

GENERAL AGREEMENT ON

TARIFFS AND TRADE

RESTRICTED

TBT/Notif.92.391

21 December 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>FINLAND</u>
2. Agency responsible: Ministry of Social Affairs and 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): Medicinal products
5. Title and number of pages of the notified document: Partly Revision of the Drug Statute (of 24 July 1987/693) (available in Finnish, 3 pages)
6. Description of content: It is proposed that a holder of a wholesaling authorization granted by another State belonging to the European Economic Area (EEA) in accordance with Community provisions could be engaged in the distribution of medicinal products without a specific authorization as far as the activity is carried out without fixed premises in Finland. The wholesaler referred to above would have to give a notice to the Ministry of Social Affairs and Health prior to the distribution activity. A responsible director of a wholesaler shall be obliged, in the case of medicinal products coming from third countries, to secure that each production batch has undergone in Finland or in another country belonging to the EEA all the tests or checks necessary to ensure the quality of medicinal products in accordance with requirements of marketing authorization. Medicinal products imported from the countries belonging to the EEA must be accompanied by a document that makes it possible to ascertain that appropriate quality controls have been carried out. Time-limits will be set up for procedures for granting marketing authorization of medicinal products and for granting authorizations to manufacture medicinal products or to carry out pharmaceutical wholesaling business equal to provisions in the EEC Directives 65/65/EEC Article 7, 75/319/EEC Article 20 and 92/25/EEC Article 4.

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7. Objective and rationale: EEA Agreement
8. Relevant documents: Directives 65/65/EEC, 75/319/EEC, 92/25/EEC
9. Proposed date of adoption and entry into force: Entry into force of the EEA Agreement
10. Final date for comments: 4 January 1993 The document will be issued in the Statutes of Finland.
11. Texts available from: National enquiry point [X] or address of other body: