

GENERAL AGREEMENT ON

RESTRICTED

TBT/Notif.92.283

6 October 1992

Special Distribution

TARIFFS AND TRADE

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: National Agency for Welfare and Health/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): Medicines
5. Title: Act on the Revision of the Medicines Act (of 10 April 1987/395) (available in Finnish, 5 pages).
6. Description of content: The provisions in the Medicinal Act concerning so called semi-medicinal products will be abolished. Such traditionally used medicinal products whose constituent or constituents originate in herbals, animals, bacteria or minerals could be authorized deviating from the ordinary requirements relating to efficacy and safety in accordance with the provisions of EC-directive 87/21/EEC. Homeopathic and anthroposophical medicinal products will be subject to a simplified registration procedure in accordance with the provisions which are prepared in the EEC. The provisions with regard to the authorization to engage in activity as a wholesaler in medicinal products will be amended by a provision according to which the recognition of the authorization granted by another State within the European Economic Area will be enacted in Statute (of 24 July 1987/693).
7. Objective and rationale: Agreement on EEA
8. Relevant documents: Directives 65/65/EEC, 87/21/EEC, 92/25/EEC, 92/28/EEC and proposals of the Commission COM(90)72 final-SYN251, COM(90)72 final-SYN252, COM(91)313 final-SYN251, COM(91)313 final-SYN252
9. Proposed date of adoption and entry into force: Entry into force: when the agreement on EEA shall be operative.
10. Final date for comments: 20 November 1992
11. Texts available from: National enquiry point [X] or address of other body: