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The Gazette of the Democratic Socialist Republic of Sri Lanka

EXTRAORDINARY

අංක 2243/20 - 2021 සැප්තැම්බර් මස 04 වැනි සෙනසුරාදා - 2021.09.04

No. 2243/20 - SATURDAY, SEPTEMBER 04, 2021

(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 under Section 142 of the National Medicines Regulatory Authority Act, No. 5 of 2015.

Dr. **KEHELIYA RAMBUKKWELLA,**
Minister of Health.

Colombo,
04.09.2021.

Regulations

1. These regulations may be cited as the Medical (Pricing of Medical Devices) Regulations, No. 1 of 2021.

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

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

Provided however, where the existing market price of the medical device at the date of publication of these regulations 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 that Schedule,, such medical device shall be sold at an existing market price at the date of publication of these regulations without any increase of price.

3. The importer or manufacturer shall legibly print or mark in indelible ink the maximum retail price specified in column II of the Schedule on the label of the commercial package or unit of a medical device 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 unit of existing stock of any medical device 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 a 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 retail 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 or 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 or 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 –

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

SCHEDULE

(regulation 2)

No.	*Column I*	*Column II*
	Approved Name of the Medical device	*Maximum Retail Price per unit (MRP) (LKR)*
1.	Fingertip Pulse Oximeter	3000.00

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