fractionation of Australian plasma vs plasma fractionation of plasma from other countries.
2) Policies regarding batch /plant failure.
    1) How are supply concerns addressed when plasma is processed from many different countries?
    2) The approach to the presence of infection in non Australian plasma products but processed at the same plant?
    3) Increasing competition.

The success of competitive tender arrangements are highly dependent upon carefully defining the requirements for plasma fractionation and ensuring these requirements are met. Although at the moment there is substantial over supply of plasma products world wide, it is anticipated this will not be the case in the future. It is disappointing the review does not seem to be addressing patient care implication in the event of failure of tender arrangements and seems to be restricting itself to economic considerations.

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