The following notification is being circulated in accordance with Article 10.4.

1. **Party and Agency**: SWEDEN: National Board of Health and Welfare

2. **Provision of the Agreement**: 2.5.2

3. **Product(s) covered, CCCN Heading (National Tariff Heading where applicable)**: Special preparations (e.g. ointment, antiseptic preparations, toothpaste containing fluorine)

4. **Title of project**: Draft regulation on certain exemptions from the Drug Ordinance (SFS 1962:701)

5. **Description**: On certain conditions, preparations (e.g. ointments, antiseptic preparations, toothpaste containing fluorine) may be exempted from the Drug Ordinance. Preparations referred to in the draft regulation must not be composed in a way that abuse or injurious effects are caused. Furthermore, these preparations must be clearly labelled in Swedish. The labelling shall comprise a.i. a declaration of the contents, the name of the producer and the date of expiration.

6. **Objective and rationale**: Protection for human health

7. **Relevant document(s)**: This draft regulation is to replace the regulation MF 1963:132 dated 27 December 1963.

8. **Where published, when adopted**: In the statute book of the National Board of Health and Welfare

9. **Final date for submission of comments**: 13 July 1981

10. **Proposed date of adoption and entry into force**: Not yet decided