L.N. 399 of 2003

MEDICINES ACT, 2003
(ACT NO. III OF 2003)

Government Health Services (List of Available Medicinal Products) Regulations, 2003

IN excerise of the powers conferred by article 106 (d) of the Medicines Act, 2003, the Minister of Health has made the following regulations:-

Title and commencement.

1. (1) The title of these regulations is the Government Health Services (List of Available Medicinal Products) Regulations, 2003.

(2) These regulations shall come into force on the 1st May, 2004.

Application.

2. These regulations shall apply where an applicant of a market authorisation wishes to apply for the coverage of a medicinal product on the list of medicines available within the Government Health Services.

Request by applicant.

3. (a) An applicant may, when requesting a market authorisation or after being granted a market authorisation, further request that a medicinal product be covered by the list of medicines included in the Government Health Services. In such cases the applicant shall forward a separate application to the Superintendent of Public Health in accordance with the requirements laid down by the Superintendent of Public Health. The applicant shall furnish the Superintendent of Public Health with adequate information.

(b) The Superintendent of Public Health shall within 90 days of receipt of the application or of the issue of a market authorisation (in the case where the application was submitted before the issue of a market authorisation), communicate the decision to the applicant. If the information supporting the application is inadequate, the time limit shall be suspended and the applicant shall be notified of what detailed additional information is required.

(c) Any decision not to cover a medicinal product in the list of medicines of the Government Health Services shall include the criteria used to determine this decision and information as to the remedies available to the applicant.

Decision to exclude a medicine.

4. Any decision to exclude a medicine or a category of medicinal products from the list of medicines of the Government Health Services shall contain a statement of reasons based on objective criteria and be published in an appropriate publication, as determined by the Superintendent of Public Health.

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