

A.L. 165 ta' l-2007**ATT DWAR IL-MEDIĊINI
(KAP. 458)****Regolamenti ta' l-2007 dwar Prodotti Mediċinali Disponibbli
fis-Servizzi tas-Sahha tal-Gvern**

BIS-SAHHA tas-setghat moghtija bl-artikolu 106 (d) ta' l-Att dwar il-Mediċini, il-Ministru tas-Sahha, l-Anzjani u Kura fil-Komunità ghamel dawn ir-regolamenti li ġejjin:-

1. It-titolu ta' dawn ir-regolamenti hu **Regolamenti ta' l-2007** Titolu.
dwar **Prodotti Mediċinali Disponibbli fis-Servizzi tas-Sahha tal-Gvern.**

2. (1) Dawn ir-regolamenti japplikaw meta applikant ghal Skop.
awtorizzazzjoni ghat-tqeghid fis-suq (hawn iżjed 'il quddiem imsejjah "l-applikant") ikun irid japplika biex jiddahhal prodott mediċinali fil-lista ta' prodotti mediċinali koperti mis-Servizzi tas-Sahha tal-Gvern, minn hawn 'il quddiem imsejha "Il-Lista Formularja tal-Gvern".

(2) Dawn ir-regolamenti ma ghandhom bl-ebda mod jillimitaw lis-Suprintendent tas-Sahha Pubblika milli jinkludi xi prodott mediċinali fil-Lista Formularja tal-Gvern.

3. (1) Is-Suprintendent tas-Sahha Pubblika ikun responsabbli Responsabbiltajiet.
ghall-implimentazzjoni ta' dawn ir-regolamenti u jkun assistit minn Kumitat li jista' jikkonsulta ma' l-esperti li huwa stess jinnomina. Huwa ghandu jkollu s-sostenn ta' segretarjat li jaġixxi bhala segretarjat tal-Kumitat u tas-sottogrupperi ta' esperti.

(2) Is-Suprintendent tas-Sahha Pubblika, il-membri tal-Kumitat u l-esperti ghandhom jiddikjaraw kull interess li jkollhom, u s-Suprintendent tas-Sahha Pubblika jkollu d-dritt li jirrofta lil dawk il-membri jew esperti tal-kumitat li jkollhom konflitt ta' interess.

4. (1) Il-Lista Formularja tal-Gvern ghandha tinkludi lista ta' Il-Lista Formularja tal-Gvern.
prodotti mediċinali msemmija skond l-Isem Mhux Proprjetarju Internazzjonali (INN). Dawk il-prodotti ghandhom jiġu klassifikati skond il-klassifika Anatomika, Terapewtika u Kimika (ATC).

(2) Il-Lista Formularja tal-Gvern m'għandhiex tinkludi ismijiet proprjetarji ta' prodotti, kemm-il darba ma jkunx hemm ċirkostanzi eċċezzjonali fejn tista' tiġi kompromessa s-sigurtà tal-pazjent.

(3) Il-Lista Formularja tal-Gvern għandha tinkludi kondizzjonijiet li huma koperti mis-Servizzi tas-Sahha tal-Gvern skond il-jedd għal mediċini li jingħataw b'xejn, il-provvista fis-Servizzi tas-Sahha tal-Gvern (kura primarja u sekondarja, l-użu li jsir fi kliniċi jew sptarijiet speċifiċi), il-kriterji ta' min johroġ ir-riċetti u l-użu li jsir fis-Servizzi tas-Sahha tal-Gvern (l-identifikazzjoni ta' min johroġ ir-riċetta għal mediċini partikolari, kondizzjonijiet dwar kif jinkitbu r-riċetti, protokoll, linji direttivi terapewtiċi jew linji direttivi kliniċi).

(4) Prodotti li m'humix klassifikati bħala prodotti mediċinali skond it-tifsira li hemm fl-Att dwar il-Mediċini, jistgħu jiġu inkluzi fil-Lista Formularja tal-Gvern.

(5) Il-metodu ta' kif jiġi determinat il-proporzjon li għandu jintuża sabiex tiġi stabbilita l-ekwivalenza, għal dawk il-prodotti mediċinali differenti fi hdan l-istess grupp terapewtiku, għandu jiġi komunikat.

Applikazzjoni.

5. (1) Applikant jista' jitlob li prodott mediċinali jkun inkluz fil-Lista Formularja tal-Gvern. F'dawk il-każijiet l-applikant għandu jippreżenta applikazzjoni separata lis-Suprintendent tas-Sahha Pubblika skond il-htigiet stabbiliti mis-Suprintendent, kif speċifikat fil-formola ta' applikazzjoni li hemm annessa ma' Skeda I li tinsab ma' dawn ir-regolamenti.

(2) Is-Suprintendent tas-Sahha Pubblika għandu fi żmien 90 ġurnata minn meta jirċievi l-applikazzjoni jikkomunika d-deċiżjoni tiegħu lill-applikant. Jekk l-informazzjoni li tingħata b'sostenn ta' l-applikazzjoni ma tkunx adegwata, it-terminu taż-żmien għandu jiġi sospiż u l-applikant għandu jiġi avżat dwar dik l-informazzjoni addizzjonali dettaljata li tista' tkun meħtieġa.

(3) Kull deċiżjoni li prodott mediċinali ma jiġix inkluz fil-Lista Formularja tal-Gvern għandha tiġi komunikata lill-applikant u għandu jkun fiha:

(a) dikjarazzjoni tar-raġunijiet ibbażata fuq il-kriterji fi Skeda II li tinsab ma' dawn ir-regolamenti, inkluzi, jekk dawn ikunu adatti, l-opinjoni jew ir-rakkomandazzjonijiet ta' l-esperti li fuqhom tkun ġiet ibbażata d-deċiżjoni;

(b) informazzjoni dwar ir-rimedji li l-applikant ghandu disponibbli taht il-ligijiet fis-sehh u dwar it-termini moghtija biex jiġu applikati dawk ir-rimedji.

6. (1) Kull deċiżjoni li prodott mediċinali jiġi eskluż mil-Lista Formularja tal-Gvern ghandu jkun fiha dikjarazzjoni tar-raġunijiet ibbażati fuq kriterji oġġettivi u verifikabbli. Dawk id-deċiżjonijiet, inklużi, jekk ikunu adatti, kull opinjoni jew rakkomandazzjoni ta' l-esperti li fuqhom tkun giet ibbażata d-deċiżjoni ghandhom jiġu komunikati lill-persuna li tkun responsabbli ghal dan.

Deċiżjoni li prodott jiġi eskluż.

(2) Kull persuna responsabbli ghandha tiġi mgharrfa bir-rimedji li jkollha disponibbli taht il-ligijiet viġenti u t-termini moghtija biex jiġu applikati dawn ir-rimedji.

7. Kull deċiżjoni biex tiġi eskluża xi kategorija ta' prodotti mediċinali mil-Lista Formularja tal-Gvern ghandu jkun fiha dikjarazzjoni tar-raġunijiet ibbażati fuq kriterji oġġettivi u verifikabbli u din ghandha tiġi stampata f'pubblikazzjoni adatta skond ma jistabbilixxi s-Suprintendent tas-Sahha Pubblika.

Esklużjoni ta' kategorija ta' prodotti mediċinali.

8. Ebda haġa f'dawn ir-regolamenti m'ghandha tipprekludi lis-Suprintendent tas-Sahha Pubblika milli jagħmel kontrolli u jimponi kundizzjonijiet fil-każ tal-ksib u l-provvista ta' prodott mediċinali li jkunu koperti mis-Servizzi tas-Sahha tal-Gvern.

Kontrolli li jsiru mis-Suprintendent tas-Sahha Pubblika.

9. Dawn ir-regolamenti jirrevokaw ir-Regolamenti ta' l-2003 dwar Servizzi tas-Sahha tal-Gvern (Lista Prodotti Mediċinali Disponibbli).

Jirrevoka A.L. 399 ta' l-2003.

SKEDA I

Regolament 5(1)

Rif. Nru. _____

Form T01

Applikazzjoni lis-Suprintendent tas-Saħħa Pubblika sabiex jiġi ikkunsidrat prodott mediċinali biex dan jiġi kopert mil-Lista Formularja tal-Gvern skond ir-Regolamenti ta' l-2007 dwar Prodotti Mediċinali Disponibbli fis-Servizzi tas-Saħħa tal-Gvern.

Din l-applikazzjoni għandha timentela b' mod ċar u kollha kemm hi, inkella din tintbagħat lura u ma tiġix ikkunsidrata. It-termini taż-żmien li hemm speċifikati fil-legislazzjoni għat-teħid tad-deċiżjoni għandhom japplikaw għaladarba l-applikazzjoni tiġi validata u aċċettata.

1. Partikolaritajiet ta' l-Applikant

1.1 *Isem id-Detentur ta' l-Awtorizzazzjoni għat-Tqeghid fis-Suq*

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1.2 *Indirizz*

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1.3 *Numru tat-telefon*

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2. Partikolaritajiet tal-Prodott Mediċinali

2.1 *L-Isem tal-Prodott*

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2.2 *Ingredjent attiv*

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| 2.3 | <i>Ghamla farmaċewtika</i> |
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| 2.4 | <i>Qawwa tal-prodott</i> |
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| 2.5 | <i>Mod ta' kif u mnejn jinghata</i> |
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| 2.6 | <i>Qjies(qjisien)/daqs(daqsijiet) tal-pakkett propost li jkun ser jittqiegħed/jittqiegħdu fuq il-Lista Formularja tal-Gvern</i> |
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| 2.7 | <i>Indikazzjonijiet għaliex ikun qiegħed jintalab il-prodott [l-indikazzjonijiet għandhom ikunu koperti minn Sommarju tal- Karatteristiċi tal-Prodott (SPC) hekk kif ikun approvat lokalment].</i> |
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| 2.8 | <i>Pożoloġija / Reġim tad-dosaġġ (kif koperti minn SPC)</i> |
| | |
| 2.9 | <i>Kemm idum għaddej il-kors tal-kura (meta dan ikun japplika)</i> |
| | |
| 2.10 | <i>Grupp farmakoterapewtiku:</i> |
| | Kodiċi ATC _____ |
| | Grupp farmakoterapewtiku _____ |

3. Status ta' l-Awtorizzazzjoni

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| 3.1 <i>Status ta' l-Awtorizzazzjoni tal-prodott mediċinali f' Malta. (immarka skond ma japplika)</i> |
| 3.1.1 Awtorizzazzjoni skond il-proċeduri tal-Komunita' infurzati bir-Regolamenti tal-Kunsill (KE) Numru 726/2004 tal-Parlament Ewropew u tal-Kunsill tal- 31 ta' Marzu 2004, fejn jigu stabbiliti proċeduri Komunitarji għall-awtorizzazzjoni u s-sorveljanza ta' prodotti mediċinali għall-użu mill-bniedem u għall-użu veterinarju u fejn tiġi stabbilita l-Aġenzija Ewropea dwar il-Mediċini, bl-emendi. <input type="checkbox"/> |
| 3.1.2 Awtorizzazzjoni Nazzjonali għall-bejgħ [tinkludi wkoll prodotti approvati bil-Proċedura ta' Għarfien Reċiproku (MRP) u bil- Proċedura Deċentralizzata (DCP)] |

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| 3.2 <i>Numru ta' l-Awtorizzazzjoni</i> |
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| 3.3 <i>Data tal-hruġ ta' l-Awtorizzazzjoni</i> |
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| 3.4 <i>Data ta' l-iskadenza ta' l-Awtorizzazzjoni</i> |
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4. Kalkolu tan-nefqa

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| 4.1 <i>Stima ta' Nefqa għal kull Unit</i> Lm . |
| Ikkwota Mnejn ingiebet l-informazzjoni fuq in-nefqa: |

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| 4.2 <i>Nefqa totali għal kull Pazjent (Annwali jew għal kull kors ta' kura)</i> Lm . |
| (Jekk joghġbok spjega kif wasalt għal din il-figura) |

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| 4.3 <i>Numru kalkolat ta' pazjenti li x'aktarx jehtiegu il-prodott mediċinali (għid kif wasalt għal din l-informazzjoni)</i> |
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4.4 Valutazzjoni farmako-ekonomika tal-prodott mediċinali (dan m'ghandux isir tabilfors u s-Suprintendent tas-Sahha Pubblika jirriserva d-dritt li jagħmel il-valutazzjoni tiegħu)

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5. Aktar informazzjoni dwar il-Prodott Mediċinali

5.1 Raġunijiet għaliex il-prodott mediċinali qieghed jintalab li jiġi ikkunsidrat li jkun kopert mil-Lista Formularja tal-Gvern

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5.2 Paragun ta'dan il-prodott mediċinali ma' prodotti mediċinali simili jew alternattivi, jew ma' xi kura oħra disponibbli fis-suq

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5.3 Paragun ta'dan il-prodott mediċinali ma' prodotti mediċinali oħra fuq il-Lista Formularja tal-Gvern skond:

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| • Innovazzjoni |
| • Effettività/titjib terapewtiku |
| • Nefqa u valutazzjoni ekonomika |
| • Relazzjoni bejn il-valur u l-benefiċċji li jagħti il-prodott mediċinali għall-flus li jintefqu |
| • Sigurtà |
| • Effikaċja |
| • Impatt fuq il-kwalità tal-hajja |
| • Disponibilità u versatilità tal-prodott mediċinali |
| • Oħrajn |

Elenka kull informazzjoni dwar il-prodott li qegħda tintehmez:

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| SPC kif approvat |
| Kopja awtentikata ta' l-Awtorizzazzjoni għat-tqegħid fis-suq |
| Kitba li tissostanzja kull informazzjoni mogħtija |
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Qiegħed b'dan nikkonferma:

- i) Li safejn naf jien u nikkonoxxi, id-dettalji kollha li tajt f'din il-formola ta' applikazzjoni u d-dokumenti kollha ipprezentati, huma korretti u kompleti.
- ii) Naf sew li l-lista ta' mediċini disponibbli fi hdan is-Servizzi tas-Saħħa tal-Gvern hi skond il-klassifika ATC u li l-prodott mediċinali għandu jitqies skond l-ingredjent attiv li jkollu u mhux bħala prodott proprjetarju/ta' xi ditta.
- iii) Naf bil-kriterji li japplikaw skond il-liġi (Att dwar is-Sigurtà Soċjali, Kap. 318 artikolu 23; Regolamenti ta' l-2007 dwar Prodotti Mediċinali Disponibbli fis-Servizzi tas-Saħħa tal-Gvern).

Firma ta' l-Applikant

Isem b'ITTRI KAPITALI

Data _____

Fil-kaz li l-applikant, għall-finijiet ta' din l-applikazzjoni, ikun irid jinnomina persuna awtorizzata biex:-

a) jikkomunika/jiffirma f' ismu jew

b) jaġixxi f'kolli f' ismu,

għandhom jiġu provduti dettalji ta' min ikun qiegħed jiġi nominat u t-tip ta' awtorizzazzjoni li jkollu.

Firma ta' l-Applikant

Isem b'ITTRI KAPITALI

Data _____

Firma ta' min jiġi nominat

Isem b'ITTRI KAPITALI

Data _____

Għall-uffiċċju biss: L-applikazzjoni waslet fi ___/___/___

SKEDA II

Regolament 5(3)(a)

Il-Kriterji li jiġu kunsidrati mis-Suprintendent tas-Saħħa Pubblika, mill-Kumitat u mill-esperti li dawn jikkonsultaw ruħhom magħhom meta jiġu biex jiddeċiedu jekk għandhomx jinkludu prodott mediċinali fuq il-Lista Formularja tal-Gvern.

1. Jedd għal mediċini li jingħataw b'xejn kif speċifikat fl-Att dwar is-Sigurtà Soċjali, Kap. 318, artikolu 23 u l-Hames Skeda Taqsimata II li tinsab ma' l-istess Att dwar Mard u Kondizzjonijiet li dwarhom tista' tingħata Għajnuna Medika Bla Hlas. Jinkludi wkoll prodotti mediċinali meħtieġa għall-għoti ta' kura f'Istituzzjonijiet tal-Gvern.
2. L-istatus ta' registrazzjoni tal-prodott mediċinali f'Malta.
3. Prodott mediċinali jew kategorija ta' prodotti mediċinali għall-kura ta' kondizzjonijiet li joħroġu mill-iskop tas-Servizzi tas-Saħħa tal-Gvern jista' jiġi eskluż għalkollox mil-Lista Formularja tal-Gvern.
4. Il-valur, l-ammont u r-relevanza ta' l-informazzjoni u l-evidenza disponibbli dwar il-prodott mediċinali partikolarment f'dawk li huma r-relazzjoni bejn il-valur u l-benefiċċji li jagħti għall-flus li jintefqu, kemm is-servizz nazzjonali tas-saħħa jiflah jidhol għall-ispiza involuta u jkopriha skond il-mezzi disponibbli, l-impatt soċjali u epidemjologiku, paragon ma' mediċini oħra disponibbli u modalitajiet oħra ta' kura.
5. Htigiet djanjostiċi u htigiet oħrajn għall-ħruġ ta' riċetti, għall-użu u għas-sorveljar tal-prodott mediċinali partikolarment jekk jirrikjedu spejjeż addizzjonali.
6. Il-possibilità ta' sorveljar ta' l-użu tal-prodott mediċinali u s-sorveljar ta' l-eżitu tal-kura.
7. Kondizzjonijiet għall-provvista, għall-ħruġ ta' riċetti, għall-użu u għas-sorveljar tal-prodott mediċinali li jiddeterminaw il-kopertura ta' prodott mediċinali mis-Servizzi tas-Saħħa tal-Gvern.
8. Il-fatt li pazjenti jkun nbdew fuq il-kura jew li pazjenti kienu jagħmlu parti minn provi kliniċi ma jaffettwax id-deċiżjoni biex prodott mediċinali jiġi inkluz fil-Lista Formularja tal-Gvern.

L.N. 165 of 2007

**MEDICINES ACT
(CAP. 458)**

**Availability of Medicinal Products within the Government
Health Services Regulations, 2007**

IN exercise of the powers conferred by article 106 (d) of the Medicines Act, the Minister of Health, the Elderly and Community Care has made the following regulations:-

1. The title of these regulations is the Availability of Medicinal Products within the Government Health Services Regulations, 2007. Title.

2. (1) These regulations shall apply where the holder of a marketing authorisation (hereinafter referred to as “the applicant”) wishes to apply for the inclusion of a medicinal product on the list of medicinal products covered by the Government Health Services, hereinafter referred to as “The Government Formulary List”. Scope.

(2) These regulations shall not limit in any way the Superintendent of Public Health from including any medicinal product in The Government Formulary List.

3. (1) The Superintendent of Public Health shall be responsible for the implementation of these regulations and shall be assisted by a Committee which may consult with experts as designated by himself. He shall be supported by a secretariat which acts as secretariat to the Committee and any sub-groups of experts. Responsibilities.

(2) The Superintendent of Public Health, the members of the Committee and any experts shall declare their interest, and the Superintendent of Public Health will have the right to refuse any committee members or experts on the basis of conflict of interest.

4. (1) The Government Formulary List shall include a list of medicinal products by the International Non-proprietary Name (INN). The products in this list shall be classified according to the Anatomical Therapeutic Chemical (ATC) classification. The Government Formulary List.

(2) The Government Formulary List shall not include proprietary names of products, unless in exceptional circumstances where patient safety may be compromised.

(3) The Government Formulary List shall include conditions specific to coverage within the Government Health Services in terms of entitlement to free medicines, supply within the Government Health Services (primary and secondary care, use in specific clinics or hospitals), prescriber criteria and use within the Government Health Services (specific prescribers, conditions for prescribing, protocols, therapeutic guidelines or clinical guidelines).

(4) Products which are not classified as medicinal products in terms of the definition of the Medicines Act may be included on the Government Formulary List.

(5) The method for determining the ratio to be used for establishing equivalence, for different medicinal products within the same therapeutic group, shall be communicated.

Application.

5. (1) An applicant may request that a medicinal product be included in the Government Formulary List. In such cases the applicant shall forward an application to the Superintendent of Public Health in accordance with the requirements laid down by the said Superintendent, as specified in the application form attached in Schedule I to these regulations.

(2) The Superintendent of Public Health shall within 90 days of receipt of the application, 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 such detailed additional information as may be required.

(3) Any decision not to include a medicinal product in the Government Formulary List shall be communicated to the applicant and it shall contain:

(a) a statement of reasons based upon the criteria in Schedule II to these regulations, including, if appropriate, any expert opinions or recommendations on which the decision is based;

(b) information about the remedies available to the applicant under the laws in force and of the time limits allowed for applying such remedies.

Decision to exclude.

6. (1) Any decision to exclude a medicinal product from the Government Formulary List shall contain a statement of reasons based on objective and verifiable criteria. Such decisions, including, if appropriate, any expert opinions or recommendations on which the

decisions are based, shall be communicated to the person who is responsible therefor.

(2) Any such person as may be responsible shall be informed of the remedies available to him under the laws in force and the time-limits allowed for applying such remedies.

7. Any decision to exclude a category of medicinal products from the Government Formulary List shall contain a statement of reasons based on objective and verifiable criteria and shall be published in an appropriate publication to be determined by the Superintendent of Public Health. Exclusion of a category of medicinal products.

8. Nothing in these regulations shall preclude the Superintendent of Public Health from applying controls and conditions in the case of the procurement and supply of any medicinal product that is covered by the Government Health Services. Superintendent of Public Health may apply controls.

9. These regulations revoke the Government Health Services (List of Available Medicinal Products) Regulations, 2003. Revokes L.N. 399 of 2003.

SCHEDULE I

Regulation 5(1)

Ref. No. _____

Form T01

Application to the Superintendent of Public Health for the consideration of a medicinal product to be covered by the Government Formulary List as per the Government Health Services (Medicinal Products) Regulations, 2007.

This application is to be filled in clearly and completely, otherwise it will be returned and will not be considered. The time lines for the decision specified in the legislation apply once the application is validated and accepted.

1. Details of Applicant

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| 1.1 | <i>Name of Marketing Authorisation Holder</i> |
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| 1.2 | <i>Address</i> |
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| 1.3 | <i>Telephone number</i> |
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2. Details of Medicinal Product

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| 2.1 | <i>Product Name</i> |
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| 2.2 | <i>Active Ingredient</i> |
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| 2.3 | <i>Pharmaceutical form</i> |
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2.4 Strength

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2.5 Method and Route of Administration

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2.6 Proposed pack size/s to be placed on the Government Formulary List

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2.7 Indications for which the product is being requested [indications should be covered by locally approved Summary of Product Characteristics (SPC)].

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2.8 Posology / Dosage regimen (as covered by SPC)

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2.9 Duration of treatment course (where applicable)

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2.10 Pharmacotherapeutic Group:

ATC Code _____
 Pharmacotherapeutic Group _____

3. Authorisation Status**3.1 Authorisation of the medicinal product in Malta (tick where applicable)****3.1.1**

Authorisation in accordance with procedures laid down in Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, as amended.

3.1.2

National Marketing Authorisation [also includes products approved through the Mutual Recognition Procedure (MRP) and the Decentralised Procedure (DCP)]

5. Further Information regarding the Medicinal Product

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| 5.1 | <i>Reasons for requesting the medicinal product to be considered for coverage by the Government Formulary List</i> |
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| 5.2 | <i>Comparison of this medicinal product to similar or alternative medicinal products or other treatments available on the market</i> |
| | |

| | |
|------------|---|
| 5.3 | <i>Comparison of this medicinal product to other medicines on the Government Formulary List in terms of:</i> |
| | • Innovation |
| | • Therapeutic effectiveness/improvement |
| | • Cost and economic evaluation |
| | • Cost-effectiveness |
| | • Safety |
| | • Efficacy |
| | • Impact on quality of life |
| | • Availability and versatility of medicinal product |
| | • Other |

List any information about the product which is being attached:

| |
|--|
| Approved SPC |
| Authenticated copy of Marketing Authorisation |
| Literature to substantiate any information given |
| |
| |

I, hereby confirm:

- i) That to the best of my knowledge and belief, all the particulars I have given in this application form and all the documentation submitted, are correct and complete.
- ii) I am fully aware that the list of medicines available within the Government Health Services is by ATC classification and that the medicinal product will be considered by its active ingredient and not as a proprietary/branded product.
- iii) I am aware of the criteria that apply through the legislation (Social Security Act, Cap. 318, article 23; Availability of Medicinal Products within the Government Health Services Regulations, 2007.).

Signature of Applicant

Name in BLOCK LETTERS

Date _____

In the case where the applicant, for the purpose of this application, would like to nominate a person authorised to:

- a) communicate/sign on his behalf or
- b) act fully on his behalf,

there shall be provided details of the nominee and the type of authorisation available..

Signature of Applicant

Name in BLOCK LETTERS

Date _____

Signature of Nominee

Name in BLOCK LETTERS

Date _____

For office use only: Application received on ___/___/___

SCHEDULE II

Regulation 5(3)(a)

The Criteria which are taken into account by the Superintendent of Public Health, the Committee and any experts with which they consult in deciding whether or not to include a medicinal product on the Government Formulary List.

1. Entitlement to free medicines as specified in the Social Security Act, Cap. 318, article 23 and the Fifth Schedule Part II to the same Act regarding Diseases and Conditions in respect of which Free Medical Aid may be accorded. As well as medicinal products required for the provision of care within Government Institutions.
2. The registration status of the medicinal product in Malta.
3. A medicinal product or a category of medicinal products to treat conditions which fall outside the scope of the Government Health Services may be entirely excluded from the Government Formulary List.
4. The value, extent and relevance of the information and evidence available about the medicinal product particularly in terms of cost-effectiveness, affordability by the national health services, social and epidemiological impact, comparison to other available medicines and other treatment modalities.
5. Diagnostic and other requirements for the prescription, use and monitoring of the medicinal product particularly if additional costs are incurred.
6. The possibility for monitoring the use of the medicinal product and the outcome of treatment.
7. Conditions for the supply, prescription, use and monitoring of the medicinal product which determine the coverage of a medicinal product by the Government Health Services.
8. The fact that patients were started on treatment or were part of a clinical trial does not affect the decision for inclusion of a medicinal product on the Government Formulary List.