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3 May 2006

The Secretary
Review of Australia's Plasma Fractionation Arrangements
Department of Health and Ageing
GPO Box 9848
MDP 47
Canberra ACT 2601
Australia

Dear Sir/Madam

Re: Plasma Fractionation Arrangements

The following comments are offered on behalf of both the NSW Immunoglobulin User Group and the Australasian Society of Clinical Immunology & Allergy (ASCIA).

1. **Annual supply**:

   Any new arrangements for supply of intravenous immunoglobulin (IVIG) in Australia should take into account the fact that the current supply does not meet current needs:

   - The current Australian IVIG supply managed by the NBA is based on guidelines[1] which are several years old, acknowledged to be out of date and currently under review. Based on current literature and utilisation experience it can be reliably anticipated that new guidelines will expand the range of approved indications for use of IVIG through the national system.

   - Many patients currently receiving IVIG for approved indications (AHMAC Category 1 conditions[1]) do not receive sufficient IVIG to meet their dose size and/or frequency requirements.

   - There are many patients, for example those with rare conditions, who require IVIG which is currently not available through the national supply because there do not exist publications of randomised control trials or other suitable evidence on which guidelines could be based. Currently the needs of these patients, most of whom are critically ill, must be met from personal or hospital budgets, an unfair imposition which does not have parallels for other blood products.

   The new arrangements should be devised to meet the current shortfall in the national supply for the above reasons and projections for increasing numbers of patients through population growth.

[1] http://www.nba.gov.au/PDF/ivig.pdf

2. **Rational use of IVIG**

   - To ensure that IVIG continues to be used appropriately it is recommended that there be investment in an audit process of distribution and use and the collection of clinical data (monitoring usage and clinical outcomes as well as documenting the pattern of cases for which requests for IVIG were not being approved). The feedback provided could assist government, professional bodies, health services and individual providers to use IVIG in accordance with the prevalent guidelines.

   - It is recommended that there be investment in education of providers regarding appropriate use of IVIG.

   The members of the committee recognise that while such processes might be an impost on available funds, these exercises are expected to prove to be cost effective.

3. **Source plasma**:

   Australia has one of the world's safest blood product records. Any contract for plasma products for this country should ensure that Australian donors are used wherever possible. Since Australia is currently not self-sufficient any future contractors should be required to use Australian volunteer donors for their fractionation processes.

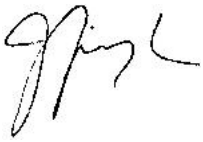
4. **Security of supply of IVIG**:

   The current contract for processing of locally collected plasma has been associated with batch failures, difficulties in meeting supply targets and inability to supply Australia's total requirements for IVIG. A future contract should address these issues. If plasma collected in Australia is to be processed overseas there must be contingencies for dealing with transport difficulties and a realistic national reserve, preferably of product manufactured from Australian source plasma.

5. **IVIG manufacturing process**: The Australian supply currently includes two liquid products both of which are sucrose free and have excellent safety and tolerability records. The manufacturer of IVIG in any future contract must be able to demonstrate that the product to be supplied meets or exceeds all the characteristics of the products currently available.

Please do not hesitate to make contact with me or any other members of the committee should you require further clarification, support documentation or any further advice on any of the matters under consideration.

Yours sincerely,



John B. Ziegler
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