NOTIFICATION

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

1. Party to Agreement notifying: **SWITZERLAND**


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.

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: