National Supply of Products for Bleeding Disorders in Australia

Stone, Michael
National Blood Authority (NBA) Australia

A key objective for the National Blood Authority (NBA) is to ensure an adequate, safe, secure and affordable supply of blood and blood products for clinical purposes in Australia. To achieve this, the NBA undertakes national tendering, supply planning and contract management for the list of blood products which governments have agreed to fund. The NBA receives funding contributions from Commonwealth, state and territory governments and uses these funds to pay for the products supplied into the Australian health system under NBA supply contracts.

From 2003, the supply arrangements managed by the NBA have included:

- Plasma derived clotting factor products sourced from CSL Limited/CSL Behring (Australia) Pty Ltd, manufactured from domestically collected plasma. The clotting factor products supplied under this contract are pdFVIII (AHF, Biostate), pdFIX (MonoFIX), prothrombin complex concentrate (Prothrombinex).
- Imported recombinant and plasma derived clotting factor products, sourced through contracts established by tender from suppliers outside Australia. The primary products are rFVIII and rFIX. NovoSeven (rFVIIa), FEIBA, pdFXI, pdFVXIII, pdFVII, Protein C are also purchased as imported products.

Through recurrent cycles of tendering and contracting for imported clotting factor products the NBA has established arrangements which provide assured, continuous supply of these products and has maintained or improved value for money over time. Competitive procurement from multiple suppliers, where available, has also maintained competitive pressure on price and performance levels both at the time of tendering and through the term of the resulting contracts.

2003-2006

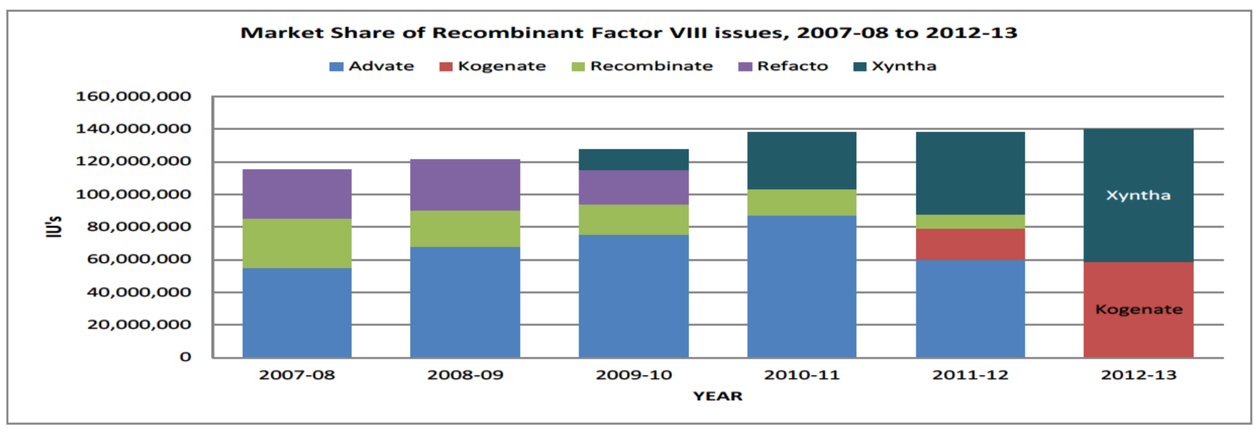
- National contracts had been tendered for prior to the commencement of the NBA, including for the following products:
  - rFVIII: Advate, Recombinate
  - rFIX: BeneFIX
- In 2004 governments announced a decision to fund increased access for recombinant FVIII and FIX products where appropriate for all Australians with haemophilia. The NBA closely managed the supply contracts for imported rFVIII and rFIX to ensure that the resulting increased demand could be met.
- By 30 June 2006 70% of factor VIII and 62% of factor IX demand was being met by recombinant products.

2006-2011

- The NBA decided not to exercise available contract options and undertook a new tender process for supply from 1 July 2006. Based on the outcomes of a supply risk analysis, the tender process sought a second supplier for rFVIII to increase supply security. The products available following this tender included:
  - rFVIII: Advate, Recombinate, Refacto AF (subsequently changed to Xyntha)
  - rFIX: BeneFIX
- At the end of the initial term of the contracts in 2009, a decision was made to extend the contracts, to 2011. Price negotiation at the time of extension provided improved value for money.

2011-2014

- The NBA undertook a national tender process for supply from 1 July 2011. The products available following this tender were:
  - rFVIII: Xyntha, Kogenate FS
  - rFIX: BeneFIX
- The tender lead to substantially reduced prices and expenditure savings for rFVIII.
- An outcome of the tender was cessation of the previous contract for Advate and Recombinate, with the result that 75% of patients who had been receiving treatment with those products were required to change to a different product over a transition period of 12 months.



From 2014

- In 2013 the NBA decided not to exercise available contract options and undertook a new tender process for supply from 1 July 2014.
- Substantial price reductions are expected to result from the tender, resulting in savings of 20% or more of previously forecast expenditure.
- At the time of writing the tender outcomes had not been announced.
- In addition to this tender, in May 2014 funding governments approved the addition of fibrinogen concentrate for patients with congenital fibrinogen deficiency to the NBA supply arrangements. This decision is expected to be implemented by 1 July 2014.

Tender decision making

The NBA seeks to obtain information broadly to inform each decision on whether to extend contracts or to retender, and how tenders should be designed:

- Clinical and stakeholder consultations: e.g. emerging clinical practice and demand trends, clinical/patient value of various product characteristics, value-add services
- Industry consultations: e.g. potential price, contract terms to increase value, supply security options, service offerings, potential new products
- General industry intelligence
- Where questions of policy arise, the NBA seeks guidance from funding governments through the Jurisdictional Blood Committee.

Based on feedback, tender criteria include aspects of value for clinicians or patients, such as technical product characteristics, ease and reliability of use, storage conditions, and evidence based aspects which objectively support clinical acceptability.

Within appropriate probity rules, the NBA seeks the involvement of clinical and scientific experts and patient representatives in tender evaluation committees and processes.

Supply security measures

NBA contracts include a range of measures to manage against supply security risks:

- multiple suppliers (where available, and where there is sufficient demand)
- in-country reserve holdings, and access to global supply reserves
- preferred customer arrangements and alternative product obligations
- performance guarantees and financial undertakings

Service and performance requirements

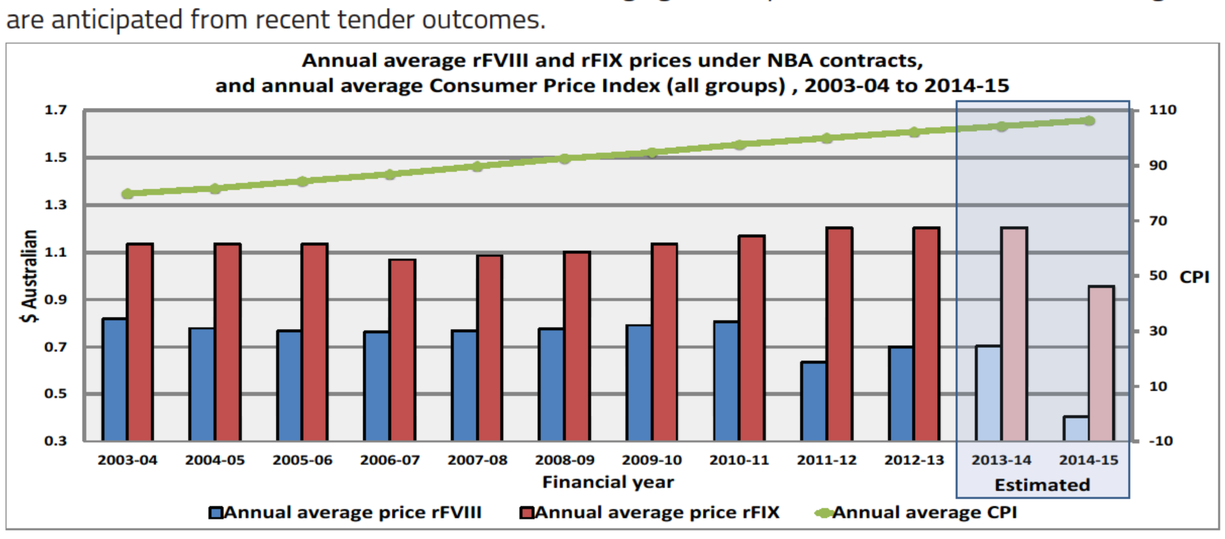
NBA contracts include performance obligations on suppliers on matters such as product ordering, distribution and delivery; product support; and supplier responsiveness to customer feedback. Since 2011 the contracts have included requirements in relation to the home delivery service provided for many patients.

Failure against key performance indicators may have financial consequences for suppliers.

Suppliers are required to retain documentary records to substantiate all orders and deliveries for products paid for under NBA contracts, and these records are subject to sample auditing on a quarterly basis. Health services or other recipients of products may at times be asked to provide copies of records to assist in NBA audits of supplier invoices.

Value for money

NBA tendering for clotting factors, particularly for rFVIII and rFIX, has provided value for money and material savings for governments by ensuring that changes in average product prices have, in general, remained less than the rate of inflation. Given changing industry conditions more material savings are anticipated from recent tender outcomes.



Future products

A number of new clotting factor products are in development by a number of companies. The NBA's 2014 tender did not allow for any new product varieties due to significant uncertainty about timing and scope of product registration, clinically relevant product characteristics, availability and security of supply, price, availability of competitive market, and likely clinical utility and choice. Much greater information will be needed on such matters before policy, funding and access decisions by governments, and any subsequent tendering decisions by the NBA, can take place.

In the 10 years since establishment the NBA has undertaken a number of tender rounds for clotting factor products, and has developed an approach to tendering which provides reliable and secure supply of products and improved value for money for governments while at the same time responding to stakeholder input and requirements. Going forward, this approach will provide a sound basis to support decision making in relation to a range of forthcoming new varieties of clotting factor products.

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Michael Stone
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