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Legislative Council Panel on Health Services

Control and Use of Factor VIII (Antihaemophilic Factor) Products in Hong Kong

Purpose

This paper aims to brief Members on the quality and the control mechanism of Factor VIII products used in Hong Kong.

Background

2. Haemophilia is a medical term given to all blood disorders resulting from an inherited deficiency of a blood clotting factor. Many forms exist but the best known is Haemophilia A, which is caused by Factor VIII deficiency. Severely affected patients have less than 1% Factor VIII activity in their blood and are prone to developing spontaneous bleeding. Treatment is by the administration of Factor VIII to prevent and/or to stop the bleeding. Factor VIII is normally obtained from the pooled blood of a large number of blood donors. Since the mid-1990s, Factor VIII manufactured by recombinant biotechnology has also been available.

3. Acquired immune deficiency syndrome (AIDS) was first described as a syndrome in 1981. Its association with haemophilia patients was first reported in 1982. The causative agent of AIDS, the human immunodeficiency virus (HIV), was not identified until 1983, and the antibody test to detect the presence of HIV was only licensed in March 1985.

4. To safeguard blood products against contamination with HIV, the following measures have been introduced: (a) donor deferral and screening, (b) heat treatment and other means of viral inactivation, and (c) use of alternative therapy.

Introduction of Heat Treatment and Other Means of Viral Inactivation

5. The use of heat-treated Factor VIII was piloted in 1984, leading to the recommendation of its general use towards the end of the year. The First International AIDS Conference was held between 15 and 17 April 1985, after which the WHO Consultation Report recommended that the risk of transmission of HIV by Factor VIII products could be reduced through treatment by heat or by other proven methods of inactivation. The use of such treated product was recommended. By May 1985, United Kingdom, Germany and Italy had changed to the heat-treated products.

6. In the ensuing years, progress has been made in the development of other means of inactivation. Examples are solvent/detergent treatment, affinity chromatography with monoclonal antibodies. Recombinant technology has also been applied in the production of Factor VIII that could be theoretically free from infection.

HIV Situation in Haemophilia in Hong Kong

7. The first case of HIV infection in haemophilia in Hong Kong was reported in 1984. As at the end of March 2003, a total of 256 haemophiliacs have been tested for HIV antibody, of which 64 had tested positive (25%). Twenty have progressed to AIDS and 15 were known to have died. The infection occurred before heat-treated clotting factor concentrates became available.

8. Of the 64 cases of HIV positive haemophiliacs, all except one were diagnosed in the public service – Queen Mary Hospital (35), Queen Elizabeth Hospital (19) and Princess Margaret Hospital (9). Currently 27 patients are under care of the Department of Health and Hospital Authority, where antiretroviral therapy is provided to those clinically indicated.

9. Against the background of the entire HIV situation in Hong Kong, as at the end of March 2003, a cumulative total of 2,067 cases of HIV infection have been reported to the Department of Health, of which 627 has progressed to AIDS. Therefore, haemophilia accounts for 3.2% of the reported infections. So far, sexual contact has remained the commonest mode of HIV transmission, accounting for 90% of all reports with sufficient information for classification. Last year, 260 HIV infections and 53 AIDS cases were reported.

Regulatory Control of Factor VIII Products in Hong Kong

10. The Pharmacy and Poisons Ordinance (Cap. 138) stipulates that pharmaceutical products must be registered with the Pharmacy and Poisons Board (the Board) before sale in Hong Kong. Only pharmaceutical products, which meet the required standards of safety, efficacy and quality, will be approved for registration.

11. Blood products, including Factor VIII products, fall within the meaning of pharmaceutical products under the Pharmacy and Poisons Ordinance and are required to be registered with the Board. Before an application for registration is approved, the manufacturer is required to provide information on, among other things, the manufacture, purification and quality control processes employed in relation to the product. Although neither the World Health Organization, nor the European Union, nor the US Food and Drug Administration have produced guidelines or standards related to the quality requirements of Factor VIII products, the international scientific community has agreed, and manufacturers have adopted, the following measures:

(a) screening of blood donors for the absence of, among other viruses, HIV;
(b) testing of each unit of donated blood for the absence of these viruses;
(c) testing of the pooled blood for the absence of these viruses;
(d) use of one or more of the following methods during manufacturing to ensure the elimination of these viruses if still present: heat treatment, the solvent/detergent method, and the monoclonal antibody method; and
(e) testing of the finished Factor VIII product.

These measures have formed the basis for the approval of Factor VIII products for registration and use in Hong Kong.

12. Under the Import and Export Ordinance (Cap. 60), a separate import licence is required before each consignment of any pharmaceutical product (including Factor VIII product) can be imported. An import licence will only be granted if:

(a) the product to be imported has been registered;
(b) the importer is the company to whom the registration certificate of the product was issued; and
(c) the importer is a registered importer under the Pharmacy and Poisons Ordinance (and therefore meets the registration requirements, e.g. adequate storage facilities, suitable record- keeping of transactions, and establishment of a recall system of the pharmaceutical products distributed).

Department of Health
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