

AGREEMENT ON IMPORT LICENSING PROCEDURES

Notification under Articles 1.4(a), 8.2(b) and 5 of the Agreement

SINGAPORE

The following notification, dated 2 November 1998, has been received from the Permanent Mission of Singapore.

Notification under Article 5

(a) List of products subjected to licensing procedures

Chinese Proprietary Medicines (CPM) are medicinal products:

- in the tablet or capsule form for oral consumption from 1 September 1999;
- in tablet or capsule form for oral consumption, or in liquid form for oral consumption or external application, from 1 September 1999; and
- in any dosage form from 1 September 2000;

used in the system of therapeutics according to the traditional Chinese method. They shall contain one or more active substances, all of which are derived wholly from plants, animals or minerals or a combination of them, and all of these active substances are described in the current edition of "A Dictionary of Chinese Pharmacy", "The Chinese Herbal Medicine Materia Medica" or other publications approved by the Minister for Health.

CPM shall not include injectables, any items controlled under the Poisons Act or any items which contain as active substance(s) any chemically defined isolated constituents of plants, animals or minerals.

(b) Contact point for information on eligibility

Chinese Proprietary Medicine Unit, Pharmaceutical Department, Ministry of Health, 2 Jalan Bukit Merah, Singapore 169547.

(c) Administrative body for submission of application

See above.

(d) Date and name of publication where licensing procedures are published

“A Guide on the Control of Chinese Proprietary Medicine” issued by the Pharmaceutical Department, Ministry of Health in October 1998¹.

(e) Indication of whether the licensing procedure is automatic or non-automatic according to definitions contained in Articles 2 and 3

The procedure is non-automatic according to definitions contained in Articles 2 and 3 of the Agreement.

(f) In the case of automatic import licensing procedures, their administrative purpose

Not applicable.

(g) In the case of non-automatic import licensing procedures, indication of the measure being implemented through the licensing procedure

All local importers, wholesalers, manufacturers and assemblers of CPM will be licensed. Requirements of licensing include submission of company details, details of CPM handled by company and various certificates to ascertain the safety and quality of the CPM as well as manufacturing standards. All local premises will be inspected prior to licensing and upon renewal of licences.

(h) Expected duration of the licensing procedure if this can be estimated with some probability, and if not, reason why this information cannot be provided

There is no end date to the licensing system as there is an ongoing need to ensure the following:

- CPM sold in Singapore are safe and of good quality;
- CPM are labelled according to requirements; and
- efficient withdrawal from sale of CPM when such an action is deemed necessary.

Notification under Articles 1.4(a) and 8.2(b)

Copies of the legislation² on CPM control are attached:

Chinese Proprietary Medicine (CPM) Legislation:

- Medicines (Labelling of Chinese Proprietary Medicines) Regulations 1998;
- Medicines (Labelling) (Amendment) Regulations 1998;
- Medicines (Licensing, Standard Provisions and Fees) (Amendment) Regulations 1998;
- Medicines (Chinese Proprietary Medicines) (Exemption) Order 1998;
- Medicines (Prohibition of Sale and Supply) (Amendment) Order 1998; and
- Medicines (Traditional Medicines, Homeopathic Medicines and Other Substances) (Exemption) (Amendment) Order 1998.

¹ Available for consultation in the Secretariat (Market Access Division) (English and Chinese only).

² Available for consultation in the Secretariat (Market Access Division) (English only).

Cross references:

- Medicines (Labelling) Regulations;
 - Medicines (Licensing, Standard Provisions and Fees) Regulations;
 - Medicines (Prohibition of Sale and Supply) Order;
 - Medicines (Prohibition of Sale and Supply) (Amendment) Order 1995; and
 - Medicines (Traditional Medicines, Homeopathic Medicines and Other Substances) (Exemption) Order.
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