Annex B

Regulatory framework for blood donors selection

Examples in selected countries

Australia — Statutory instruments require donors to make a declaration in a prescribed form. For example, the Health (Infectious Diseases) (Donation Statement) Regulations 1999, made under the Health Act 1958, in the State of Victoria; the Blood Contaminants Act 1985 in South Australia; and the Blood Donation (Limitation of Liability) Act of 1985 in Western Australia. These declarations include a direct question on male-to-male sex.

Statutory instruments also impose penal sanctions on donors for false or misleading declarations. For example, the Human Tissue (Amendment) Act 1985 in New South Wales imposes a penalty of A$5,000 or one-year imprisonment, or both, for a false or misleading declaration.

US — The Food and Drug Administration (FDA) is the regulatory arm of the Public Health Service, responsible for the regulation of blood and blood products as well as the licensing and inspection of blood centers and blood product manufacturers. If regulations and licensing agreements were breached, the FDA could issue warning letters to suspend or revoke the license. Guidelines on blood safety are issued upon the recommendation of the FDA's Blood Products Advisory Committee. Although these guidelines do not have regulatory power, they are generally followed by most blood transfusion services in US.

The FDA's donor deferral policy in December 1984 deferred males who had had sex with more than one male (MSM) since 1979 from giving blood. In September 1985, MSM was redefined to include men who have had sex with another man, even once, since 1977. Guidelines to blood establishments recommend asking direct questions concerning risk behaviours for HIV infection but not requiring written statement from prospective donors.

UK — There is no regulatory control on blood donor selection although all regional transfusion centers in the UK are required to adhere to guidelines issued by the Department of Health (formerly the Department of Health and Social Security before 1988). The Department regularly issues leaflets on AIDS and blood donation to emphasize screening of donors, but transfusion services do not require prospective donors to make a written or oral declaration that they had not been at risk of contracting HIV.

Canada — There are no direct regulations on collecting, processing, and distributing whole blood or plasma separated from whole blood. However, the regulations made under the Food and Drugs Act, a Federal statute, apply to blood establishments who, as distributors of blood, fall within the general definition of a "manufacturer'. Manufacturers are required to establish and follow procedures that will preclude, or at least minimize, the collection of infected source materials and reduce the probability or extent of contamination of any pooled biological materials.

China — Under the blood donation law: "中華人民共和國獻血法", the Ministry of Health has issued regulations in 1998, "血站管理辦法", which prescribe the criteria for eligible blood donors ("獻血者健康檢查標準").