

**Distribution:** Public Hospitals

**Subject:** High cost, low use blood products.

**Purpose:** To clarify responsibility for meeting the cost of such products.

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### 1. Background

There has been a steady growth in the availability of high cost blood products, many of which are synthetically derived and not normally available in Australia. This appears to have led to an increased practice by hospitals and clinicians to seek Commonwealth and/or State Government financial support to purchase any blood product regardless of circumstances of cost.

In special circumstances, the cost of some of these products can be met under Commonwealth guidelines.

A number of relatively high cost, low use, imported blood products may be obtained for use by individual patients under the Therapeutic Goods Administration's (TGA) Special Access Scheme (SAS). Products include Factor IX, Factor XI and other products determined from time to time.

Outside these situations the cost of blood products is the hospital's responsibility, as is the case with most other drugs.

### 2. Commonwealth Guidelines

In 1991 the Commonwealth introduced guidelines to fund the purchase of Factor IX in limited circumstances where surgery was required. In 1993 the guidelines were amended to include Factor XI.

The guidelines recognised the need for greater flexibility in the availability of some blood products given special circumstances and the prohibitive cost to patients who need treatment.

The Commonwealth's eligibility criteria for such financial assistance are:

- the patient is required to have SAS approval from the TGA;
- the patient is required to provide a signed indemnity form to the Commonwealth against a lack of safety and/or efficacy in the product; and

- the product is to be used on a one off basis for a surgical procedure which would have the strong likelihood of improving the quality of life and economic participation of the patient.

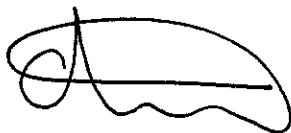
As the guidelines clearly contemplate a prior SAS approval for planned surgery, the guidelines apply only to *Category B* and *C* SAS approvals. *Category A* SAS is essentially ex post facto notification of emergency treatment in life threatening situations.

## 2. Hospital Responsibility

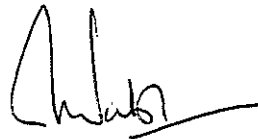
Use of blood products which falls outside these guidelines is clearly the responsibility of the hospital and any cost must be met within established budgets.

## 3. Future Developments

It is acknowledged that there is a need to develop a comprehensive policy on the use and funding of blood products across all levels of Government. This matter is being addressed by the Australian Health Ministers Advisory Council.



**DR C W BROOK**  
DIRECTOR, PUBLIC HEALTH



**DR MICHAEL WALSH**  
DIRECTOR ACUTE HEALTH SERVICES