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The Gazette of the Democratic Socialist Republic of Sri Lanka

EXTRAORDINARY

අංක 2006/45 - 2017 පෙබරවාරි මස 17 වැනි සිකුරාදා - 2017.02.17
No. 2006/45 - FRIDAY, FEBRUARY 17, 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,
17th February, 2017.

Regulations

1. These regulations may be cited as the Medical Devices Pricing Regulations, No. 01 of 2017.

2. No manufacturer, importer, distributor, trader, pharmacist or 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 Column II of the Schedule hereto, above the Maximum Retail Price (MRP) stipulated in the corresponding entry in Column IV thereof.

3. 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.

4. 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.

5. Any manufacturer, importer, distributor, trader, pharmacist, or 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.

6. It shall be the duty of every manufacturer, distributor, trader, importer, pharmacist, 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.

7. "Private Medical Institution" shall have the same meaning as in Section 20 of the Private Medical Institutions (Registration) Act, No. 21 of 2006.

SCHEDULE

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

Column I	*Column II* **Brand Name/ Approved Name**	*Column III* **Manufacturer**	*Column IV* **MRP (SLR)**
1	AcrySert Preloaded delivery system	Alcon	17,000.00
2	AcrySof IQ SN60WF with cartridge	Alcon	16,400.00
3	Tecnis 1 piece	Abbot Medical	16,200.00
4	enVista	Baush & Lomb	15,500.00
5	Tecnis monofocal	Abbot Medical	15,500.00
6	Hoya iSert 251	Hoya	12,100.00
7	Nidek Nex-Load system SP SZ–1	Nidek	11,750.00
8	Aqua Sense Aaris	Aaren Scientific	9,800.00
9	Bi-flex HB (877FABY standard IOL)	Medicontur	8,900.00
10	Bunny HP	Hanita Marketing	8,700.00

Contd.

Column I	*Column II* **Brand Name/ Approved Name**	*Column III* **Manufacturer**	*Column IV* **MRP (SLR)**
11	1 - Stream preloaded	MD Tech	7,100.00
12	Aurovue EV	Aurolab	4,950.00
13	AcrySof SP SA60AT with cartridge	Alcon	13,100.00
14	AcrySof EXPAND MA60MA with cartridge	Alcon	13,100.00
15	Sensar 1 piece	Abbot Medical	12,800.00
16	Sensar	Abbot Medical	11,750.00
17	AcrySof MP MA60AC	Alcon	11,150.00
18	Hoya PY60R	Hoya	7,900.00
19	Acriva UD (blue filter)	VSY Biotech	6,900.00
20	Supra Phob Preloaded system	Appasamy	6,500.00
21	Acriva UD	VSY Biotech	6,500.00
22	Akreos - MI 60	Baush & Lomb	14,800.00
23	Akeros AO	Baush & Lomb	11,600.00
24	Akreos Adapt	Baush & Lomb	10,850.00
25	Bunny AFM	Hanita Marketing	10,600.00
26	CT Asphina 404	Carl Zeiss Meditec	10,500.00
27	CT Spheris 204	Carl Zeiss Meditec	8,200.00
28	Bunny AF	Hanita Marketing	7,200.00
29	C-Flex Aspheric 970C/920H	Rayner	6,000.00

Contd.

Column I	*Column II* **Brand Name/ Approved Name**	*Column III* **Manufacturer**	*Column IV* **MRP (SLR)**
30	Aspira - aAy	Human optics	5,700.00
31	Ocuva	VSY Biotech	4,000.00
32	Auroflex	Aurolab	1,800.00
33	Seelens	Hanita Marketing	6,200.00
34	C–Flex IOL (Spherical 570C)	Rayner	5,100.00
35	Aspira AS	Human Optics	5,200.00
36	Tecsoft Tetra	Fred Hollows	4,800.00
37	Tecsoft Flex	Fred Hollows	4,500.00
38	Acryfold	Appasamy	3,000.00

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