

WORLD TRADE ORGANIZATION

RESTRICTED

G/TBT/Notif.96.12

29 January 1996

(96-0331)

Committee on Technical Barriers to Trade

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	Member to Agreement notifying: <u>SWITZERLAND</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2.	Agency responsible: Federal Office of Public Health
3.	Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4.	Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Blood, blood components and transplants
5.	Title and number of pages of the notified document: Ordinance Concerning the Control of Blood, Blood Components and Transplants
6.	<p>Description of content: The Ordinance is valid for all transactions involving blood, blood products and transplants, with the exception of those areas in the manufacturing, storage, registration and batch release of stabile blood products which are already controlled by law, and products which are not intended for use in man (in-vitro diagnostics).</p> <p>The Ordinance covers the requirements for granting licences, and defines the precautions to be taken when dealing with blood, blood products and transplants, such as the criteria governing acceptability of blood donors, the requirements for conducting tests for infectious agents, labelling, documentation and storage requirements, and the procedures and documentation required for handling product complaints and recalling defective products.</p> <p>A fundamental requirement is established to obtain and manufacture blood and labile blood products according to the rules of Good Manufacturing Practice, as based upon the rules of the European Council, the WHO and the Dutch Red Cross.</p>

7.	<p>Objective and rationale: The Federal Resolution concerning the control of blood, blood products and transplants (the parliamentary consultation is expected to be concluded in March 1996).</p> <p>The Resolution of the Federal Council of 9 November 1994 concerning the future Medicines Control Act.</p>
8.	<p>Relevant documents: Revised Edict: the Ordinance of 9 April 1986 concerning the prevention of transmission of dangerous infective diseases by means of blood and blood products.</p>
9.	<p>Proposed date of adoption and entry into force: 1 July 1996</p>
10.	<p>Final date for comments: 25 March 1996</p>
11.	<p>Texts available from: National enquiry point [X] or address and telefax number of other body:</p>