ශ්‍රී ලංකා ප්‍රජාතාන්ත්‍රික සමාජවාදී ජනරජයේ ගැසට් පත්‍රය

අති විශෙෂ

The Gazette of the Democratic Socialist Republic of Sri Lanka

EXTRAORDINARY

අංක 2273/04 - 2022 මාර්තු මස 28 වැනි සඳුදා - 2022.03.28

No. 2273/04 - MONDAY, MARCH 28, 2022

(Published by Authority)

PART I : SECTION (I) — GENERAL

Government Notifications

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

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 Rambukwella,
Minister of Health.

Colombo,
28th March, 2022.

Regulations

The Medical Devices Pricing Regulations, No. 01 of 2017 published in the *Gazette Extraordinary* No. 2006/45 of February 17, 2017, as amended by regulations published in *Gazette Extraordinary* No. 2114/54 of March 15, 2019 and regulations published in *Gazette Extraordinary* No. 2241/43 of August 19, 2021 are hereby further amended as follows: -

(1) by the repeal of regulation 2 thereof and the substitution therefor, of the following: -

"2. (1) The maximum retail price of the Medical devices described by brand name or approved name specified in Column II of the Schedule hereto (hereinafter referred to as the "Scheduled Medical devices") manufactured by such

manufacturer specified in corresponding entry in Column III of that Schedule shall be as specified in corresponding entry in Column IV of the Schedule hereto.

(2) A manufacturer, importer, trader, provider, distributor, pharmacist, medical practitioner, medical institution including a private medical institution, pharmacy or person who or which is in possession of the Scheduled Medical devices, shall not sell, offer for sale or charge for such Scheduled Medical devices above the maximum retail price specified in Column IV of the Schedule or revised retail price as may be determined in accordance with the provisions of regulation 3 (2).";

(2) by the insertion of the following new regulation immediately after regulation 2 thereof:-

"3 (1) Every trader, provider, distributor, pharmacist, medical practitioner, Medical institution including a private medical institution, pharmacy or person who or which is in possession of the Scheduled Medical devices, for the purpose of sale shall maintain the price of the Scheduled Medical devices, at the maximum retail price or revised retail price whichever is less.

(2) On the date of publication of these regulations, a manufacturer or importer who sells any Medical devices at a revised retail price under the Medical Devices (Pricing) Regulations, published in *Gazette Extraordinary* No. 2241/43 of August 19, 2021 which is less than the maximum retail price specified in Column IV of the Schedule hereto may increase proportionately such revised retail price by a total twenty-nine *per centum* (29%):

Provided however, such increase of revised retail price of the Scheduled Medical devices shall not exceed the maximum retail price specified in Column IV of the Schedule hereto.";

(3) by the repeal of regulation 4 thereof and the substitution therefor, of the following: -

"4. Any manufacturer or importer shall print or mark on the commercial package or label of the Scheduled Medical devices the maximum retail price specified in Column IV of the Schedule hereto, or the revised retail price, whichever is less, in the stock manufactured or available in the market as expeditiously as possible:

Provided however, the maximum retail price or the revised retail price whichever is less shall be printed or marked in the commercial package or label of the Scheduled Medical devices before the expiry of a period of forty-five days from the date of publication of these regulations.";

(4) by the repeal of regulation 5 thereof and the substitution therefor, of the following: -

"5. Any person who contravenes the provisions of these regulations commits an offence and shall be triable under section 131 of the National Medicines Regulatory Authority Act, No. 5 of 2015.";

(5) by the repeal of regulation 6 thereof and the substitution therefor, of the following: -

"6. It shall be the duty of every manufacturer, importer, trader, provider, distributor, pharmacist, medical practitioner, medical institution including a private medical institution, pharmacy or a person who or which is in possession of the Scheduled medical devices for the purpose of sale, to display at every retail outlet the maximum retail price of the Scheduled medical devices or the revised retail price whichever is less.";

(6) by the insertion of the following new regulation immediately after regulation 6 thereof:-

"6A. Where any brand name or approved name of the Scheduled Medical devices and the maximum retail price of such brand name or approved name of the Scheduled Medical devices are not specified in Column IV of the Schedule hereto, the National Medicines Regulatory Authority shall fix the price for the Scheduled Medical devices in such brand name or approved name.";

(7) by the repeal of regulation 7 thereof and the substitution therefor, of the following: -

"7. In these regulations –

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

"Person" includes anybody of persons corporate or unincorporate;" and

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

(8) by the repeal of the Schedule and the substitution therefor, of the following: -

"SCHEDULE

(Regulation 2)

INTRAOCULAR LENSES/LENSES WITH DELIVERY SYSTEM (PRELOADED/PROVIDED WITH CARTRIDGE)

Column I	*Column II*	*Column III*	*Column IV*
	Brand Name /Approved Name	**Manufacturer**	**Maximum Retail Price MRP (SLR)**
1.	AcrySert Preloaded delivery system	Alcon	**Rs. 27,348.00**
2.	AcrySof IQ SN60WF with cartridge	Alcon	**Rs. 26,378.44**
3.	Tecnis 1 piece	Abbot Medical	**Rs. 26,055.03**
4.	enVista	Baush & Lomb	**Rs. 24,930.15**
5.	Tecnis monofocal	Abbot Medical	**Rs. 24,930.15**
6.	Hoya iSert 251	Hoya	**Rs. 19,474.49**
7.	Nidek Nex-Load system SP SZ–1	Nidek	**Rs. 19,474.49**
8.	Aqua Sense Aaris	Aaren Scientific	**Rs. 15,762.38**
9.	Bi-flex HB (877FABY standard IOL)	Medicontur	**Rs. 14,342.22**
10.	Bunny HP	Hanita Marketing	**Rs. 13,990.70**
11.	I-Stream preloaded	MD Tech	**Rs. 11,902.64**
12.	Aurovue EV	Aurolab	**Rs. 7,965.56**
13.	AcrySof SP SA60AT with cartridge	Alcon	**Rs. 21,091.50**
14.	AcrySof EXPAND MA60MA with cartridge	Alcon	**Rs. 21,091.50**
15.	Sensar 1 piece	Abbot Medical	**Rs. 20,592.27**

Column I	*Column II*	*Column III*	*Column IV*
	Brand Name /Approved Name	**Manufacturer**	**Maximum Retail Price MRP (SLR)**
16.	Sensar	Abbot Medical	**Rs. 18,912.05**
17.	AcrySof MP MA60AC	Alcon	**Rs. 17,210.66**
18.	Hoya PY60R	Hoya	**Rs. 12,711.14**
19.	Acriva UD (blue filter)	VSY Biotech	**Rs. 11,108.19**
20.	Supra Phob Preloaded system	Appasamy	**Rs. 10,461.38**
21.	Acriva UD	VSY Biotech	**Rs. 10,545.75**
22.	Akreos - MI60	Baush & Lomb	**Rs. 23,812.30**
23.	Akeros AO	Baush & Lomb	**Rs. 18,658.95**
24.	Akreos Adapt	Baush & Lomb	**Rs. 17,435.64**
25.	Bunny AFM	Hanita Marketing	**Rs. 17,084.12**
26.	CT Asphina 404	Carl Zeiss Meditec	**Rs. 16,873.20**
27.	CT Spheris 204	Carl Zeiss Meditec	**Rs. 13,189.22**
28.	Bunny AF	Hanita Marketing	**Rs. 11,586.26**
29.	C-Flex Aspheric 970C/920H	Rayner	**Rs. 9,702.09**
30.	Aspira-aAY	Human Optics	**Rs. 9,167.77**
31.	Ocuva	VSY Biotech	**Rs. 6,439.94**
32.	Auroflex	Aurolab	**Rs. 2,896.57**
33.	Seelens	Hanita Marketing	**Rs. 9,976.28**
34.	C–Flex IOL (Spherical 570C)	Rayner	**Rs. 8,225.69**
35.	Aspira AS	Human Optics	**Rs. 8,366.30**
36.	Tecsoft Tetra	Fred Hollows	**Rs. 7,733.55**
37.	Tecsoft Flex	Fred Hollows	**Rs. 7,241.42**
38.	Acryfold	Appasamy	**Rs. 4,921.35**

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

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 RAMBUKWELLA,
Minister of Health.

Colombo,
28th March, 2022.

Regulations

The Medical Devices Pricing Regulations, No. 05 of 2017, published in the *Gazette* Extraordinary No. 2030/47 of August 04, 2017, as amended by regulations published in *Gazette* Extraordinary No. 2114/54 of March 15, 2019 and by regulations published in *Gazette* Extraordinary No. 2241/43 of August 19, 2021 are hereby further amended as follows : -

(1) by the repeal of regulation 2 thereof and the substitution therefor, of the following: -

"2. (1) The maximum retail price of the Medical devices specified in Column I of the Schedule hereto (hereinafter referred to as the "Scheduled Medical devices") described by any brand name, models, sizes or pack sizes, shall be as specified in corresponding entry in Column II of the Schedule hereto.

(2) A manufacturer, importer, trader, provider, distributor, pharmacist, medical practitioner, medical institution including a private medical institution, pharmacy or person who or which is in possession of the Scheduled Medical devices, shall not sell, offer for sale or charge for such Scheduled Medical devices above the maximum retail price specified in Column II of the Schedule or revised retail price as may be determined in accordance with the provisions of regulation 3 (2).";

(2) by the repeal of regulation 3 thereof and the substitution therefor, of the following: -

" 3. (1) Every trader, provider, distributor, pharmacist, medical practitioner, Medical institution including a private medical institution, pharmacy or person who or which is in possession of the Scheduled Medical devices, for the purpose of sale shall maintain the price of the Scheduled Medical devices, at the maximum retail price or revised retail price whichever is less.

(2) On the date of publication of these regulations, a manufacturer or importer who sells any Medical devices at a revised retail price under the Medical Devices (Pricing) Regulations, published in *Gazette* Extraordinary No. 2241/43 of August 19, 2021 which is less than the maximum retail price specified in Column II of the Schedule hereto may increase proportionately such revised retail price by a total twenty-nine per centum (29%):

Provided however, such increase of revised retail price of the Scheduled Medical devices shall not exceed the maximum retail price specified in Column II of the Schedule hereto.";

(3) by the repeal of regulation 5 thereof and the substitution therefor, of the following:

"5. Any manufacturer or importer shall print or mark on the commercial package or label of the Scheduled Medical devices the maximum retail price specified in Column II of the Schedule hereto, or the revised retail price, whichever is less, in the stock manufactured or available in the market as expeditiously as possible:

Provided however, the maximum retail price or the revised retail price whichever is less shall be printed or marked in the commercial package or label of the Scheduled Medical devices before the expiry of a period of forty-five days from the date of publication of these regulations.";

(4) by the repeal of regulation 6 thereof and the substitution therefor, of the following: -

"6. Any person who contravenes the provisions of these regulations commits an offence and shall be triable under section 131 of the National Medicines Regulatory Authority Act, No. 5 of 2015.";

(5) by the repeal of regulation 7 thereof and the substitution therefor, of the following: -

"7. It shall be the duty of every manufacturer, importer, trader, provider, distributor, pharmacist, medical practitioner, medical institution including a private medical institution, pharmacy or a person who or which is in possession of the Scheduled medical devices for the purpose of sale, to display at every retail outlet the maximum retail price of the Scheduled medical devices or the revised retail price whichever is less.";

(6) by the insertion of the following new regulation immediately after regulation 7 thereof :-

"8. Where any brand name, model, size or pack size of the Scheduled Medical devices and the maximum retail price of such brand name, model, size or pack size of the Scheduled Medical devices are not specified in Column II of the Schedule hereto, the National Medicines Regulatory Authority shall fix the price for the Scheduled Medical devices in such brand name, model, size or pack size.";

(7) by the repeal of regulation 8 thereof and the substitution therefor, of the following: -

"9. 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 unincorporate ; and

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

(8) by the repeal of the Schedule and the substitution therefor, of the following: -

SCHEDULE

(Regulation 2)

No.	*Column I*	*Column II*
	Item	***Maximum Retail Price (MRP) (SLR)***
1.	Bare Metal Stent	**Rs. 38,597.45**
2.	Drug Eluting Stent	**Rs. 168,732.00**

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

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 RAMBUKWELLA,
Minister of Health.

Colombo,
28th March, 2022.

Regulations

The Medical Devices (Pricing) Regulations, 2018 published in the *Gazette* Extraordinary No. 2086/37 of August 31, 2018, as amended by regulations published in *Gazette* Extraordinary No. 2114/54 of March 15, 2019 and by regulations published in *Gazette* Extraordinary No. 2241/43 of August 19, 2021 are hereby further amended as follows: -

(1) by the repeal of regulation 2 thereof and the substitution therefor, of the following: -

"2. (1) The maximum retail price of the Medical devices in approved name specified in Column I of the Schedule hereto (hereinafter referred to as the "Scheduled Medical devices") described by any brand name, models, sizes or pack sizes, shall be as specified in corresponding entry in Column II of the Schedule hereto.

(2) A manufacturer, importer, trader, provider, distributor, pharmacist, medical practitioner, medical institution including a private medical institution, pharmacy or person who or which is in possession of the Scheduled Medical devices, shall not sell, offer for sale or charge for such Scheduled Medical devices above the maximum retail price specified in Column II of the Schedule or revised retail price as may be determined in accordance with the provisions of regulation 3 (2).";

(2) by the repeal of regulation 3 thereof and the substitution therefor, of the following: -

"3 (1) Every trader, provider, distributor, pharmacist, medical practitioner, Medical institution including a private medical institution, pharmacy or person who or which is in possession of the Scheduled Medical devices, for the purpose of sale shall maintain the price of the Scheduled Medical devices, at the maximum retail price or revised retail price whichever is less.

(2) On the date of publication of these regulations, a manufacturer or importer who sells any Medical devices at a revised retail price under the Medical Devices (Pricing) Regulations, published in *Gazette* Extraordinary No. 2241/43 of August 19, 2021 which is less than the maximum retail price specified in Column II of the Schedule hereto may increase proportionately such revised retail price by a total twenty-nine *per centum* (29%):

Provided however, such increase of revised retail price of the Scheduled Medical devices shall not exceed the maximum retail price specified in Column II of the Schedule hereto.";

(3) by the repeal of regulation 5 thereof and the substitution therefor, of the following:

"5. Any manufacturer or importer shall print or mark on the commercial package or label of the Scheduled Medical devices the maximum retail price specified in Column II of the Schedule hereto, or the revised retail price, whichever is less, in the stock manufactured or available in the market as expeditiously as possible:

Provided however, the maximum retail price or the revised retail price whichever is less shall be printed or marked in the commercial package or label of the Scheduled Medical devices before the expiry of a period of forty-five days from the date of publication of these regulations.";

(4) by the repeal of regulation 6 thereof and the substitution therefor, of the following: -

"6. Any person who contravenes the provisions of these regulations commits an offence and shall be triable under section 131 of the National Medicines Regulatory Authority Act, No. 5 of 2015.";

(5) by the repeal of regulation 7 thereof and the substitution therefor, of the following: -

"7. It shall be the duty of every manufacturer, importer, trader, provider, distributor, pharmacist, medical practitioner, medical institution including a private medical institution, pharmacy or a person who or which is in possession of the Scheduled medical devices for the purpose of sale, to display at every retail outlet the maximum retail price of the Scheduled medical devices or the revised retail price whichever is less.";

(6) by the repeal of regulation 8 thereof and the substitution therefor, of the following: -

"8. Where any brand name, model, size or pack size of the Scheduled Medical devices and the maximum retail price of such brand name, model, size or pack size of the Scheduled Medical devices are not specified in Column II of the Schedule hereto, the National Medicines Regulatory Authority shall fix the price for the Scheduled Medical devices in such brand name, model, size or pack size.";

(7) by the insertion of definition for the term of expression "person", immediately after definition of "medical practitioner":-

"" person" includes any body of persons corporate or unincorporate;"; and

(8) by the repeal of the Schedule and the substitution therefor, of the following: -

"**SCHEDULE"**

(Regulation 2)

MAXIMUM RETAIL PRICES OF TWO SELECTED MEDICAL DEVICES

No.	***Column I***	***Column II***
	Approved Name	***Maximum Retail Price (MRP) (SLR)***
1.	BLOOD GLUCOSE MONITORING SYSTEM	4,429.22 Per Unit
2.	TEST STRIPS FOR BLOOD GLUCOSE MONITORING SYSTEM	80.15 Per Strip

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

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 RAMBUKWELLA,
Minister of Health.

Colombo,
28th March, 2022.

Regulations

The Medical (Pricing of Medical Devices) Regulations No. 1 of 2021 published in the *Gazette Extraordinary* No. 2243/20 of September 04, 2021 is hereby amended as follows :-

(1) by the repeal of regulation 2 thereof and the substitution therefor, of the following: -

"2 (1) The maximum retail price of the Medical device in approved name specified in Column I of the Schedule hereto (hereinafter referred to as the "Scheduled Medical device") described by any brand name, models, sizes or pack sizes, shall be as specified in corresponding entry in Column II of the Schedule hereto.

(2) A manufacturer, importer, trader, provider, distributor, pharmacist, medical practitioner, medical institution including a private medical institution, pharmacy or person who or which is in possession of the Scheduled Medical device, shall not sell, offer for sale or charge for such Scheduled Medical device above the maximum retail price specified in Column II of the Schedule or revised retail price as may be determined in accordance with the provisions of sub regulation (4) of this regulation**.**

(3) Every trader, provider, distributor, pharmacist, medical practitioner, Medical institution including a private medical institution, pharmacy or person who or which is in possession of the Scheduled Medical device, for the purpose of sale shall maintain the price of the Scheduled Medical device, at the maximum retail price or revised retail price whichever is less.

(4) On the date of publication of these regulations, a manufacturer or importer who sells any Medical device at a revised retail price under the Medical (Pricing of Medical Devices) Regulations No. 1 of 2021 published in the *Gazette* Extraordinary No. 2243/20 of September 04, 2021 which is less than the maximum retail price specified in Column II of the Schedule hereto may increase proportionately such revised retail price by a total twenty-nine per centum (29%):

Provided however, such increase of revised retail price of the Scheduled Medical device shall not exceed the maximum retail price specified in Column II of the Schedule hereto.";

(2) by the repeal of regulations 3 and 4 thereof and the substitution therefor, of the following: -

"3. Any manufacturer or importer shall print or mark on the commercial package or label of the Scheduled Medical device the maximum retail price specified in Column II of the Schedule hereto, or the revised retail price, whichever is less, in the stock manufactured or available in the market as expeditiously as possible:

Provided however, the maximum retail price or the revised retail price whichever is less shall be printed or marked in the commercial package or label of the Scheduled Medical device before the expiry of a period of forty-five days from the date of publication of these regulations.";

(3) by the repeal of regulation 6 thereof and the substitution therefor, of the following: -

"6. It shall be the duty of every manufacturer, importer, trader, provider, distributor, pharmacist, medical practitioner, medical institution including a private medical institution, pharmacy or a person who or which is in possession of the Scheduled medical device for the purpose of sale, to display at every retail outlet the maximum retail price of the Scheduled medical device or the revised retail price whichever is less.";

(4) by the repeal of regulation 8 thereof and the substitution therefor, of the following: -

"8. Where any brand name, model, size or pack size of the Scheduled Medical device and the maximum retail price of such brand name, model, size or pack size of the Scheduled Medical device are not specified in Column II of the Schedule hereto, the National Medicines Regulatory Authority shall fix the price for the Scheduled Medical device in such brand name, model, size or pack size.";

(5) by the repeal of regulation 9 thereof and the substitution therefor, of the following: -

"9. Any person who contravenes the provisions of these regulations commits an offence and shall be triable under section 131 of the National Medicines Regulatory Authority Act, No. 5 of 2015.";

(6) by the repeal of regulation 10 thereof and the substitution therefor, of the following:-

"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 unincorporate ;" and

"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 PRICE OF SELECTED MEDICAL DEVICE

No.	***Column I***	***Column II***
	Approved Name	***Maximum Retail Price per unit (MRP) (SLR)***
1.	Pulse Oximeter	Rs. 3870.00

EOG 03-1012/4