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The Gazette of the Democratic Socialist Republic of Sri Lanka

EXTRAORDINARY

අංක 2160/28 - 2020 ජනවාරි මස 29 වැනි බදාදා - 2020.01.29

No. 2160/28 - WEDNESDAY, JANUARY 29, 2020

(Published by Authority)

PART I : SECTION (I) — GENERAL

Government Notifications

L.D.B 9/2016 (II).

THE NATIONAL MEDICINES REGULATORY AUTHORITY ACT, No. 5 OF 2015

REGULATIONS made by the Minister of Health, and Indigenous Medical Services under Section 142 of the National Medicines Regulatory Authority Act, No. 5 of 2015.

PAVITHRA WANNIARACHCHI (M.P.) (Attorney-at-Law),
Minister of Health, and Indigenous Medical Services.

Colombo,
29th January, 2020.

Regulations

1. These regulations may be cited as the Pricing of Medical Devices Regulations, No. 1 of 2020.

2. (1) A person shall not sell or charge for any medical devices specified in column I of the Schedule hereto higher than the prices specified in the corresponding entries in column II of that Schedule.

(2) The prices specified in column II of the Schedule shall be the maximum retail price for the medical devices specified in column I of that Schedule:

Provided however, where the existing market price of the medical devices specified in column I of the Schedule in terms of International Reference Prices and other factors is lower than the maximum retail price specified in column II of the Schedule, such medical devices shall be sold at an existing price without any increase of price.

3. The importer or manufacturer shall legibly print or mark in indelible ink the maximum retail prices specified in column II of the Schedule on the label of the commercial package or units of medical devices specified in column I of that Schedule.

4. Notwithstanding the provisions of regulation 3, the importer or manufacturer shall print or mark the maximum retail price on the label of the commercial package or units of existing stock of the medical devices specified in column I of the Schedule within a period of three months from the date of publication of these regulations.

5. A person who sells or charges for any medical device specified in column I of the Schedule shall issue a receipt clearly indicating the approved name with or without brand name, model, type, size, pack size and the price of such medical device as a separate item.

6. Every person who sells or charges for any medical device specified in column I of the Schedule shall display the maximum retail price of such medical device in the immediate pack or conspicuous place.

7. Where a maximum retail price of any approved name with or without brand name, model, type, size or pack size of any medical device similar to the medical device specified in column I of the Schedule is not specified in the Schedule, the maximum retail price of such medical device shall be the maximum retails price of the medical device specified in column I of that Schedule.

8. Where any approved name with or without brand name, model, type, size, pack size of a medical device is not specified in the Schedule, the maximum retail price for the brand or approved name, model, type, size, pack size of the medical device not so specified shall be the introductory price determined under Section 118 of the National Medicines Regulatory Authority Act, No. 5 of 2015.

9. Any person who contravenes the provisions of these regulations commits an offence.

10. In these regulations –

"Medical Practitioner" shall have the same meaning as in the Medical Ordinance (Chapter 105);

"person" includes any body of persons corporate or unincorporated;

"Private Medical Institution" shall have the same meaning as in the Private Medical Institutions (Registration) Act, No. 21 of 2006.

SCHEDULE

(regulation 2)

MAXIMUM RETAIL PRICES OF SELECTED MEDICAL DEVICES

No.	*Column I*	*Column II*
	Approved Name of the Medical devices	*Maximum Retail Price per unit (MRP) (SLR)*
1.	Disposable Face Mask – Non woven (Earloop type or Tie on type)	15.00
2.	Disposable Surgical Face Mask – Non woven (Earloop type or Tie on type)	15.00
3.	Face Mask (N95 type – particulate respirator)	150.00

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