

GENERAL AGREEMENT ON

RESTRICTED

TBT/Notif.92.284

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 (10 April 1987/395) and the Sickness Insurance Act (of 4 July 1963/364) (available in Finnish and Swedish, 4 pages).
6. Description of content: The definition of medicinal product will be amended to correspond to the definition in Article 1 of EC-directive 65/65/EEC. The definition of proprietary medicinal product will be amended in order to enable so called parallel import. The precondition of a reasonable price for obtaining an authorization to place a proprietary medicinal product on the market will be abolished. The proprietary medicinal product will be covered by the sickness insurance system only if the wholesale price of the medicinal product is appreciated to be reasonable. An authority will be established to decide that. An authorization to place a proprietary medicinal product on the market can be applied for by the person responsible for placing that product on the market. The authorization shall be valid for five years and renewable for five-year periods. The provisions of the prohibition of the manufacture, import and supply of the medicinal product and the provisions of the suspension of the authorization to place a proprietary medicinal product on the market will be amended to correspond to the provisions of the EC-directives 65/65/EEC and 75/319/EEC.
7. Objective and rationale: Agreement on EEA
8. Relevant documents: Directive 65/65/EEC, 75/319/EEC, 81/851/EEC, 85/432/EEC

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9. Proposed date of adoption and entry into force:

Entry into force: when the agreement of EEA shall be operative

10. Final date for comments: 20 October 1992

11. Texts available from: National enquiry point or address of other body: