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The Secretary,
Review of Australia's Plasma Fractionation Arrangements,
Department of Health and Ageing,
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ACT 2601.

Submission to Plasma Fractionation Review from Haematology Society of ANZ

As the professional body representing practicing Clinical Haematologists in Australia, the HSANZ is pleased to provide this written submission to the Review. By way of introduction, Clinical Haematologists are the physicians usually responsible for the prescription of plasma-derived products to patients with bleeding disorders and for many patients with immune deficiencies. Members of the Society are also involved in collection of plasma through the Australian Red Cross Blood Service, and run the hospital Pathology departments and Transfusion services which co-ordinate the storage and supply of plasma product supplies for a majority of patients. As such, members of HSANZ are well placed to comment on the impacts that changes in demand, products and administrative process have had on patients, staff and organizations at the "coal-face" of health care provision.

The most important point which the Society wishes to emphasise to the Review relates to the 4th Term of Reference: Assess issues under (3) against the following evaluation criteria:safety, quality, efficacy, security of supply and the potential impact on expenditure……

Plasma products are biological agents, and variations between specific products from different sources and manufacturers mean that these products should not simply be viewed as interchangeable commodities. From a clinical perspective, different products may have different clinical efficacy, different side effects profiles, different methods of reconstitution or delivery, and different requirements for storage and access. Significant differences between products in any of these areas means increased costs – either health cost to the patient or staff costs to the Hospital. By way of example, the recent requirement to use intravenous immunoglobulin (IVIG) from various international sources for patients has had the following impacts:

(i) anecdotal evidence of adverse events occurring in patients who had previously tolerated other products well. Access to adverse event data to investigate this issue further has been complicated by the introduction of new suppliers to the market;

(ii) concerns among clinicians treating patients with inherited and acquired immune deficiencies to reduce infective morbidity and mortality, that imported products sourced from different populations are inferior to Australian-sourced product. It is reasonably presumed that Australian-sourced products reflect local antibody profiles and thereby give the greatest chance of protection against local pathogens. In other patient populations (patients with Kawasaki disease - TSAI, MH et al. J Pediatr 2006;148:38-43), published data do indicate differences in outcomes for different IVIG preparations.

(iii) additional burdens for patients and staff alike because of major differences in times and schedules of infusions. A “simple” change in product has resulted in major inconveniences for many patients, significant increases in staff time to deliver therapy, and significant investment by nursing staff, transfusion staff and ARCBS staff in developing new protocols for delivery. Experts on the panel will be aware that a major barrier to quality of clinical care in the hospital setting is lack of uniformity of therapy for a specific indication or procedure. Choice from this perspective is a negative, and repeated changing between different specific products is poor clinical practice.
(iv) increased costs to hospitals and transfusion services because of increased infusion times, requirements to change procedures, and in some instances increased costs of pathology tests (one product required renal function testing prior to prescription).

In relation to other Terms of Reference, HSANZ also wishes to address the following issues:

1. Demand trends for plasma products - IVIG
(i) Strong growth is expected in the need for IVIG for both main areas of current use, immune deficiency replacement and immuno-modulation therapy for auto-immune diseases. This growth is a consequence of arithmetic population growth coupled with significant increases in prevalence of both acquired immune deficiencies and auto-immune diseases as the community ages.
(ii) Immune thrombocytopenia (ITP) is a major indication for IVIG, and alternative therapies are on the horizon, including anti-CD20 antibodies and thrombopoietin receptor agonists. Potentially, these alternatives may lead to a future decrease in demand for IVIG. However, neither of these potential alternatives has been proved to be superior to IVIG and neither is licenced, or likely to be licenced for use in ITP in the immediate future. Future clinical trials will establish the place of alternatives to IVIG in the management of autoimmune thrombocytopenia. Even if more efficacious, these new therapies will be very expensive, and therefore access issues are likely to be a major barrier to their clinical uptake.
(iii) HSANZ supports the principle of self-sufficiency of plasma supply and reaffirms its support for a policy of voluntary unpaid donorship as the safest source of this supply.

2. Regulatory requirements
(i) HSANZ believes that maintenance of Australia’s high regulatory standards is the best guarantee of safe quality product for Australian patients, and should be the major criterion upon which future policy is based.
(ii) Any changes to current plasma fractionation arrangements, such as competition, should be required to demonstrate how they will maintain and not reduce the extremely high safety and availability of the various fractionated products used in Australia.

Thank you for giving due consideration to these submissions from the Society representing the major clinical end-users of plasma products.

Yours sincerely,

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President, HSANZ