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

DH Circular 22/2019
DH 417/2018

7th March 2019

Attention All: Consultants
Medical Officers
Pharmacists
Pharmacy Technicians
Nurses

Amendment to Legal Notice 58/2018 regarding the Exceptional Medicinal Treatment Committee Regulations

Following the amendment to Legal Notice 58 of 2018, as amended by Legal Notice 448 of 2018 regarding the Exceptional Medicinal Treatment Committee Regulations, the Exceptional Medicinal Treatment Policy and associated Schedule of Review Criteria for assessment of Exceptional Medicinal Treatment Requests have been updated accordingly.

All concerned are kindly requested to familiarise themselves with these documents which are to be found annexed to this circular.

For your attention please.

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Chief Medical Officer

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Effective date: January 2019

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 Exceptional Medicinal Treatment Policy (EMTP) 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 Definitions

For the purpose of this policy:

Exceptional Medicinal Treatment (EMT) 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.

Government Formulary List (GFL) 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

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

An Urgent EMT request is being defined as a request for medicinal treatment which needs to be assessed before the next scheduled EMTC meeting.

A Critical EMT request is being defined as a submission for medicinal treatment which, if not administered immediately, can result in life-threatening consequences for the patient and thus needs to be initiated with immediate effect.

2.3 Exceptional Medicinal Treatment Committee

The Committee shall assess requests for EMT in cases where such treatment is:

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

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.

4. PROCEDURE

4.1 Application

An Application for EMT shall be made to the Directorate for Pharmaceutical Affairs (DPA) through an application in the form prescribed by the Chief Medical Officer.

The DPA 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

4.1.1 Application for Renewal / Change in dose of an approved EMT:

- Application needs to be endorsed by a Consultant in the medical class. Endorsement by Clinical Chair/Lead Clinician is not required
- The bottom part of the expired permit can be filled in and used as an EMT renewal application.

- The EMTC reserves the right to request a progress report prior to assessing and approving renewals.

4.1.2 Application for an EMT which has previously been approved through the EMTP for the same requested indication for previous patients.

- Application needs to be signed by a Consultant in the medical class and endorsed by the respective Clinical Chair. The Clinical Chair can delegate authority to endorse requests to Lead Clinicians.
- The EMTC reserves the right to request feedback from clinician about treatment outcomes of previously approved cases.

4.1.3 Application for an EMT/Indication which has never been approved in the past:

- Application needs to be signed by a Consultant in the medical class and endorsed by the respective Clinical Chair.

4.2 Processing of EMT Application

- Once application is received, 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 1).*

- The DPA shall file the application, assessment and Schedule of Review Criteria to the Exceptional Medicinal Treatment Committee for appraisal.

- The Exceptional Medicinal Treatment Committee will assess the submission and issue an approval or rejection.

- The EMTC may request further information to be presented by the DPA in order for a decision to be made.

4.3 Urgent EMT Requests

- For the purpose of this policy, an Urgent EMT request is being defined as a submission which needs to be assessed before the next scheduled EMTC meeting.

- Urgent EMT submissions 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.

4.4 Critical EMT requests:

- For the purpose of this policy, a Critical EMT request is being defined as a submission for Medicinal treatment which, if not administered immediately, can result in life-threatening consequences for the patient and thus needs to be initiated with immediate effect.

- The EMTC authorizes the Medical Doctor and Dispensing Pharmacist to adopt a procedure whereby the patient is provided with the necessary critical medicine in the shortest time possible.

- The Medical Doctor can endorse the request on behalf of the Clinical Chair/Lead Clinician/Consultant as per requirements listed above.

- The Medical Doctor will liaise with the Dispensing Pharmacist and an emergency supply will be provided until the next working day of the respective Department, after which the normal submission process will be carried out and request treated as Urgent EMT.

- The Dispensing Pharmacist will alert the procurement body that stock of the critically required medicine was depleted.

4.5 Decisions

Decisions taken by the EMTC will be final unless there is new evidence that was not previously available or considered. In such cases, the request can be sent back to DPA who shall in turn submit to the EMTC for reconsideration in the light of the new evidence.

4.6 Notification of Decisions

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

5.0 Terms of Reference of the EMTC

The Exceptional Medicinal Treatment Committee shall:

- Receive submissions for EMT from the Directorate for Pharmaceutical Affairs.

- Evaluate the submitted applications and information.

- 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.*

- Adopt and publish any necessary procedure to process urgent and critical submissions.

- Decide whether an EMT request is approved or rejected.

- Notify DPA of decision outcome.

6.0 Data Protection

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

Annex 1

Schedule of Review Criteria for assessment of Exceptional Medicinal Treatment Requests

Positive Criteria	
Submission is of a unique nature	
Disease is life threatening	
Disease is rare	
Request for medicinal treatment is urgent	
Schedule V Entitlement is in place	
Medicine is required for inpatient use	
ADR report submitted	
Medicine is licensed for requested indication	
Medicine possesses an orphan drug status	
Scientific/Clinical evidence of effectiveness	
Medicine has been favorably recommended by European agencies offering reimbursement guidelines	
Medicine was considered for introduction onto the GFL and recommended already	
Medicine was already approved for other indications through the EMTP	
Cost of Requested Medicine is cheaper than alternative available on the GFL	
Negative Criteria	
Medicinal product was considered for introduction onto the GFL and rejected already	
Medicine will be required as part of the Treatment Pathway for the requested indication	
Alternative treatment is available	
Alternative treatment is less costly	
Implication of receiving other similar cases	
COST	
Annual cost per patient	
Total Annual cost for all patients who will need this medicine if approved	
EMTC funding available	

SUBSIDIARY LEGISLATION 528.08

EXCEPTIONAL MEDICINAL TREATMENT COMMITTEE REGULATIONS

23rd March, 2018

LEGAL NOTICE 58 of 2018, as amended by Legal Notice 448 of 2018.

Citation.

1. The title of these regulations is the Exceptional Medicinal Treatment Committee Regulations.

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. *Substituted by: L.N.448 of 2018*.

5. (1) The Committee shall receive applications for exceptional medicinal treatment from the Directorate for Pharmaceutical Affairs through an application in the form prescribed by the Chief Medical Officer.

(2) Applications for exceptional medicinal treatment:

(a) which have not been previously approved for the requested indication, shall be submitted to the Directorate for Pharmaceutical Affairs by a Consultant in the medical class and endorsed by the respective Clinical Chair;

(b) which have previously been approved for the same requested indication, shall be submitted to the Directorate for Pharmaceutical Affairs by a Consultant in the medical class and endorsed by the

respective Clinical Chair. The Clinical Chair can delegate authority to endorse these requests to the Lead Clinician;

(c) for renewals or for a change in dose of an approved exceptional medicinal treatment, shall be submitted to the Directorate for Pharmaceutical Affairs by a Consultant in the medical class.

(3) The Directorate for Pharmaceutical Affairs will from their part file the submission and assessment to the Exceptional Medicinal Treatment Committee for appraisal.

(4) The applications submitted to the Committee shall be evaluated according to rules established by the Chief Medical Officer from time to time.

Amended by: L.N. 448 of 2018.

6. (1) 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.

(2) The Committee may adopt and publish any necessary procedure to process urgent and critical submissions.

LEĠISLAZZJONI SUSSIDJARJA 528.08

REGOLAMENTI DWAR IL-KUMITAT GĦAT-TRATTAMENT MEDIĊINALI EĊĊEZZJONALI

23 ta' Marzu, 2018

L-AVVIŻ LEGALI 58 tal-2018,kif emendat bl-Avviż Legali 448 tal-2018.

Titolu.

1. It-titolu ta' dawn ir-regolamenti hu Regolamenti dwar il-Kumitat għat-Trattament Mediċinali Eċċezzjonali.

Tifsir.

2. F'dawn ir-regolamenti, kemm-il darba ir-rabta tal-kliem ma tkunx teħtieġ xort'oħra:-

"Il-Ħames Skeda" tfisser intitolament għal għajnuna medika bla ħlas għall-kondizzjoni medika sofferta u suġġetta għal dawk il-persuni li jissodisfaw id-dispożizzjonijiet dwar it-test tal-mezzi stabbiliti fit-Taqsima II tal-imsemmija Skeda tal-Att dwar is-Sigurtà Soċjali; Kap. 318.

"Kumitat" tfisser il-Kumitat għat-Trattament Mediċinali Eċċezzjonali;

"Lista Formularja tal-Gvern" tfisser lista ta' trattamenti mediċinali disponibbli fis-servizz nazzjonali tas-saħħa kif definita fil-Regolamenti dwar Prodotti Mediċinali Disponibbli fis-Servizzi tas-Saħħa tal-Gvern; L.S. 458.31.

"Mard Rari" tfisser kwalunkwe mard jew kondizzjoni jew diżordni medikali li taffetwa inqas minn wieħed minn kull elfejn persuna;

"Ministru" tfisser il-persuna responsabbli mill-Ministeru għas-Saħħa;

"Trattament Mediċinali Eċċezzjonali" tfisser trattament mediċinali ipprovdut f'każijiet ta' mard speċifiku liema trattament mediċinali mhux elenkat fuq il-Lista Formularja tal-Gvern jew ma huwiex skond il-politika tal-lista Formularja tal-Gvern.

Kumitat għat-Trattament Mediċinali Eċċezzjonali.

3. (1) Għandu jiġi stabbilit Kumitat li jkun magħruf bħala l-Kumitat għat-Trattament Mediċinali Eċċezzjonali.

(2) Il-Kumitat għandu jevalwa t-talbiet għat-trattament mediċinali eċċezzjonali f'każijiet fejn dak it-trattament:

(a) ma jkunx elenkat fuq il-Lista Formularja tal-Gvern;

(b) ikun elenkat fuq il-Lista Formularja tal-Gvern iżda mhux skont protokolli, indikazzjonijiet jew kriterji ta' min joħroġ ir-riċetti;

(ċ) jinvolvi mediċini b'marka speċifika;

(d) jinvolvi mediċini għat-trattament ta' mard rari.

Ħatra tal-Kumitat.

4. (1) Il-Ministru għandu jaħtar il-Kumitat li għandu jkun magħmul minn:

(a) *Chairperson*;

(b) Uffiċjal Mediku Ewlieni jew rappreżentant mid-Dipartiment għall-Politika tas-Saħħa;

(ċ) żewġ spiżjara, waħda minnhom mid-Direttorat għall-Affarijiet Farmaċewtiċi;

(d) żewg kliniċisti;

(e) rappreżentant mit-Taqsima tal-Akkwisti u l-Provvisti fi ħdan il-Ministeru għas-Saħħa;

(f) rappreżentant għall-pazjenti.

(2) Il-Ministru għandu jaħtar segretarju għal Bord li jkun membru fis-servizz pubbliku.

(3) Il-Kumitat għandu jipprovdi għal kull kwistjoni jew proċedura li jidhirlu meħtieġ għall-aħjar twettiq tal-funzjonijiet tal-Kumitat.

(4) Il-Kumitat għandu jingħata baġit annwali u barra minn hekk għandu jibgħat rapport finanzjarju annwali lis-Segretarju Permanenti fi ħdan il-Ministeru għas-Saħħa u dan skont id-deċiżjonijiet meħuda mill-kumitat.

Dmirijiet tal-Kumitat.
Sostitwit: A.L. 448 tal-2018.

5. (1) Il-Kumitat għandu jirċievi applikazzjonijiet għal trattament mediċinali eċċezzjonali mid-Direttorat għall-Affarijiet Farmaċewtiċi permezz ta' applikazzjoni fil-forma preskritta mill-Uffiċjal Mediku Ewlieni.

(2) L-applikazzjonijiet għal trattament mediċinali eċċezzjonali:

(a) li qatt ma ġew approvati qabel għall-indikazzjoni mitluba, għandhom jintbagħtu lid-Direttorat għall-Affarijiet Farmaċewtiċi minn Konsulent Mediku u approvati mill-Kap Kliniku rispettiv;

(b) li diġà ġew approvati qabel għall-istess indikazzjoni

mitluba, għandhom jintbagħtu lid-Direttorat għall-Affarijiet Farmaċewtiċi minn Konsulent Mediku u approvati mill-Kap Kliniku rispettiv. Il-Kap Kliniku jista' jiddelega l-awtorità li japprova dawn it-talbiet lill-Kliniku Ewlieni;

(ċ) għat-tiġdid jew għal bidla fid-doża ta' trattament mediċinali eċċezzjonali approvat, għandhom jintbagħatu lid-Direttorat għall-Affarijiet Farmaċewtiċi minn Konsulent Mediku.

(3) Id-Direttorat għall-Affarijiet Farmaċewtiċi għandhom, min-naħa tagħhom, jippreżentaw is-sottomissjoni u l-valutazzjoni tagħhom lill-Kumitat għall-evalwazzjoni.

(4) L-applikazzjonijiet mibgħuta lill-Kumitat għandhom jiġu evalwati skont ir-regoli maħruġa mill-Uffiċjal Mediku Ewlieni minn żmien għal żmien.

Emendat: A.L. 448 tal-2018.

6. (1) Każijiet Urġenti għandhom jiġu evalwati mic-*Chairperson* f'konsultazzjoni ma' mill-inqas wieħed mill-kliniċisti tal-Kumitat kif ukoll wieħed mill-ispiżjara tal-Kumitat. Id-Direttorat għall-Affarijiet Farmaċewtiċi għandu jiddetermina liema trattament huwa meqjus bħala urġenti u li għalhekk jeħtieġ deċiżjoni urġenti.

(2) Il-Kumitat jista' jaddotta u jippublika kull proċedura meħtieġa sabiex jiġu proċessati sottomossjonijiet urġenti u kritiċi.