

GENERAL AGREEMENT ON

TARIFFS AND TRADE

RESTRICTED

TBT/Notif.92.261
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: <u>SWITZERLAND</u>
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): Immunobiological products which are utilized for the prevention, diagnosis or treatment of infectious diseases in patients
5. Title: Ordinance on Immunobiological Products
6. Description of content: The ordinance foresees various control procedures for immunobiological products: (a) an authorization for the manufacture and import of immunobiological products from third countries; (b) an authorization for the wholesale distribution of immunobiological products (if there is no valid authorization under (a)); (c) registration before marketing; (d) an import permission for every single consignment; (e) an authorization for every single lot (batch release). The ordinance also includes provisions on advertising for immunobiological products and general release.
7. Objective and rationale: The reason for the revision is the implementation of 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.

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8. Relevant documents: The planned ordinance will replace the current decree of 23 August 1989 on immunobiological products. It is based on article 30 of the Law on Epidemics of 18 December 1970 and on the EC Directives 65/65, 75/318, 75/319, 78/25, 87/22, 89/342, 89/381, 91/356.

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: