MEDICINES ACT (CHAPTER 176, SECTION 30)

MEDICINES (PROHIBITION OF SALE AND SUPPLY) ORDER

ARRANGEMENT OF PARAGRAPHS

Paragraph

- 1. Citation
- 2. Definitions
- 3. Restriction on sale and supply of medicinal products
- 4. Restriction on importation, sale and supply of Chinese proprietary medicine
- Prohibition on importation, sale and supply of Chinese proprietary medicine containing poisons
 The Schedules

[31st March 1987]

Citation

1. This Order may be cited as the Medicines (Prohibition of Sale and Supply) Order.

Definitions

- 2. In this Order
 - "Chinese proprietary medicine" has the same meaning as in the Medicines (Traditional Medicines, Homoeopathic Medicines and other Substances) (Exemption) Order (O 6);
 - "expiry date" means the date after which, or the month and year after the end of which, a medicinal product should not be used, or the date before which, or the month and year before the beginning of which, a medicinal product should be used.

Restriction on sale and supply of medicinal products

3.—(1) No person shall sell or supply to any person any medicinal product —

- (a) after the expiry date stated in the label on the container or package immediately enclosing the container of the medicinal product;
- (b) which is harmful or unsafe or not in conformity as regards strength, quality or purity with the specification of the medicinal product registered with the licensing authority or, in the case of a medicinal product not registered with the licensing authority, with the specification of the manufacturer; or
- (c) which contains any of the substances in excess of the respective quantities specified in the First Schedule.

[S 711/2012 wef 01/01/2013]

(2) Sub-paragraph (1)(c) shall not apply to any medicinal product in respect of which a product licence has been granted and remains in force.

Restriction on importation, sale and supply of Chinese proprietary medicine

- **4.**—(1) No person shall import, or sell or supply to any person, any Chinese proprietary medicine for oral consumption which contains
 - (a) total aerobic microbial count of more than 10⁵ per gram or millilitre;
 - (b) total yeast and mould count of more than 5 x 10² per gram or millilitre;
 - (c) any Escherichia coli in 1 gram or 1 millilitre;
 - (d) any Salmonella in 1 gram or 1 millilitre; or
- (e) any Staphylococcus aureus in 1 gram or 1 millilitre, of the Chinese proprietary medicine.
- (2) No person shall import, or sell or supply to any person, any Chinese proprietary medicine for external application which contains
 - (a) total aerobic microbial count of more than 10⁴ per gram or millilitre;

- (b) total yeast and mould count of more than 5×10^2 per gram or millilitre;
- (c) any Pseudomonas aeruginosa in 1 gram or 1 millilitre; or
- (*d*) any Staphylococcus aureus in 1 gram or 1 millilitre, of the Chinese proprietary medicine.
- (3) Sub-paragraphs (1)(a) and (b) and (2)(a) and (b) shall not apply to any Chinese proprietary medicine which contains any active substance which is derived from plants, animals or a combination thereof and which has been produced by fermentation processes.

Prohibition on importation, sale and supply of Chinese proprietary medicine containing poisons

- 5. No person shall import, or sell or supply to any person, any Chinese proprietary medicine which contains any item specified in the Poisons List in the Schedule to the Poisons Act (Cap. 234), unless that item
 - (a) is a substance specified in the first column of the Second Schedule and satisfies the limit or condition in the second column of that Schedule; and
 - (b) is present naturally in the ingredients of the Chinese proprietary medicine.

[S 711/2012 wef 01/01/2013]

FIRST SCHEDULE

Paragraph 3(1)(c)

Substance.	Quantity (by weight).
1. Arsenic	5 parts per million.
2. Copper	150 parts per million.
3. Lead	20 parts per million.
4. Mercury	0.5 part per million.

[S 711/2012 wef 01/01/2013]

SECOND SCHEDULE

Paragraph 5(a)

POISONS ALLOWED IN CHINESE PROPRIETARY MEDICINES

First column	Second column
Substance	Limit or condition allowed
1. Boric acid; sodium borate	Not more than 5% boric acid, or 5% sodium borate or 5% of a combination of both
2. Ephedra, alkaloids of	< 1%
3. Lobelia, alkaloids of	< 0.1%
4. Lovastatin	< 1%
5. Pomegranate, alkaloids of	As pomegranate bark only
6. Berberine; its quarternary compounds; their salts	No limit.

[S 711/2012 wef 01/01/2013]

[G.N. Nos. S 256/86; S 8/93; S 375/95; S 261/96; S 498/98]

LEGISLATIVE HISTORY

MEDICINES (PROHIBITION OF SALE AND SUPPLY) ORDER (CHAPTER 176, O 4)

This Legislative History is provided for the convenience of users of the Medicines (Prohibition of Sale and Supply) Order. It is not part of this Order.

1. G. N. No. S 256/1986 — Medicines (Prohibition of Sale and Supply)
Order 1986

Date of commencement : 31 March 1987

2. 1990 Revised Edition — Medicines (Prohibition of Sale and Supply)
Order

Date of operation : 25 March 1992

3. G. N. No. S 8/1993 — Medicines (Prohibition of Sale and Supply) (Amendment) Order 1993

Date of commencement : 1 February 1993

4. G. N. No. S 375/1995 — Medicines (Prohibition of Sale and Supply) (Amendment) Order 1995

Date of commencement : 1 September 1995

5. G. N. No. S 261/1996 — Medicines (Prohibition of Sale and Supply) (Amendment) Order 1996

Date of commencement : 7 June 1996

6. G. N. No. S 498/1998 — Medicines (Prohibition of Sale and Supply) (Amendment) Order 1998

Date of commencement : 1 September 1999

7. 2000 Revised Edition — Medicines (Prohibition of Sale and Supply)
Order

Date of operation : 31 January 2000

8. G. N. No. S 711/2012 — Medicines (Prohibition of Sale and Supply) (Amendment) Order 2012

Date of commencement : 1 January 2013