**L.N. 58 of 2018**

# HEALTH ACT
# (CAP. 528)

## Exceptional Medicinal Treatment Committee Regulations, 2018

IN EXERCISE of the powers conferred by article 30 of the Health Act, the Minister responsible for Health, has made the following regulations:-

Citation and commencement.

**1.** (1) The title of these regulations is the Exceptional Medicinal Treatment Committee Regulations, 2018.

(2) These regulations shall come into effect on such date as the Minister for Health may by notice in the Gazette appoint.

Interpretations.

**2.** In these regulations, unless the context otherwise requires:-

"Committee" means the Exceptional Medical Treatment Committee;

"Exceptional Medicinal Treatment" means medicinal treatment provided in cases of diseases when the medicinal treatment is not on the Government Formulary List or is not according to the Government Formulary List policies;

"Fifth Schedule" means an entitlement to free medical aid to their medical condition as suffered and subject to these persons satisfying the means test provisions as laid down in Part II of the said Schedule of the Social Security Act;

Cap. 318.

"Government Formulary List" means a list of medicinal treatments available within the national health service as defined in the Availability of Medicinal Products within Government Health Services Regulations;

S.L.458.31.

"Minister" means the person responsible for the Ministry for Health;

"Rare Disease" means any disease or medical condition or disorder that effects less than one per two thousand persons.

Exceptional Medicinal Treatment Committee.

**3.** (1) There shall be a Committee to be known as the Exceptional Medicinal Treatment Committee.

(2) The Committee shall assess requests for exceptional medicinal treatment in cases where such treatment is:

(a) not listed on the Government Formulary List;

(b) medicines are listed on the Government Formulary List but not according to protocol, indication or prescribed criteria;

(c) specifically branded medicines;

(d) medicines for the treatment of Rare Diseases.

Appointment of Committee.

**4.** (1) The Minister shall appoint the Committee which shall be composed of:

(a) a Chairperson;

(b) Chief Medical Officer or a representative of the Department of Policy in Health;

(c) two Pharmacists one of which is from the Directorate for Pharmaceutical Affairs;

(d) two Clinicians;

(e) a representative of the Central Procurement and Supplies Unit within the Ministry for Health;

(f) a Patient Representative.

(2) A secretary to the Board shall be appointed by the Minister who shall be a member of the public service.

(3) The Committee shall provide for any matter or procedure it may deem necessary for the better implementation of the functions of the Committee.

(4) The Committee shall be provided with an annual budget and moreover shall submit an annual financial report to the Permanent Secretary within the Ministry for Health supporting the decisions taken by the Committee.

Duties of the Committee.

**5.** The Exceptional Medicinal Treatment Committee shall:

(a) receive applications for Exceptional Medicinal Treatment from the Directorate for Pharmaceutical Affairs;

(b) the applications shall be submitted to the Directorate for Pharmaceutical Affairs by a Medical Consultant and endorsed by the respective clinical chair of the respective Department at Mater Dei Hospital, through an application in the

form prescribed by the Chief Medical Officer;

(c) the application shall be received by the Directorate for Pharmaceutical Affairs who will from their part file the submission and assessment to the Exceptional Medicinal Treatment Committee for appraisal;

(d) the applications submitted to the Exceptional Medicinal Treatment Committee shall be evaluated according to rules established by the Chief Medical Officer from time to time.

**6.** Urgent Cases shall be assessed by the Chairperson in consultation with at least one of the clinicians sitting on the Committee as well as one pharmacist sitting on the Committee. The Directorate for Pharmaceutical Affairs shall determine which treatment is deemed to be urgent thus requiring an urgent decision.

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