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The Gazette of the Democratic Socialist Republic of Sri Lanka

EXTRAORDINARY

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No. 2030/47 - FRIDAY, AUGUST 04, 2017

(Published by Authority)

PART I : SECTION (I) — GENERAL

Government Notifications

L.D.B. 9/2016

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

REGULATIONS made by the Minister of Health, Nutrition and Indigenous Medicine under Section 142 read together with Section 118 of the National Medicines Regulatory Authority Act, No. 5 of 2015.

Dr. Rajitha Senaratne,
Minister of Health, Nutrition and Indigenous Medicine.

Colombo,
4th August, 2017.

Regulations

1. These regulations may be cited as the Medical Devices Pricing Regulations, No. 05 of 2017.

2. No manufacturer, importer, distributor, trader, provider, pharmacist, medical practitioner, a medical institution inclusive of a private medical institution or a person who is in possession of a medical device shall sell, offer for sale or charge for any medical device described by brand name or approved name and set out in the Schedule hereto, above the Maximum Retail Price (MRP) stipulated therein.

3. A manufacturer, importer, distributor, trader, provider, pharmacist, medical practitioner, a medical institution inclusive of a private medical institution or a person who is in possession of a medical device set out in the Schedule hereto, currently sells the said medical device at a price less than the maximum retail price set out in the Schedule hereto, is required to maintain the existing price without any price increase.

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4. Every person or institution referred to in regulation 2, who sells or offer for sale or charges for any medical device which is described by its brand name or approved name and set out in the Schedule hereto, shall issue a receipt clearly indicating the brand name or the approved name and the price of such medical device as a separate item.

5. The relevant Maximum Retail Price as set out in the Schedule, of each unit of item in the stock of such medical device manufactured or available for sale shall be printed or marked in their respective commercial package or label as expeditiously as practicable, prior to the expiry of a period of forty five days from the date of publication of these regulations.

6. Any manufacturer, importer, distributor, trader, provider, pharmacist, medical practitioner, a medical institution inclusive of private medical institution or a person who is in possession of such medical devices who contravenes the provisions of these regulations commits an offence and shall be triable under Part IV of the National Medicines Regulatory Authority Act, No. 5 of 2015.

7. It shall be the duty of every manufacturer, importer, distributor, trader, provider, pharmacist, medical practitioner, a medical institution inclusive of private medical institution and a person who is in possession of such medical devices to display at every retail outlet the Maximum Retail Price of the medical devices set out in the Schedule hereto.

8. In these regulations –

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

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

SCHEDULE

	Item	*Maximum Retail Price (MRP)*
1.	Bare Metal Stent	Rs. 24, 000.00
2.	Drug Eluting Stent	Rs. 105, 000.00

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