

L.D.B. 7/2009

**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 read with paragraph (d) of section 145 of the aforesaid Act.

Pavithra Devi Vanniarachchi  
**Minister of Health**

Colombo,  
....., 2021

**REGULATIONS**

The Cosmetics Regulations No. 38 of 1984 published in the *Gazette* Extraordinary No. 378/3 of December 2, 1985 is hereby amended as follows: -

1. by the repeal of regulation 39 thereof and the substitution therefor of the following new regulations: -

“39. (1) A person shall not advertise or promote any cosmetic without registering such cosmetic with the National Medicines Regulatory Authority (in these regulations referred to as the “Authority”) and obtaining a licence thereon.

(2) A person shall not advertise or promote any cosmetic without prior written approval of the Authority.

(3) Any person who wishes to obtain the written approval under sub-regulation (2) shall-

(a) submit an application to the Authority in a form as may be determined by the Authority accompanied by the relevant fee specified in the Schedule V hereto; and

(b) submit all necessary documents along with the application.

(4) Upon the receipt of the application under sub-regulation (3), the Authority shall, on the consideration of the matters contained I the application and documents,

either grant the written approval issue for advertising or promoting the cosmetic to which the application relates or for reasons to be recorded by it refuse to grant a written approval. The Authority shall, in writing inform the applicant of his decision and in a case of refusal to grant a written approval, it shall state its reasons therefor.

(5) Every written approval granted under sub-regulation (4) shall be in a form as determined by the Authority and such written approval shall, until revoked earlier, be valid for one year from the date of grant and shall be subject to such terms and conditions specified therein.

(6) The Authority may revoke a written approval granted under sub-regulation (4), if the Authority is satisfied that the person to whom the written approval is granted has violated any regulations made under the provisions of Cosmetics, Devices and Drugs Act, No.27 of 1980 or any of the terms and conditions of the written approval.

**39A.** (1) A written approval granted under sub-regulation (4) of regulation 39, shall be renewable on an application being made in that behalf to the Authority not later than thirty days before the expiry of the written approval and be accompanied by a fee specified in the Schedule V hereto.

(2) A written approval shall be renewed by the Authority, only if the Authority is satisfied that the person to whom the written approval is granted has not violated any regulations made under the provisions of Cosmetics, Devices and Drugs Act, No.27 of 1980 or any of the terms and conditions of the written approval.

**39B.** (1) A person shall not advertise or promote any cosmetic as a treatment, prevention or cure for any disease, disorder or abnormal physical state set out in Schedule VI hereto.

(2) A person shall not advertise or promote any cosmetic in a manner that is false, misleading, deceptive or likely to create an erroneous impression regarding its composition, efficacy and safety.”.

(2) by the addition of new regulation 43 immediately after regulation 42 thereof-

“43. For the purpose of these regulations -

“cosmetic” shall have the same meaning assigned to it by the National Medicines Regulatory Authority Act, No. 5 of 2015.”;

(3) by the addition of new Schedules V and VI immediately after Schedule IV thereof-

### SCHEDULE V

[Regulation 39(3)(a) and 39A]

#### FEES / RENWAL FEES

No.	Category	Sri Lankan Rupees
1.	Processing Fee	Rs. 10,000/-
2.	Fees for the Approval	Rs. 35,000/-
3.	Fees to Evaluate Extra Details or for Other Changes which Require Review	Rs. 5000/-

### SCHEDULE II

[Regulation 39B(1)]

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|-------------------------------|--|
| 1. Anxiety State              | 30. Nausea and Vomiting in Pregnancy     |
| 2. Appendicitis               | 31. Nocturnal Emissions                  |
| 3. Arteriosclerosis           | 32. Obesity                              |
| 4. Asthma                     | 33. Edematous State                      |
| 5. Bladder Disease            | 34. Parangi                              |
| 6. Blood Poisoning            | 35. Pleurisy                             |
| 7. Cachexia                   | 36. Pneumonia poliomyelitis              |
| 8. Cancer                     | 37. Rabies                               |
| 9. Catarrh                    | 38. Tetanus                              |
| 10. Convulsions               | 39. Rheumatic Fever                      |
| 11. Depression                | 40. Rheumatoid Arthritis                 |
| 12. Diabetes                  | 41. Septicemia                           |
| 13. Diphtheria                | 42. Sexual Impotency                     |
| 14. Disorders of Menstruation | 43. Sexual Underdevelopment              |
| 15. Epilepsy                  | 44. Sinusitis                            |
| 16. Gall Bladder Disease      | 45. Small Pox                            |
| 17. Gangrene                  | 46. Spermatorrhoea                       |
| 18. Glaucoma                  | 47. Stroke                               |
| 19. Goitre                    | 48. Thyroid Disease                      |
| 20. Heart Disease             | 49. Tonsillitis                          |
| 21. Hernia                    | 50. Trachoma                             |
| 22. Hypertension              | 51. Tuberculosis                         |
| 23. Hypotension               | 52. Tumours                              |
| 24. Impetigo                  | 53. Ulcer of the Gastro Intestinal Tract |
| 25. Infantile Paralysis       | 54. Vaginitis                            |
| 26. Kidney Disease            | 55. Venereal Disease                     |
| 27. Leprosy                   | 56. White Discharge                      |
| 28. Liver Disease             | 57. Wasting Disease                      |
| 29. Locomotor Ataxia          | 58. Yaws                                 |

(4) (a) Any person who engages in advertising or promoting any cosmetic on the date of the commencement of these regulations shall, notwithstanding the provisions contained in regulation 39 of these regulations, be permitted to continue to be engaged in advertising or promoting as such from the date of the commencement of these regulations, for a period of one month.

(b) Prior to the expiry of the period of one month referred to in sub-regulation (a), a person who engages in advertising or promoting any cosmetic on the date of the commencement of these regulations shall be required to make an application under regulation 39 of these regulations for a written approval for the advertisement or promotion of cosmetics.