

GENERAL AGREEMENT ON

TARIFFS AND TRADE

RESTRICTED

TBT/Notif.93.153

6 May 1993

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>AUSTRIA</u>
2. Agency responsible: Federal Ministry of Health, Sports and Consumer Protection
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): Pharmaceutical specialities containing laxatively-acting anthrachinon derivatives; pharmaceutical specialities containing antiarrhythmics of Classes Ia, Ib, Ic or III according to Vaughan Williams; pharmaceutical specialities containing paracetamol or its compounds.
5. Title and number of pages of the notified document: Ordinance of the Federal Minister of Health, Sports and Consumer Protection Concerning Certain Data of Specialist Information and Consumer Information for the Use of Certain Pharmaceutical Specialities (7 pages).
6. Description of content: According to the current standard of scientific knowledge it is decreed that the passages "fields of application", "side-effects", "contra-indication" and "special warnings to ensure safe use" of the specialist information and the consumer information for the use of pharmaceutical specialities mentioned above in Section 4 must include additional information.
7. Objective and rationale: To ensure the safety of medicines and to prevent harmful effects on human health.
8. Relevant documents: Austrian Federal Law Gazette No. 185/1983 Austrian Federal Law Gazette No. 748/1988 Austrian Federal Law Gazette No. 45/1991
9. Proposed date of adoption and entry into force: 1 July 1993
10. Final date for comments: 30 June 1993
11. Texts available from: National enquiry point [X] or address of other body: