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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
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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)

| <i>Column I</i> | <i>Column II</i> Brand Name/ Approved Name | <i>Column III</i> Manufacturer | <i>Column IV</i> 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 | Bausch & 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.

| <i>Column I</i> | <i>Column II</i> Brand Name/ Approved Name | <i>Column III</i> Manufacturer | <i>Column IV</i> 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) | VSYS Biotech | 6,900.00 |
| 20 | Supra Phob Preloaded system | Appasamy | 6,500.00 |
| 21 | Acriva UD | VSYS Biotech | 6,500.00 |
| 22 | Akreos - MI 60 | Bausch & Lomb | 14,800.00 |
| 23 | Akeros AO | Bausch & Lomb | 11,600.00 |
| 24 | Akreos Adapt | Bausch & 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.

| <i>Column I</i> | <i>Column II</i> Brand Name/ Approved Name | <i>Column III</i> Manufacturer | <i>Column IV</i> MRP (SLR) |
|-----------------|--|--|--|
| 30 | Aspira - aAy | Human optics | 5,700.00 |
| 31 | Ocuva | VSX 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 |