

# **Medicines (Prohibition of Sale, Supply and Importation) Order**

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## **FIRST SCHEDULE**

## **SECOND SCHEDULE Poisons allowed in Chinese proprietary medicines**

## **Legislative History**

### **MEDICINES ACT (CHAPTER 176, SECTION 30)**

### **MEDICINES (PROHIBITION OF SALE, SUPPLY AND IMPORTATION) ORDER**

**O 4**

**G.N. No. S 256/1986**

**REVISED EDITION 2000**

(31st January 2000)

[31st March 1987]

## Citation

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

*[S 657/2019 wef 01/01/2020]*

## 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, supply and importation of medicinal products

3.—(1) Subject to sub-paragraph (1A), a person must not sell or supply to any other 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]*

*[S 657/2019 wef 01/01/2020]*

(1A) A person must not sell, supply or import any topical antiseptic that contains mercury or any compound of mercury.

*[S 657/2019 wef 01/01/2020]*

(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.

*[S 657/2019 wef 01/01/2020]*

### **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  $10^5$  per gram or millilitre;
- (b) total yeast and mould count of more than  $5 \times 10^2$  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  $10^4$  per gram or millilitre;
- (b) total yeast and mould count of more than  $5 \times 10^2$  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)

	<i>Substance.</i>	<i>Quantity (by weight).</i>
1.	Arsenic	5 parts per million.
2.	Cadmium	0.3 part per million.
3.	Lead	10 parts per million.
4.	Mercury	0.5 part per million.

[\[S 414/2019 wef 01/09/2019\]](#)  
[\[S 711/2012 wef 01/01/2013\]](#)

## SECOND SCHEDULE

Paragraph 5(a)

### POISONS ALLOWED IN CHINESE PROPRIETARY MEDICINES

<i>First column</i>	<i>Second column</i>
<i>Substance</i>	<i>Limit or condition allowed</i>
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 quaternary compounds; their salts	No limit
7. Tetrahydropalmatine; its isomers; their salts	Container of the Chinese proprietary medicine to be labelled with a recommended dosage of the medicine containing not more than 19 mg of the substance per day

[\[S 215/2018 wef 01/06/2018\]](#)  
[\[S 711/2012 wef 01/01/2013\]](#)  
[\[G.N. Nos. S 256/86; S 8/93; S 375/95; S 261/96; S 498/98\]](#)

## LEGISLATIVE HISTORY

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

*formerly known as the Medicines (Prohibition of Sale and Supply) Order*

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

**9. G.N. No. S 215/2018—Medicines (Prohibition of Sale and Supply) (Amendment) Order 2018**

Date of commencement : 1 June 2018

**10. G.N. No. S 414/2019—Medicines (Prohibition of Sale and Supply) (Amendment) Order 2019**

Date of commencement : 1 September 2019

**11. G.N. No. S 657/2019—Medicines (Prohibition of Sale and Supply) (Amendment No. 2) Order 2019**

Date of commencement : 1 January 2020