NOTIFICATION

The following notification is being circulated in accordance with Article 10.4

1. Party to Agreement notifying: **SWEDEN**

2. Agency responsible: Ministry of Health and Social Affairs/1983 Drugs Commission

3. Notified under Article 2.5.2 [X] 2.6.1 □ 7.3.2 □ 7.4.1 □ Other:

4. Products covered (CCCN where applicable, otherwise national tariff heading):
   
   | Drugs (CCCN Chapter 30) |

5. Title:

   Official Report (SOU 1987:20) by the 1983 Drugs Commission
   
   (A Summary in English is available)

6. Description of content:

   The report contains a draft Act on drugs which if adopted, will replace the Ordinance on drugs (Swedish Code of Statute, SFS 1962:701). In the 6th paragraph it is suggested that drugs shall be registered under "substance names" which combines the generic name of the active substance included in the drug with the name of the manufacturing company. If there is no generic name or if the generic name is not adequate the "substance name" will be expressed in another way which as much as possible gives equivalent information about the drug.

   The report also contains proposals regarding labelling of drugs and confidentiality in connection with the approval of drugs. These proposals have not yet been expressed as draft regulations. Drug packages shall be labelled with the "substance name". A trade-mark labelling may also be used but may not be more outstanding than the "substance name". Regarding confidentiality it is proposed that parts of the application which concern risks relating to human health and safety (clinical documentation) in general ought to become public at the time of approval. However, in some situations it will be possible to make exceptions from this requirement.

7. Objective and rationale:

   Safe and suitable drugs at a reasonable cost


9. Proposed date of adoption and entry into force:

   Will be decided later

10. Final date for comments: 13 November 1987

11. Texts available from: National enquiry point [X] or address of other body