## Committee on Technical Barriers to Trade

## NOTIFICATION

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

| 1. | Party to Agreement notifying: BELGIUM |
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| 2. | Agency responsible: Ministry of Public Health and Environment, Inspectorate of <br> Pharmaceutical Products, Cité administrative de l'Etat, Quartier Vésale, 1010 Brussels |
| 3. | Notified under Article 2.5.2 [X], 2.6.1 [ ], 7.3.2 [ ], 7.4.1 [ ], other: |
| 4. | Products covered (HS or CCCN where applicable, otherwise national tariff heading. <br> ICS numbers may be provided in addition, where applicable): Medicinal products, <br> disinfectants and antiseptics, surgical ligatures, sterile dressings, sterile equipment, <br> certain dietary products, replacement parts or internal prostheses. |

5. Title and number of pages of the notified document: Royal Decree on the Manufacture and Wholesale Distribution of Medicinal Products and their Dispensation
6. Description of content: The aim is to supervise the manufacture, holding, trade in and wholesale distribution of medicinal products and their import and export by means of authorization granted by the Ministry of Public Health. Key words: medicinal products, manufacture, wholesale distribution.
7. Objective and rationale: To replace Royal Decree of 6 June 1960, making the text more readable and bringing it into line with the various legislative provisions which have been introduced since that date.
8. Relevant documents: Royal Decree of 6 June 1960 on the manufacture and wholesale distribution of medicinal products and their dispensation. Directives 65/65/EEC, 75/318/EEC, 75/319/EEC, 81/851/EEC, 81/852/EEC, 91/356/EEC, 91/412/EEC, 92/25/EEC. Act of 25 March 1964 on medicinal products.
9. Proposed date of adoption and entry into force: 60 days
10. Final date for comments:
11. Texts available from: National enquiry point [X] or address and telefax number of other body:
