7 July 1993

Proposed Revised Specification for Clotting Factor Concentrates

Purpose

The proposed revision in the specifications for the locally used clotting factor concentrates addresses the following issues related to their use :

(i) To eliminate the potential for transmitting infectious agents

(ii) To minimise any undesirable immune effects to the HIV-infected hemophiliac patients so as to stabilise their condition.

Proposed Revised Specification

2. For clotting factor concentrates derived from human donors, the following criteria should all be satisfied :

(i) The product should have been prepared from plasma units which have been individually tested and found to be negative for HbsAg, HIV and HCV.

(ii) The potential for transmission of infectious agents should have been eliminated by proven effective methods, either solvent detergent treatment, super dry heating or pasteurization.

(iii) The product should be of high purity, using separation precedures involving column chromatographic steps in its preparation.

3. These recommendations will be conveyed to the Department of Health, Hospital Authority and other interest parties for reference.

Monitoring

4. It is recommended that the following areas be monitored so that appropriate revision to the specifications be made when required :

(i) The relative safety and efficacy of recombinant clotting factor concentrates as compared with those derived from human sources.

(ii) The relative advantage of pure versus "ultra"-pure (Prepared by immunoaffinity chromotography) clotting factor concentrates in stabilising the conditions of HIV-infected haemophiliac patients.

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