GENERAL AGREEMENT ON

TARIFFS AND TRADE

RESTRICTED

TBT/Notif.92.260
24 September 1992
Special Distribution

Committee on Technical Barriers to Trade

NOTIFICATION

The following notification is being circulated in accordance with Article 10.4.

1. Party to Agreement notifying: SWITZERLAND

2. Agency responsible: Federal Office of Public Health

3. Notified under Article 2.5.2 [X], 2.6.1 [], 7.3.2 [], 7.4.1 [], other:

4. Products covered (HS or CCCN where applicable, otherwise national tariff heading):

In vitro diagnostic agents i.e. products which are used for the diagnosis of infectious diseases on clinical specimen.

5. Title: Ordinance on In Vitro Diagnostic Agents

6. Description of content:

- In vitro diagnostic agents for direct or indirect diagnosis of infectious diseases caused by the Human Immunodeficiency Virus (HIV), the Hepatitis B virus (HBV) or the Hepatitis C Virus (HCV) may only be marketed with prior authorization of the Federal Office of Public Health (pre-market approval). Other in vitro diagnostic agents must be reported to the Federal Office of Public Health before being brought onto the market for the first time (notification).

- In vitro diagnostic agents may only be marketed in Switzerland if they are suitable for the intended application, if the presentation complies with the relevant provisions and if the manufacturer has established a quality assurance system and can ensure consistent manufacture and quality controls.

- Public advertising for in vitro diagnostic agents is prohibited. Release to the public is only exceptionally permissible and subject to authorization by the Federal Office of Public Health.

7. Objective and rationale: Currently, in vitro diagnostic agents are subject to the Ordinance of 23 August 1989 on Immunobiological Products. This Ordinance implements the EC Directives 65/65, 75/318, 75/319, 78/25, 87/22, 89/342, 89/381, 91/356, 92/25, 92/26, 92/27 and 92/28. As these directives do not regulate in vitro diagnostic agents, these products shall be separated out from the Ordinance on Immunobiological Products and regulated in a separate ordinance. This will further clarify and facilitate the possible implementation of the future EC Directive on in vitro diagnostic agents.

8. Relevant documents: The Ordinance is based on Article 30 of the Law on Epidemics of 18 December 1970
9. Proposed date of adoption and entry into force: 1 January 1993
10. Final date for comments: 2 November 1992
11. Texts available from: National enquiry point [X] or address of other body: