

# WORLD TRADE ORGANIZATION

G/TBT/Notif.99/644  
22 December 1999

(99-5528)

## Committee on Technical Barriers to Trade

### NOTIFICATION

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

1.	<b>Member to Agreement notifying:</b> <u>CZECH REPUBLIC</u> <b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b>
2.	<b>Agency responsible:</b> Ministry of Health <b>Agency or authority designated to handle comments regarding the notification shall be indicated if different from above:</b>
3.	<b>Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
4.	<b>Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Pharmaceuticals (HS Chapter 30)
5.	<b>Title, number of pages and language(s) of the notified document:</b> Amendment to the Act No. 79/1997 Coll., on Pharmaceuticals and Amendments to Some Related Acts (in Czech)
6.	<p><b>Description of content:</b> Items related to the process of registration of medicinal products – simplification of procedure, adoption of the EU time limit, possibility of recognition of foreign expertise, classification of the product for general sale during registration process, data exclusivity period of 6 years related to the first authorisation in the EU, notification procedure of 30 days for Type I variations, definition of Urgent Safety Restriction, possibility of use of non-registered products (named patient use).</p> <p>Items related to clinical trials – definitions of adverse drug reaction and events used according to the International Conference on Harmonisation (ICH), more detailed principles of good clinical practice.</p> <p>Blood banks and collection centres in GMP regime and supervised by drug regulatory authority.</p> <p>Establishing of responsible person in a pharmacy.</p>
7.	<b>Objective and rationale, including the nature of urgent problems where applicable:</b> Implementations of further relevant parts of Acquis Communautaire, especially provisions included in Directive 65/65/EEC, 89/381/EEC, 91/356/EEC, 92/26/EEC and Regulations 541/95 and 542/95 as amended. Relevant orders decrees will describe these issues more in details.
8.	<b>Relevant documents:</b> Act 79/1997 Coll.

<b>9.</b>	<b>Proposed date of adoption:</b> <b>Proposed date of entry into force:</b> 30 June 2000
<b>10.</b>	<b>Final date for comments:</b> 28 February 2000
<b>11.</b>	<b>Texts available from: National enquiry point [X] or address, e-mail and telefax number of the other body:</b>