

WORLD TRADE ORGANIZATION

G/TBT/N/CHE/4
7 June 2001

(01-2798)

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 edicinal products, ordinance on the requirements for the marketing authorisation of medicinal products.
6.	Description of content: The ordinances regulate: the requirements for the marketing authorization, the medicinal product's characteristics and information, the criteria for classifying the sales category of the medicinal product, post-marketing surveillance, the requirements for duty of reporting (pharmacovigilance), the Principles of Good Laboratory Practice, batch release.
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 2001
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: