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The Gazette of the Democratic Socialist Republic of Sri Lanka

EXTRAORDINARY

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No. 2146/3 - MONDAY, OCTOBER 21, 2019

(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, Nutrition and Indigenous Medicine under Section 142 read with Section 118 of the National Medicines Regulatory Authority Act, No. 5 of 2015.

Dr. RAJITHA SENARATNE (M.P.)
Minister of Health, Nutrition and
Indigenous Medicine.

Colombo,
11th October, 2019.

Regulations

1. These regulations may be cited as Pricing Regulations, 2019.

2. These regulations shall apply to and in relation to pricing of medicines, medical devices and borderline products (hereinafter referred to as "medicinal products") in these regulations.

3. The Authority shall, for the determination of introductory prices of medicinal products, consider the prevailing market prices in Sri Lanka and any other countries of similar products within the same therapeutic class, regional and international reference prices and any other factors determined by the Pricing Committe including information from any other relevant sources, the cost, insurance an freight value of the medicinal products and the applicable exchange rate.

4. The pricing committee shall consist of the following :-

(a) ex-officio members

(i) the Chairman of the National Medicines Regulatory Authority ;

(ii) the Chief Executive Officer of the National Medicines Regulatory Authority ;

(iii) a representative of the Consumer Affairs Authority ; and

(iv) a pharmacist of the National Medicines Regulatory Authority.

(b) seven persons from among persons who have expertise, experience or proven capacity in the fields of Medicine, Pharmacy, Economics, Commerce, Accountancy, Law or any other related field.

5. The Authority shall appoint one of the members of the Pricing Committee as the Chairman of the Committee.

6. The quorum for any meeting of the Pricing Committee shall be seven members.

7. The Pricing Committee may regulate its own procedure in regard to its meetings and transaction of business at such meetings.

8. The members of the Pricing Committee shall be paid such allowances as the Authority may determine.

9. The powers and functions of the Pricing Committee shall include -

(a) assisting the Authority in obtaining relevant information and data from the manufacturers, importers, wholesale dealers, retail pharmacists, prescribers, dispensers and any other person in Sri Lanka or any other country which may influence the determination of the price of any individual medicinal product or a group of medicinal products ;

(b) recommending to the Authority a reduction or increase in prices or maintaining the existing price of a medicinal products or a group of medicinal products ;

(c) monitoring the price fluctuations of a medicinal product ;

(d) collecting data on the use of a medicinal product or a group of medicinal products in Sri Lanka ;

(e) recommending to the Authority the methods of determining the introductory price and maximum retail price of medicinal products and price revisions of such medicinal products. ;

(f) advising the Authority on any other matter relating to pricing of a medicinal product ;

(g) from time to time, take into consideration the medicinal products which shall be subject to revision of prices.

10. The holder of the certificate of registration or the local manufacturer of any medicinal product shall submit reports on the quantities imported or supplied to the market of such registered product, to the Authority once in every six months.

11. It shall be the responsibility of the importer or the local manufacturer to inform the retailers, wholesale dealers and other relevant parties of the Maximum Retail Price (MRP) fixed by the Minister and the date of implementation.

12. Every manufacturer or importer shall mark the retail unit price of each medicinal product in the commercial package.

13. A person who sells a particular medicinal product at a price higher than the price fixed as the Maximum Retail Price (MRP) commits an offence.

14. Notwithstanding the above provisions, the Pricing Committee may, from time to time, considering the need for setting a Maximum Retail Price (MRP), for a particular medicinal product or group of medicinal products in the best interest of the public shall make recommendations to the Minister to revise the Maximum Retail Price (MRP) and may require relevant data from any holder of a certificate of registration of any medicinal product or local manufacturer.

15. The Pricing Committee may from time to time decide on the number of price revisions for any medicinal product during a calendar year.

16. Each application for registration or renewal of registration of any medicinal product shall set out the existing and the intended Maximum Retail Price (MRP), of the medicinal product together with the method of deciding the Maximum Retail Price (MRP). The application shall be as recommended by the Authority. Where appropriate, the Pricing Committee may, after studying the price of any medicinal product, give its recommendation with respect to the Maximum Retail Price (MRP) to the Medicines Evaluation Committee established under section 43 of the National Medicines Regulatory Authority Act, No. 5 of 2015.

17. The pricing committee may require such information as it considers necessary in respect of costs including freight, insurance and any other cost from manufacturers, importers and traders and such manufacturers, importers or traders shall provide the required information with proper explanation and account of such data.

18. No manufacturer, importer or any other person shall carry out any activity influencing the price or the availability of any medicinal product which may lead to -

(a) the existence or possible existence of a monopoly situation ;

(b) the creation or possible creation of a merger situation ;

(c) the prevalence of any anti-competitive practice.

19. 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.

11 - 628

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