OFFICE of the DEPUTY PRIME MINISTER
MINISTRY for HEALTH
15, PALAZZO CASTELLANIA, MERCHANTS STREET, VALLETTA, MALTA

DH CIRCULAR 15/2018
DH 417/2018

6th March 2018

Attention All: Consultants
Medical Officers
Pharmacists
Pharmacy Technicians
Nurses

Re: Set up of the Exceptional Medicinal Treatment Committee

It is being brought to your attention that following the *publication of L.N. 58 of 2018: Health Act (Cap. 528); Exceptional Medicinal Treatment Committee Regulations, 2018*, a Committee was set up, named The Exceptional Medicinal Treatment Committee (EMTC).

The objective of the EMTC is to assess requests for exceptional medicinal treatment in a consistent, transparent and sustainable way guided by strict criteria.

The EMT Policy is being attached which includes the Procedure to be adopted, the submission details, the EMT Request Form, the EMTC Terms of Reference and the Schedule of Review Criteria for assessment of Exceptional Medicinal Treatment Requests.

For your attention please.

Dr. Denis Vella Baldacchino
Chief Medical Officer

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Effective date: March 2018

Exceptional Medicinal Treatment Policy

1. PURPOSE

To set up a transparent process in the evaluation of Exceptional Medicinal Treatment Requests on a named patient basis for patients with an exceptional need for medicinal treatment that currently is not covered by an existing policy of the National Health Service (NHS).

2. BACKGROUND

2.1 Introduction

This Policy will apply to all Exceptional Medicinal Treatment requests which will be assessed in a consistent, transparent and sustainable way guided by strict criteria. It will be applied fairly and without discrimination on any grounds.

2.2 Exceptional Medicinal Treatment

An Exceptional Medicinal Treatment (EMT) is a medicinal treatment which is not covered by an existing policy on the Government Formulary List such as:

- Medicines Not listed on the GFL
- Medicines listed on the GFL but not according to protocol, indication or prescriber criteria
- Branded Medicines
- Medicines for the treatment of Rare Diseases

A rare disease is defined in the EU as one that presents prevalence less than 5 per 10,000 persons in the European Union.

3. POLICY

3.1 Policy Statement

To provide high quality, cost-effective, affordable exceptional medicinal treatment to patients that meets their individual needs through decisions based on what assessed research evidence has shown provides effective clinical outcomes.

3.2 Procedure

- Applications shall be submitted to the Directorate for Pharmaceutical Affairs by a Medical Consultant through an application in the form prescribed by the Chief Medical Officer *(Attached).* This application must be endorsed by the Clinical Chair of the respective department.

- A short assessment will be compiled by DPA pharmacists which includes filling up of the *Schedule of Review Criteria for assessment of Exceptional Medicinal Treatment Requests (Annex 2).*

- The DPA shall file the submission and assessment to the Exceptional Medicinal Treatment Committee for appraisal.

3.3 Submissions

Submissions of EMT requests will be made to the Directorate for Pharmaceutical Affairs (DPA) who can be contacted on the following contact details:

Directorate for Pharmaceutical Affairs,
Administration Building,
St. Luke's Hospital,
G'Mangia

Tel: 2595 5232

Email: dpa.health@gov.mt

3.4 Terms of Reference of the EMTC

The Exceptional Medicinal Treatment Committee shall:

- Receive applications for exceptional medicinal treatment from the Directorate for Pharmaceutical Affairs.

- Shall evaluate the submitted applications and decide whether an EMT request should be approved or rejected.

- Shall be guided by criteria that for ease of procedure are incorporated in a schedule called the *Schedule of Review Criteria for assessment of Exceptional Medicinal Treatment Requests.*

3.5 Urgent EMT Requests

For the purpose of this policy Urgent Cases are being defined as a submission which needs to be assessed before the next scheduled EMTC meeting.

The Director for Pharmaceutical Affairs shall determine which treatment is deemed to be urgent thus requiring an urgent decision.

Urgent Cases shall be assessed by the EMTC Chairperson in consultation with at least one of the clinicians sitting on the Committee as well as one pharmacist sitting on the Committee.

3.6 Decisions

Decisions taken by the EMTC will be final unless there is new evidence that was not previously available or considered in which case the request can be sent back to DPA for reconsideration by the EMTC in the light of the new evidence.

3.7 Notification of Decisions

Notification of the decisions taken regarding approval or rejection of requests are referred to the DPA who will in turn notify the person who had submitted the EMT request. The CPSU are informed of the decisions taken so that the procurement process is initiated when an approval is granted.

3.8 Data Protection

Patient details are required in order to process the request form however these are processed and stored according to data protection Regulations.

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Annex 2

Schedule of Review Criteria for assessment of Exceptional Medicinal Treatment Requests

Positive Criteria	
Treatment is of an exceptional nature	
Disease is of serious nature or life threatening	
Disease is rare	
Request for treatment is urgent	
Entitlement is in place	
Cost of Requested Medicine is cheaper than alternative available on the GFL	
Medicine is licensed for the particular indication under consideration	
Medicine possesses an orphan drug status	
Scientific/Clinical evidence of effectiveness	
Medicine has been favorably recommended by international agencies offering reimbursement guidelines	
Negative Criteria	
Medicinal product was considered for introduction onto the GFL and rejected already	
Alternative treatment is available	
Alternative treatment is less costly	
Negative HTA recommendation	
Annual cost per patient in relation to survival/quality of life	

Directorate for Pharmaceutical Affairs
Ministry for Health
Administration Building, St. Luke's Hospital, G'Mangia
Email: dpa.health@gov.mt Tel. No: 2595 5232

Exceptional Medicinal Treatment Request Form

1. Patient Details

Patient's Name

Date of Birth | **I.D. Card Number** | **Mobile Number**

Address

2. Details of Medicine Requested and Clinical Indications

Request

- ☐ First Application
- ☐ Renewal (refer to Section 7)
- ☐ In-patient use
- ☐ Out-patient use

Entitlement to Free Medicines

- ☐ Schedule V Condition
- ☐ Schedule II
- ☐ No Schedule II or Schedule V entitlement

Medication Requested | **Dosage Form and Strength**

Dosage Regimen | **Expected Duration of Therapy**

Clinical Indications

3. Current and/or Previous Medications

Please provide details of all therapies/interventions tried for this condition (kindly indicate current treatment)

Name of Intervention	Date of Intervention	Approximate Time Frame if applicable	Dosage Regimen if Applicable	Outcome of Therapy/Reason for Stopping Therapy

This form will be returned if any section is not completed

Data Protection Statement

All personal data is required to provide you with health care services as necessary, and is processed in accordance with the Data Protection Act, and as permitted by law. Further information about your data can be obtained on request

4. Standard Treatment and Proposed New Treatment

Reason/s why drug is being requested.	
What is the clinical severity? *Where possible include standard scoring systems*.	
Please indicate the following: • standard treatment for this indication and stage of disease • other possible treatment options (Formulary/Non-Formulary)	
What are the circumstances that make standard treatment or other treatment options inappropriate for this patient?	
Will this drug be used as monotherapy? If not, kindly indicate combination regimen	

5. Information on Exceptionality

Explain why this case is being regarded as exceptional. *Does the patient have a condition which is genuinely unusual or with a unique clinical factor? Is the patient more likely to gain significantly more benefit from the medicinal than might be expected from the average patient with a similar condition?*	
How many other similar patients are envisaged to require this treatment over the next 12 months?	

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6. Evidence of Clinical Effectiveness

What is the evidence of effectiveness of the requested treatment in this situation?	
What is the anticipated benefit of requested treatment in terms of quality of life, symptoms, expected survival, impact of facilitating subsequent treatment, etc.?	
Indicate **objective measures/ validated markers** which can predict/ monitor response to treatment as well as **minimum timeframe** after which clinical response can be assessed.	
Has this treatment been attempted locally in other similar patients before, and in the affirmative, what results were achieved?	

Any scientific evidence or relevant information to support this request can be sent via email to dpa.health@gov.mt

7. Renewal of Treatment

If the patient is currently taking the requested product, please provide evidence of its efficacy.	

8. Applicant Details

Signature of Consultant	**Signature of Clinical Chairperson**
Name in BLOCK LETTERS and Registration Number	**Name in BLOCK LETTERS and Registration Number**
Date:	**Date:**

For Office Use only: ☐ *Approved* ☐ *Not Approved* *Date:* _____

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