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Department of Health and Ageing



Blood products for the treatment of haemophilia – priorities for government

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Objectives of the National Blood Agreement

- Provide an adequate, safe, secure and affordable supply of blood products, blood related products and services
- Promote safe, high quality management and use of blood products, blood related products and services



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Plasma Fractionation Review: AUSFTA commitments

Under the Australia-United States Free Trade Agreement (AUSFTA), the Commonwealth agreed to:

- Review Australia's arrangements for the supply of plasma fractionation services, to conclude by 1 January 2007
- On completion of the review, recommend to States and Territories that future fractionation arrangements be consistent with the AUSFTA Government Procurement tender processes



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Plasma Fractionation Review: Terms of Reference

1. Examine projected demand for plasma products and impacts on supply of plasma and fractionation services
2. Identify requirements needed to ensure safety, quality and efficacy
3. Identify issues arising as a result of any increase in competition for the provision of fractionation services
4. Assess issues under ToR (3) against the criteria of safety, quality, efficacy, security of supply, and the potential impact on expenditure under the National Blood Agreement



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Plasma Fractionation Review: The review process

- Review announced in February 2006
- Ministerially-appointed committee, chaired by Philip Flood AO
- Extensive consultations in Australia and overseas
- Review Report released in December 2006



Plasma Fractionation Review: Product demand forecasts

The Review made the following forecasts of demand for key plasma products.

Clotting Factors

- 11.6% average annual growth rate in Factor VIII (both plasma derived and recombinant combined) over next 10 years. Modest growth projected for pdFVIII.
- Modest increase in future demand for plasma derived Factor IX.

IVIg

- By 2015-16 demand for IVIg will be between 2985 and 3687 kg per annum (cf. 1667 kgs consumed in 2005-06). 8% growth per annum estimated.

Albumin

- Average of estimates in demand for albumin was ~5% growth per annum.
- Increased use of albumin expected in surgical treatment of cardiovascular disease



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Plasma Fractionation Review: Future supply of plasma in Australia

Key issue - increasing volume of plasma collected in Australia to meet demand for fractionated products

- Over the last 10 years, demand for IVIg has been the driving factor in the plasma products sector
- Since 2003- 04, domestic IVIg supply has been supplemented with imported IVIg to meet demand
- Australia collects ~16 litres of plasma for fractionation per 1000 population.
- This is relatively high by world standards, but keeping pace with forecast demand presents a challenge



Plasma Fractionation Review: Conclusions of the review

Offshore fractionation of Australian plasma would involve:

- significant initial start-up expenditure
- extensive transitional planning
- longer lead times
- extensive contingency plans and risk mitigation plans
- investment associated with registration, compliance and approval processes



Plasma Fractionation Review: Outcomes of the review

- The Minister for Health and Ageing released the Review Report in December 2006
- Governments did not reach consensus on the question of a change to fractionation arrangements – Australia's current fractionation arrangements will continue
- In July 2007, Health Ministers agreed to a workplan to address other issues identified in the review recommendations



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Current priorities (1):

- Implement workplan to address PFR recommendations
 - Analysis of product demand trends and donation issues
 - Evaluate supply planning and budgeting
 - Uniform legislative provisions on minimum age to donate blood
 - Support appropriate use of IVIg and other blood products
 - Ongoing work includes monitoring of prices, industry and clinical developments, and risk management and mitigation.



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Current priorities (2):

- Criteria for Use of IVIg
- Year of the Blood Donor 2009
- ABDR redevelopment project



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Questions?