

A.L. 235 ta' l-2008

ATT DWAR IL-MEDIĊINI
(KAP. 458)

Regoli ta' l-2008 dwar l-Ghoti ta' Prodotti Mediċinali
mill-Fondazzjoni ghal Servizzi ta' Harsien Soċjali

BIS-SAHHA tas-setghat moghtija bl-artikolu 79 (2) ta' l-Att dwar il-Mediċini, il-Ministru għall-Politika Soċjali ghamel dawn ir-regoli li ġejjin:-

1. It-titolu ta' dawn ir-regoli hu Regoli ta' l-2008 dwar l-Ghoti ta' Prodotti Mediċinali mill-Fondazzjoni ghal Servizzi ta' Harsien Soċjali. Titolu.

2. Għall-finijiet ta' dawn ir-regoli u sakemm ir-rabta tal-kliem ma tkunx teħtieġ xort'ohra - Tifsir.

“l-Att” tfisser l-Att dwar il-Mediċini;

“l-Awtorità dwar il-Liċenzjar” tfisser l-awtorità mwaqqfa taht l-Att dwar il-Mediċini;

“il-Fondazzjoni” tfisser il-Fondazzjoni ghal Servizzi ta' Harsien Soċjali;

“fond imsemmi” tfisser fond imsemmi mill-Fondazzjoni mnejn jinghataw il-prodotti mediċinali li hemm elenkati fl-Iskeda li tinsab ma' dawn ir-regoli.

3. (1) Huma biss il-prodotti mediċinali jew klassi jew klassijiet ta' prodotti mediċinali elenkati fl-Iskeda li tinsab ma' dawn ir-regoli, li għandhom jinghataw mill-fond imsemmi. Ghoti ta' prodotti mediċinali mill-Fondazzjoni.

(2) Il-Fondazzjoni għandha tgharraf lill-Awtorità bl-indirizz tal-fond imsemmi u għandha tibda biss tagħti daww il-prodotti mediċinali għal darbha l-Awtorità dwar il-Liċenzjar tapprova lil dak il-fond imsemmi.

Awtorizzazzjoni.

4. (1) Il-Fondazzjoni ghandha biss taghti l-prodotti mediċinali elenkati fl-Iskeda li tinsab ma' dawn ir-regoli wara li tinhareg awtorizzazzjoni mill-Awtorità dwar il-Liċenzjar.

(2) Dik l-awtorizzazzjoni m'ghandha tiġi trasferita lil ebda persuna u ghandha tkun biss tapplika għall-ghoti ta' prodotti mediċinali elenkati fl-Iskeda li tinsab ma' dawn ir-regoli mill-fond imsemmi.

(3) Il-Fondazzjoni ghandha minnufih tavża lill-Awtorità dwar il-Liċenzjar b'kull prodott mediċinali li ma jibqax mehtieg li jinghata.

(4) Meta xi prodott mediċinali li ma jkunx wiehed minn dawk elenkati fl-Iskeda jkun jenhtieg li jinghata mill-fond imsemmi, il-Fondazzjoni ghandha titlob bil-miktub lill-Awtorità biex tagħmel emenda fl-Iskeda.

Validità u tiġdid ta' l-awtorizzazzjoni.

5. (1) L-awtorizzazzjoni tkun valida għal żmien sena u tista' tiġġedded wara li ssir talba bil-miktub mill-Fondazzjoni lill-Awtorità.

(2) It-talba ghandha ssir mill-inqas tliet xhur qabel ma jiskadi l-perjodu ta' validità.

(3) Ghandhom jithallsu, dwar kull awtorizzazzjoni bħal dik, dawk il-hlasijiet li soltu jsiru għal spizeriji skond ma japplikaw għal-liċenzi ta' l-ispizeriji.

Ghoti ta' mediċinali.

6. (1) L-ghoti tal-prodotti mediċinali li jinsabu fl-Iskeda jista' jsir biss mill-fond imsemmi lil pazjenti li jkollhom jedd jirċievu s-servizzi provduti mill-Fondazzjoni.

(2) Il-Fondazzjoni m'ghandha la taghti lanqas tforni b'ebda mod li jkun xi wiehed mill-prodotti mediċinali li jinsabu fl-Iskeda lill-pubbliku ġenerali.

Sustanzi narkotiċi u psikotropiċi.

7. Il-ħżin u l-ghoti ta' mediċinali narkotiċi u psikotropiċi ghandu jkun soġġett għall-istess kundizzjonijiet bħal dawk li japplikaw għall-ispizeriji.

Responsabbiltajiet ta' l-ispizjar responsabbli.

8. L-ispizjar responsabbli ghandu jiehu hsieb:

(a) li jinghataw il-prodotti mediċinali fil-fond imsemmi u li dan isir wara li tiġi pprezentata riċetta għaldaqstant;

(b) kull dover u obligazzjoni li jkunu jappartjenu lil spizjar responsabbli kif elenkati taht l-Att u kull regolamenti jew regoli

magħmulin tahtu, kif ukoll kull *standard* u kundizzjoni mahruġa mill-Awtorità minn żmien għal żmien dwar l-ispizeriji.

9. Għall-finijiet ta' din l-awtorizzazzjoni, il-Fondazzjoni tkun responsabbli għal kull dover u obligazzjoni li jappartjenu lid-detenturi ta' liċenza ta' spizerija, kif elenkata taht l-Att u kull regolamenti jew regoli magħmulin tahtu, inklużi *standards* u kundizzjonijiet mahruġa mill-Awtorità minn żmien għal żmien dwar l-ispeżeriji.

Responsabbiltajiet tal-Fondazzjoni.

10. L-Awtorità jkollha d-dritt temenda, tissospendi jew tirrevoka l-awtorizzazzjoni jekk:

Drittijiet li jappartjenu lill-Awtorità.

(a) xi haġa minn dawk imsemmija fl-applikazzjoni għall-hruġ ta' l-awtorizzazzjoni tirriżulata li tkun jew falza jew mhux kompleta;

(b) ikun hemm xi bidla fiċ-ċirkostanzi materjali dwar xi haġa minn dawk imsemmija;

(ċ) il-Fondazzjoni tkun kisret xi disposizzjoni ta' l-awtorizzazzjoni.

SKEDA

(Regola 3)

Lista ta' prodotti medicinali awtorizzati għall-iskop ta' dawn ir-regoli

ANTIDEPRESSIVI

*TCA*s Amitriptylline 10mg
 Amitriptylline 25mg
 Imipramine 10mg
 Imipramine 25mg
 Clomipramine 10mg
 Clomipramine 25mg
 Nortriptyline 10mg
 Nortriptyline 25mg
 Trimipramine 25mg
 Trimipramine 50mg

*SSRI*s Fluvoxamine 100mg
 Paroxetine 20mg
 Fluoxetine 20mg

*SNRI*s Venlafaxine 37.5mg

 Fluvoxol 0.5mg

Antidepressivi-Relatati

Mianserin 10mg
Mianserin 30mg

ANTIPSIKOTIĊI

Chlorpromazine 25mg
Chlorpromazine 100mg
Promazine 25mg
Trifluoperazine 1mg
Trifluoperazine 5mg
Sulpiride 50mg
Haloperidol 0.5mg
Haloperidol 1.5mg
Haloperidol 5mg

Antipsikotiċi-Atipici Risperidone 1mg
 Risperidone 2mg
 Quetiapine 25mg

Quetiapine 100mg
Quetiapine 200mg
Olanzapine 5mg
Olanzapine 10mg

ANTIMANIČI

Sod. Valproate 200mg
Sod. Valproate 500mg
Carbamazepine 200mg
Lithium carbonate 400mg

ANTIPILETTIČI

Phenytoin 50mg
Phenytoin 100mg

BETA-BLOCKERS

Propranolol 10mg
Propranolol 40mg

MAOIs RIVERSIBBLI

Moclobemide 150mg

STIMULANTI CNS

Dexamphetamine 5mg
Methyphenidate 10mg

ANALGESIČI OPIOJDI

Dihydrocodeine 30mg
Methadone mixture 1mg/ml

BENŽODIAŽEPINI

Diazepam 2mg, 5mg
Lorazepam 1mg, 2mg
Nitrazepam 5mg
Bromazepam 1.5mg, 3mg, 6mg
Clonazepam 0.5mg, 2mg

ANALGESIČI KOMPOSTI

Co-proxamol

ANALGESIČI

Paracetamol 500mg

B 3312

MEDIĊINALI ANTI-INFJAMMATORJI

Diclofenac 25mg
Mefenamic Acid 250mg

ANTIBIOTIĊI/DISINFETTAR TAL-ĠILDA/KREMI TOPIKALI

Augmentin 375mg
Povidone-Iodine solution
Hydrocortisone cream
Fusidic cream

MEDIĊINALI LI JINTUŻAW KONTRA T-TREGHID

Benzhexol 2mg

ANTIISTAMINI

Hydroxyzine 25mg
Promethazine 10mg, 25mg

MEDIĊINALI LI JINTUŻAW F'KAŻIJET TA' ABBUŻ MINN SUSTANZI

Disulfiram 200mg

INJEZZJONIJIET INTRAMUSKULARI

Hyoscine
Metoclopramide
Haloperidol
Flupenthixol
Zuclopenthixol
Procyclidine

L.N. 235 of 2008

**MEDICINES ACT
(CAP. 458)**

**Dispensing of Medicinal Products
(Foundation for Social Welfare Services) Rules, 2008**

IN exercise of the powers conferred by article 79 (2) of the Medicines Act, the Minister for Social Policy has made the following rules:-

1. The title of these rules is the Dispensing of Medicinal Products (Foundation for Social Welfare Services) Rules, 2008. Title.

2. For the purpose of these rules and unless the context otherwise requires - Interpretation.

“the Act” means the Medicines Act;

“the Foundation” means the Foundation for Social Welfare Services;

“the Licensing Authority” means the authority established under the Medicines Act;

“designated premises” means premises designated by the Foundation from which the medicinal products listed in the Schedule to these rules shall be dispensed.

3. (1) Only the medicinal products, or class or classes of medicinal products listed in the Schedule to these rules, shall be dispensed from the designated premises. Dispensing of medicinal products by Foundation.

(2) The Foundation shall inform the Authority of the address of the designated premises and shall only start dispensing such medicinals once the Licensing Authority approves the designated premises.

4. (1) The Foundation shall only dispense the medicinal products listed in the Schedule to these rules after an authorization is granted by the Licensing Authority. Authorization.

(2) Such authorization shall not be transferred to any person and it shall only be applicable to the dispensing of the medicinal products listed in the Schedule to these rules from the designated premises.

(3) The Foundation shall immediately notify the licensing authority of any medicinal product which is no longer required to be dispensed.

(4) The Foundation shall, when any medicinal product other than those listed in the schedule are required to be dispensed from the designated premises, in writing request the Authority to effect an amendment in the Schedule.

Validity and renewal of authorization.

5. (1) The authorization shall be valid for a period of one year and it may be renewed following a written request by the Foundation to the Authority.

(2) The request shall be submitted at least three months before the expiry of the validity period.

(3) There shall be payable, in respect of such authorization, the pharmacy fees applicable to pharmacy licences.

Dispensing.

6. (1) The dispensing of the scheduled medicinal products shall only be made from the designated premises to patients entitled to the services provided by the Foundation.

(2) The Foundation shall not dispense or supply in any manner whatsoever any of the scheduled medicinal products to the general public.

Narcotic and psychotropic substances.

7. The storage and dispensing of narcotics and psychotropic drugs shall be subject to the same conditions as are applicable to pharmacies.

Responsibilities of the managing pharmacist.

8. A managing pharmacist shall be responsible for:

(a) the dispensing of the medicinal products in the designated premises and shall do so against the presentation of a prescription;

(b) all duties and obligations pertaining to managing pharmacists in pharmacies as listed under the Act and any regulations or rules made there under, and for standards and conditions issued by the Authority from time to time in relation to pharmacies.

Responsibilities of the Foundation.

9. For the purpose of this authorization, the Foundation shall be responsible for all duties and obligations pertaining to pharmacy licence holders, as listed under the Act and any regulations or rules made there

under, including standards and conditions issued by the Authority from time to time in relation to pharmacies.

10. The Authority shall have the right to amend, suspend or revoke the authorization if: Rights pertaining to the Authority.

(a) any matter stated in the application on which the authorization was issued is found to be either false or incomplete;

(b) a material change of circumstances has occurred in relation to any of those matters;

(c) any of the provisions of the authorization have been breached by the Foundation.

SCHEDULE

(Rule 3)

List of medicinal products authorized for the purpose of these rules**ANTIDEPRESSANTS**

*TCA*s Amitriptylline 10mg
 Amitriptylline 25mg
 Imipramine 10mg
 Imipramine 25mg
 Clomipramine 10mg
 Clomipramine 25mg
 Nortriptyline 10mg
 Nortriptyline 25mg
 Trimipramine 25mg
 Trimipramine 50mg

*SSRI*s Fluvoxamine 100mg
 Paroxetine 20mg
 Fluoxetine 20mg

*SNRI*s Venlafaxine 37.5mg

 Fluvoxol 0.5mg

*Related-
 Antidepressants* Mianserin 10mg
 Mianserin 30mg

ANTIPSYCHOTICS

Chlorpromazine 25mg
 Chlorpromazine 100mg
 Promazine 25mg
 Trifluoperazine 1mg
 Trifluoperazine 5mg
 Sulpiride 50mg
 Haloperidol 0.5mg
 Haloperidol 1.5mg
 Haloperidol 5mg

*Atypical-
 Antipsychotics* Risperidone 1mg
 Risperidone 2mg
 Quetiapine 25mg
 Quetiapine 100mg

Quetiapine 200mg
Olanzapine 5mg
Olanzapine 10mg

ANTIMANICS

Sod. Valproate 200mg
Sod. Valproate 500mg
Carbamazepine 200mg
Lithium carbonate 400mg

ANTIPILEPTICS

Phenytoin 50mg
Phenytoin 100mg

BETA-BLOCKERS

Propranolol 10mg
Propranolol 40mg

REVERSIBLE MAOIs

Moclobemide 150mg

CNS STIMULANTS

Dexamphetamine 5mg
Methyphenidate 10mg

OPIOID ANALGESICS

Dihydrocodeine 30mg
Methadone mixture 1mg/ml

BENZODIAZEPINES

Diazepam 2mg, 5mg
Lorazepam 1mg, 2mg
Nitrazepam 5mg
Bromazepam 1.5mg, 3mg, 6mg
Clonazepam 0.5mg, 2mg

COMPOUND ANALGESICS

Co-proxamol

B 3318

ANALGESICS

Paracetamol 500mg

ANTI-INFLAMMATORY DRUGS

Diclofenac 25mg

Mefenamic Acid 250mg

ANTIBIOTICS/ SKIN DISINFECTION/ TOPICAL CREAMS

Augmentin 375mg

Povidone-Iodine solution

Hydrocortisone cream

Fusidic cream

DRUGS USED IN TREMOR

Benzhexol 2mg

ANTI-HISTAMINES

Hydroxyzine 25mg

Promethazine 10mg, 25mg

DRUGS USE IN SUBSTANCE ABUSE

Disulfiram 200mg

INTRAMUSCULAR INJECTIONS

Hyoscine

Metoclopramide

Haloperidol

Flupenthixol

Zuclopenthixol

Procyclidine