

WORLD TRADE ORGANIZATION

G/TBT/N/CHE/5
13 June 2001

(01-2919)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	Member to Agreement notifying: <u>SWITZERLAND</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2.	Agency responsible: Federal Office of Public Health Name and address (including telephone and fax numbers, e-mail and web-site addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: State Secretariat for Economic Affairs
3.	Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4.	Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Medicinal products
5.	Title, number of pages and language(s) of the notified document: Ordinance on Authorizations in Relation to Medicinal Products
6.	Description of content: The ordinance regulates both the requirements and obligations that must be fulfilled by a company dealing with medicinal products and the control of this company by the competent health authorities. The following require authorizations: manufacture, wholesale trade, import and export of medicinal products, commerce with medicinal products abroad and the taking of blood for transfusions or for the production of medicinal products. In the first chapter of the ordinance, its scope and important concepts are defined. Chapter 2 regulates separately the requirements for the granting of various types of establishment authorizations. The third chapter regulates the authorization processes. The authorization for the individual import of a particular medicinal product is regulated in Chapter 4. Details of the enforcement of the ordinance are to be found in Chapter 5. Lastly, Chapter 6 contains the concluding regulations
7.	Objective and rationale, including the nature of urgent problems where applicable: In order to protect the health of humans the ordinance ensures that marketed medicines and medicinal products are of a high quality, safety and efficacy and will be used correctly
8.	Relevant documents: Federal Medicines Act, FF 2000 5689 http://www.admin.ch/ch/f/ff/2000/5689.pdf .
9.	Proposed date of adoption: Autumn 2001 Proposed date of entry into force: 1 January 2002
10.	Final date for comments: 31 July 2001
11.	Texts available from: National enquiry point [X] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body: