

# WORLD TRADE ORGANIZATION

G/TBT/Notif.99.451

3 September 1999

(99-3674)

## 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>DENMARK</u> <b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b>
2.	<b>Agency responsible:</b> The Danish Medicines Agency Frederikssundsvej 378 2700 Brønshøj <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> Medicinal products having a marketing authorization
5.	<b>Title, number of pages and language(s) of the notified document:</b> Executive Order on the Labelling etc. of Medicinal Products (17 pages, available in Danish)
6.	<b>Description of content:</b> This draft is primarily a structural and linguistic amendment to the Executive Order on the Labelling of and Package Leaflets in Medicinal Products (Order No. 314 of 18 May as amended by Order No. 245 of 7 April 1994 and Order No. 641 of July 1995). However, the draft also contains an implementation of the Commissions guideline on excipients from June 1997 ("Guideline on the excipients in the label and package leaflet of medicinal products for human use") and a partial repeal of Annex No. 3 to the present executive order.
7.	<b>Objective and rationale, including the nature of urgent problems where applicable:</b> The main objective is to make a clear communication of the regulations on labelling of and package leaflets in medicinal products - and to implement the Commissions guideline from 1997.
8.	<b>Relevant documents:</b> The Consolidated Medicinal Products Act, art. 6(2) and 44(2) (basic act)
9.	<b>Proposed date of adoption:</b> <b>Proposed date of entry into force:</b> } Within 4-6 months
10.	<b>Final date for comments:</b> October 1999
11.	<b>Texts available from: National enquiry point [ ] or address, e-mail and telefax number of the other body:</b>  Dansk Standard Kollegievej 6 2920 Charlottenlund