
A.L. 188 ta' l-2009

**ATT DWAR IL-MEDIĊINI
(KAP. 458)**

**Regolamenti ta' l-2009 dwar Prodotti Mediċinali li jiġu
Provduuti mill-Klinika ĠenitoUrinarja
fis-Servizzi tas-Saħħa tal-Gvern**

BIS-SAĦĦA tas-setgħat mogħtija bl-artikolu 79(2) ta' l-Att dwar il-Mediċini, il-Ministru għall-Politika Soċjali għamel dawn ir-regolamenti li ġejjin: -

1. It-titolu ta' dawn ir-regolamenti hu **Regolamenti ta' l-2009 dwar Prodotti Mediċinali li jiġu Provduuti mill-Klinika ĠenitoUrinarja fis-Servizzi tas-Saħħa tal-Gvern.** Titolu.

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

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

“l-Awtorità” tfisser l-Awtorità dwar il-Liċenzi mwaqqfa taħt l-Att;

“fond imsemmi” tfisser il-fond tal-Klinika ĠenitoUrinarja minn fejn jiġu dispensati l-prodotti mediċinali elenkati fl-Iskeda li tinsab ma' dawn ir-regoli;

“klinika ĠenitoUrinarja” tfisser kull post li jiġi identifikat għal daqshekk mis-Suprintendent tas-Saħħa Pubblika u l-kelma “klinika” għandha tiftiehem skond hekk;

“konsulent” tfisser il-persuna li taġixxi u li tkun responsabbli għall-klinika.

3. Il-prodotti mediċinali elenkati fl-Iskeda li tinsab ma' dawn ir-regoli għandhom jiġu biss provduuti minn konsulent lil dawk il-pazjenti li jkunu qegħdin jattendu jew li jkunu ġew riferuti lill-klinika. Prodotti mediċinali li jiġu provduuti mill-konsulent.

Dmir tal-konsulent.

4. Il-konsulent għandu –

(a) jipprovdi l-prodotti mediċinali msemmija fl-Iskeda direttament lill-pazjenti li jkunu jattendu l-klinika, u huwa għandu jżomm reġistru dwar dan;

(b) jiddispensa biss dak l-ammont li jkun meħtieġ għaż-żmien speċifikat fir-riċetta;

(c) minnufih javża lill-Awtorità b'kull emenda meħtieġa fl-Iskeda;

(d) jgħarraf lill-Awtorità bl-indirizz tal-klinika u b'kull bidla li ssir f'dak l-indirizz;

(e) ikun responsabbli għal kull dmir u obbligu li jkollu x'jaqsam ma' prodotti mediċinali provduti lil pazjenti taħt l-Att u kull regolamenti jew regoli magħmulin taħtu, u għal *standards* u kondizzjonijiet maħruġin mill-Awtorità minn żmien għal żmien f'dak li għandu x'jaqsam mad-dispensa;

(f) iżomm dak l-ammont ta' prodotti mediċinali skond kull arrangament intern li jkollu ma' l-ispizerija ta' l-isptar sabiex jiġi żgurat servizz kontinwu fil-klinika;

(g) jieħu kull prekawzjoni raġonevoli sabiex jiżgura l-ħzin u d-dispensa adatti tal-prodotti mediċinali;

(h) iżomm proċedura aġġornata, miktuba u miftiehma ma' l-ispizerija ta' l-isptar li tkun qegħda tforni l-prodotti mediċinali.

Drittijiet li għandha l-Awtorità.

5. L-Awtorità jkollha dritt temenda, tissospendi jew tirrevoka l-awtorizzazzjoni jekk xi disposizzjoni ta' l-awtorizzazzjoni mogħtija taħt dawn ir-regoli jew xi disposizzjoni li għandha x'taqsam ma' xi liġi oħra, tkun inkisret mill-konsulent.

SKEDA

(Regola 3)

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

1. *Doxycycline* 100 mg darbtejn kuljum għal sebat ijiem. (Xi minn daqqiet għal 14-il ġurnata f'epididimitis u rari hafna għal 28 ġurnata f'LGV u Sifilidi Latenti)
2. *Erythromycin* 250 mg, żewġ pilloli kuljum għal 7 ijiem
3. *Metronidazole* pilloli ta' 200 mg – 2 pilloli kuljum għal 7 ijiem
4. *Ceftriaxone* injezzjonijiet ta' 250 mg im u injezzjoni ta' 1% *lignocaine* biex id-dilwizzjoni tingħata bħala doża stat
5. *Spectinomycin* 2 grammi im stat
6. *Benzathine Penicillin* injezzjonijiet ta' 1.2 miljun *unit* u injezzjoni ta' 1% *lignocaine* biex id-dilwizzjoni tingħata bħala doża stat ta' 2.4 miljun *unit*
7. *Clotrimazole* 100 mg suppożitorji
8. *Podophyllotoxin* 0.15% krema
9. *Podophyllotoxin* 0.5% soluzzjoni topikali
10. *Aciclovir* 200 mg li jingħata bħala 400 mg tliet darbiet kuljum għal sebat ijiem għal kazijiet akuti
11. *Prednisolone* 5 mg li jingħata bħala 20 mg tliet darbiet kuljum għal tliet ijiem
12. *Amoxicillin* 250 mg li jingħata bħala 500 mg tliet darbiet kuljum għal hamest ijiem

L.N. 188 of 2009**MEDICINES ACT
(CAP. 458)****Rules of 2009 on the Provision of Medicinal Products through
the GenitoUrinary Clinic within the Government Health
Services**

IN exercise of the powers conferred by article 79 (2) of the Medicines Act, the Licensing Authority has made the following rules:-

Title.

1. The title of these rules is the Rules of 2009 on the Provision of Medicinal Products through the GenitoUrinary Clinic within the Government Health Services.

Interpretation.

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

“the Act” means the Medicines Act;

“the Authority” means the licensing authority established under the Act;

“consultant” means the person who acts and is responsible for the clinic;

“designated premises” means the premises of the GenitoUrinary Clinic from which the medicinal products listed in the Schedule to these rules shall be dispensed;

“the Genito Urinary clinic” means any place designated as such by the Superintendent of Public Health and the term “clinic” shall be construed accordingly.

Provision of medicinal products by the consultant.

3. The medicinal products listed in the Schedule to these rules shall only be provided by the consultant to patients attending or who have been referred to the clinic.

Duty of consultant.

4. The consultant shall:

(a) provide the medicinal products referred to in the Schedule, directly to patients attending the clinic, and he shall keep a record thereof;

(b) dispense only those amounts which are needed for the period specified therein;

(c) immediately notify the Authority of any amendment needed in the Schedule;

(d) inform the Authority of the address of the clinic and of any changes in such an address;

(e) be responsible for all duties and obligations relating to the provision of medicinal products to patients under the Act and any regulations or rules made thereunder, and for standards and conditions issued by the Authority from time to time in relation to dispensing;

(f) keep such amount of medicinal products as per internal arrangements with the hospital pharmacy in order to ensure continuation of service at the clinic;

(g) take all reasonable precautions to ensure appropriate storage and dispensing of medicinal products;

(h) keep an updated, written and agreed procedure with the hospital pharmacy supplying the medicinal products.

5. The Authority shall have the right to amend, suspend or revoke the authorization if any of the provisions of the authorization granted under these rules or provisions related to any other legislation have been breached by the consultant.

Rights pertaining to the Authority.

SCHEDULE

(Rule 3)

List of medicinal products authorized for the purpose of these rules

1. Doxycycline 100mg bd for 7 days. (Occasionally for 14 days in epididymitis and rarely for 28 days in LGV and Latent Syphilis)
2. Erythromycin 250mg – two tablets daily for 7 days
3. Metronidazole 200mg tablets – 2 tablets daily for 7 days
4. Ceftriaxone 250mg im injections and 1% lignocaine injection for dilution to be given as stat dose
5. Spectinomycin 2grams im stat
6. Benzathine Penicillin 1.2 million units im injections and 1% lignocaine injection for dilution to be given as stat dose of 2.4 million units.
7. Clotrimazole 100mg pessaries
8. Podophyllotoxin 0.15% cream
9. Podophyllotoxin 0.5% topical solution
10. Aciclovir 200mg to be given as 400mg tds for 7 days for acute episodes
11. Prednisolone 5mg to be given as 20mg tds for 3 days
12. Amoxicillin 250mg to be given as 500mg tds for 5 days