

A.L. 386 ta' l-2005

ATT TA' L-2003 DWAR IL-MEDIĊINI
(ATT NRU. III TA' L-2003)

Regolamenti ta' l-2005 dwar it-Tqassim bl-Ingrossa ta'
Prodotti Mediċinali

BIS-SAHHA tas-setgħat mogħtija bl-artikolu 106 ta' l-Atti ta' l-2003 dwar il-Mediċini, il-Ministru tas-Sahħa, l-Anzjani u l-Kura fil-Komunità għamel dawn ir-regolamenti li ġejjin:-

1. (1) It-titolu ta' dawn ir-regolamenti hu **Regolamenti ta' l-2005 dwar it-Tqassim bl-Ingrossa ta' Prodotti Mediċinali.** Titolu, bidu u skop.

(2) Dawn ir-regolamenti għandhom jidhlu fis-sehh fit-30 ta' Ottubru, 2005.

(3) L-iskop ta' dawn ir-regolamenti hu jittrasponi Direttiva 2001/83/KEE.

2. Għall-finijiet ta' dawn ir-regolamenti:-

Tifsir.

“l-Aġenzija” tfisser l-Aġenzija Ewropea dwar il-Mediċini stabbilita bir-regolament 726/2004/KE;

“applikant” tfisser id-detentur jew il-persuna li f'isimha tkun harġet il-liċenza;

“il-Kummissjoni” tfisser il-Kummissjoni skond id-Deciżjoni tal-Kunsill 1999/468/KE tat-28 ta' Ġunju, 1999;

“Stat Membru” tfisser Stat li hu membru ta' l-Unjoni Ewropea u tinkludi l-Iżlanda, in-Norveġja u Liechtenstein;

“persuna responsabbli” tfisser persuna li tkun reġistrata bhala spizjar mal-Kunsill ta' l-Ispizjara u magħrufa bhala adatta għaldaqshekk mill-Awtorità tal-Mediċini billi dik il-persuna jkollha għarfien adegwat tal-kundizzjonijiet neċessarji għall-ħżin u t-tqassim ta' prodotti mediċinali biex tevita li dawn jitkaghbru jew jithassru, ikollha għarfien adegwat tar-regolamenti li jikkonċernaw

it-tqassim ta' prodotti mediċinali, u jkollha taghrif u gharfien ta' prattika kif imiss ta' tqassim.

Tqassim ta' prodotti mediċinali.

3. (1) (a) Huma biss dawk il-prodotti, li dwarhom tkun giet mogħtija awtorizzazzjoni għal tqegħid fis-suq mill-Awtorità tal-Liċenzjar, hawn iżjed il quddiem msejha l-Awtorità, jew mill-Aġenzija, li għandhom jitqassmu f'Malta.

(b) Fil-każ ta' tqassim bl-ingrossa u l-ħżin, il-prodotti mediċinali għandhom ikunu koperti minn awtorizzazzjoni għat-tqegħid fis-suq mogħtija mill-Aġenzija jew mill-awtorità kompetenti ta' xi Stat Membru:

Iżda fil-każ li prodotti mediċinali jkunu mahżunin imma mhux imqassmin f'Malta, tkun biss meħtieġa l-liċenza mnizzla fir-regolament 4 ta' dawn ir-regolamenti.

(2) Kull distributtur, li ma jkunx id-detentur ta' l-awtorizzazzjoni għat-tqegħid fis-suq, li jdahhal f'Malta prodott minn Stat Membru iehor, għandu javża lid-detentur ta' l-awtorizzazzjoni għat-tqegħid fis-suq b'kull prodott li jkun bi hsiebu jdahhal Malta. Fil-każ ta' prodotti li ma jkunux ingħataw awtorizzazzjoni konformement mar-Regolament 726/2004/KE, l-avviz li jingħata lill-Awtorità għandu jkun mingħajr preġudizzju għal proċeduri addizzjonali li jkun hemm provdut dwarhom bil-liġi f'dak il-waqt:

Iżda meta d-distributtur ikun bi hsiebu jqiegħed il-prodott fis-suq f'Malta, huwa għandu javża lill-Awtorità b'kull kunsinna li jdahhal f'Malta.

Il-liċenza tal-bejjiegh bl-ingrossa.

4. L-ebda persuna ma għandha tiehu f'idejha it-tqassim bl-ingrossa ta' prodotti mediċinali kemm-il darba ma jkollhiex liċenza ta' bejjiegh bl-ingrossa, hawn iżjed 'il quddiem imsejha "liċenza", għal dak l-ghan.

Spezzjoni tal-fond.

5. (1) L-Awtorità tal-Liċenzi, hawn iżjed 'il quddiem imsejha "l-Awtorità", tista' tispezzjona kull fond u tivverifika dwar kull persuna awtorizzata li tibda taħdem bhala bejjiegh bl-ingrossa ta' prodotti mediċinali.

(2) Jekk l-Awtorità jidhrilha li ma jkunx hemm konformità ma' xi wahda mill-kundizzjonijiet tal-liċenza mahruġa minnha, hija għandha tissospendi jew tirrevoka dik il-liċenza.

(3) Jekk il-liċenza tkun giet mogħtija minn Stat Membru iehor u l-Awtorità jidhrilha li d-detentur tal-liċenza ma jkunx qed

jissodisfa l-kundizzjonijiet mnizzlin fiha, l-Awtorità ghandha tinforma lill-Kummissjoni b'dan kif ukoll u lill-Istat Membru konċernat.

6. (1) L-Awtorità ghandha tipproċessa applikazzjoni ghal liċenza ta' bejjiegh bl-ingrossa fi żmien disghin jum minn meta tirċievi l-applikazzjoni. Dan iż-żmien ghandu jiġi sospiż f'dawk il-każijiet meta l-applikant jiġi mitlub jaghti aktar informazzjoni.

Ipproċessar ta' applikazzjonijiet.

(2) L-applikazzjoni ghandu jkun fiha ukoll minbarra l-partikolaritajiet imnizzlin taht l-artiklu 55 (1) ta' l-Att, l-ghamliet farmaċewtiċi tal-prodotti li jkunu se jiġu mqassmin, partikolarment dawk ta' prodotti sterili u ta' prodotti li jehtieġu hżin taht it-8 gradi ċentigradi, flimkien ma' dettalji ta' sustanzi narkotiċi jew psikotropiċi, demm, prodotti mediċinali immunologiċi, jew radjufarmaċewtiċi.

7. (1) Liċenza ghall-bejgħ bl-ingrossa ghandha tinghata biss jekk l-Awtorità tkun sodisfatta li l-applikant ta' l-inqas ikollu -

Ghoti ta' liċenza.

(a) fond adatt u adegwat, kif ukoll installazzjonijiet u apparat, sabiex jiżgura l-konservazzjoni u d-distribuzzjoni tal-prodotti mediċinali kif imiss;

(b) persunal adegwat, u partikolarment, persuna responsabbli.

(2) Ma ghandhiex tiġi mogħtija jew tiġġedded liċenza kemm-il darba l-applikant:-

(a) jagħmilx il-fond, l-installazzjonijiet u l-apparat aċċessibbli f'kull waqt għall-ispezzjoni;

(b) ma jgħibx il-kunsinni ta' prodotti mediċinali mingħand persuni li huma stess ikollhom il-liċenza tad-distribuzzjoni, jew li jkunu eżenti milli jiksibu dik l-awtorizzazzjoni taht id-disposizzjonijiet tar-regolament 3(4) tar-Regolamenti ta' l-2005 dwar il-Manifattura u l-Importazzjoni ta' Prodotti Mediċinali għall-Użu mill-Bniedem;

(ċ) ma jfornix prodotti mediċinali lil persuni li huma nfushom ikollhom liċenza għal tqassim bl-ingrossa jew li jkunu xort'ohra awtorizzati jew intitolati li jissupplixxu prodotti mediċinali lill-pubbliku;

(d) ma jkollux pjan ta' emergenza li jkun jiżgura implimentazzjoni effettiva ta' kull ġbir mill-ġdid ta' prodotti mediċinali mis-suq kif ikun ordnat mill-Awtorità jew esegwit

b'koperazzjoni mal-produttur jew mad-detentur ta' l-awtorizzazzjoni ghat-tqeghid fis-suq ghall-prodott mediċinali konċernat;

(e) ma jzommx *records* disponibbli ghall-ispezzjoni mill-Awtorità għal żmien hames snin minn transazzjoni fi prodotti mediċinali li jkunu ġew riċevuti jew mibgħutin, u li jkun fihom din l-informazzjoni li ġejja:-

(i) id-data;

(ii) l-isem u l-għamla farmaċewtika tal-prodott mediċinali;

(iii) il-kwantità riċevuta jew fornuta;

(iv) l-isem u l-indirizz tal-fornitur jew destinatariju, kif imiss;

(f) ma' jkunx jonora l-prinċipji u l-linji direttivi għal prattika ta' tqassim sew ta' prodotti mediċinali kif pubblikati mill-Kummissjoni.

Dmir tal-bejjiegh
bl-ingrossa.

8. (1) Ikun id-dmir tal-bejjiegh bl-ingrossa, meta jforni prodotti mediċinali lil xi persuna awtorizzata jew li tista' tfornihom lill-pubbliku, li jinkludi dokument li bih jagħmilha possibli li tiġi aċċertata d-data, l-isem u l-għamla farmaċewtika tal-prodott mediċinali, il-kwantità fornuta u l-isem u l-indirizz tal-fornitur jew tad-destinatarju.

(2) Barra minn dan, il-bejjiegh bl-ingrossa għandu, dwar kull prodott li jkun qed iqassam f'Malta, jagħti lill-Awtorità kopja awtentikata ta' l-awtorizzazzjoni għat-tqeghid fis-suq flimkien ma' ittra ta' introduzzjoni mahruġa mid-detentur ta' l-awtorizzazzjoni għat-tqeghid fis-suq li tkun tagħti lill-bejjiegh bl-ingrossa l-użu ta' dik l-awtorizzazzjoni għat-tqeghid fis-suq:

Iżda li l-bejjiegh bl-ingrossa jista' biss jeżerċita l-bejgħ bl-ingrossa ta' prodotti mediċinali f'Malta li dwarhom l-ebda kopja awtentikata ta' awtorizzazzjoni għat-tqeghid fis-suq valida bħal dik u ittra ta' introduzzjoni ma jkunu mwassla għand l-Awtorità, jekk ikollu fil-pussess tiegħu liċenza ta' importazzjoni parallela mahruġa skond il-liġi.

(3) Kull bejjiegh bl-ingrossa għandu, sa fejn jaslu r-responsabilitajiet tiegħu, jiżgura li jingħata forniment kif imiss u kontinwu ta' prodotti mediċinali lill-ispjizeriji u lil persuni li jkunu

awtorizzati li jfornu prodotti mediċinali biex jiġu sodisfatti l-htigijiet tal-pazjenti.

9. Il-persuna responsabbli jkollha d-dmir li:

Dmir tal-persuna responsabbli.

(a) tiżgura li jinżammu l-kundizzjonijiet tal-liċenza;

(b) tiżgura li l-kundizzjonijiet għall-ħżin ta' prodotti mediċinali isir skond il-htigiet ta' l-awtorizzazzjoni għat-tqegghid fis-suq u l-ittikkettjar;

(ċ) iżzomm kontinwament taht għajnejha l-postijiet kollha użati għall-ħżin u d-distribuzzjoni;

(d) iżzomm *records* skond ma jkun mehtieġ taht dawn ir-regolamenti;

(e) tiżgura li tinżamm sistema ta' kwalità mid-detentur tal-liċenza skond Prattika ta' Distribuzzjoni kif imiss.

10. Id-disposizzjonijiet ta' dawn ir-regolamenti għandhom japplikaw ukoll għal prodotti mediċinali omeopatiċi.

Prodotti mediċinali omeopatiċi.

11. Ir-Regolamenti ta' l-2004 dwar l-Importazzjoni u d-Distribuzzjoni bl-Ingrossa ta' Prodotti Mediċinali, qeghdin b'dawn jiġu mhassrin.

Thassir ta' A.L. 154 ta' l-2004.

L.N. 386 of 2005

**MEDICINES ACT, 2003
(ACT NO. III OF 2003)**

Wholesale Distribution of Medicinal Products Regulations, 2005

IN exercise of the powers conferred by article 106 of the Medicines Act, 2003, the Minister of Health, the Elderly and Community Care has made the following regulations:-

Title and commencement.

1. (1) The title of these regulations is the Wholesale Distribution of Medicinal Products Regulations, 2005.

(2) These regulations shall come into force on the 30th October, 2005.

(3) The scope of these regulations is to transpose Directive 2001/83/EEC.

Interpretation.

2. For the purposes of these regulations-

“the Agency” means the European Medicines Agency established by Regulation (EC) No 726/2004;

“applicant” includes a holder or licensee;

“the Commission” means the Commission in accordance with Council Decision 1999/468/EC of 28th June, 1999;

“Member State” means a State which is a member of the European Union and includes, Iceland, Norway and Liechtenstein;

“responsible person” means a person registered as a pharmacist with the Pharmacy Council and recognised as suitable by the Medicines Authority since such person possesses adequate knowledge of the conditions required for the storage and distribution of medicinal products in order to avoid their deterioration or damage, has adequate knowledge of the regulations concerning the distribution of medicinal products, and has knowledge and understanding of good distribution practice.

Distribution of medicinal products.

3. (1) (a) Only products in respect of which a marketing authorisation has been granted by the Licensing Authority, hereinafter referred to as “the Authority”, or the Agency shall be distributed in Malta.

(b) In the case of wholesale distribution and storage, medicinal products shall be covered by a marketing authorisation granted by the Agency or by the competent authority of a Member State:

Provided that in the case where medicinal products are stored but not distributed in Malta, only the licence laid down in regulation 4 hereof, shall be required.

(2) Any distributor, not being the marketing authorisation holder, who brings into Malta a product from another Member State, shall notify the marketing authorisation holder and the Authority of each product he intends to bring into Malta. In the case of products which have not been granted an authorisation pursuant to Regulation (EC) No 726/2004, the notification to the Authority shall be without prejudice to additional procedures provided for in the law at the time:

Provided that where the distributor intends to place the product on the market in Malta, he shall notify the Authority of each batch he brings into Malta.

4. No person shall engage in the wholesale distribution of medicinal products unless he is in possession of a wholesale dealer's licence, hereinafter referred to as "licence", to that effect.

5. (1) The Licensing Authority, hereinafter referred to as "the Authority", may inspect any premises and check any person authorised to engage in the activity of wholesaler in medicinal products.

(2) If the Authority deems that any of the conditions of the licence issued by it has not been met, it shall suspend or revoke such licence.

(3) If a licence has been granted in another Member State and the Authority deems that the licensee is not fulfilling the conditions set therein, it shall inform the Commission and the Member State concerned.

6. (1) The Authority shall process an application for a wholesale dealer's licence within ninety days of receipt of the application. This period shall be suspended in those cases where the applicant is requested to furnish additional data.

(2) The application shall, apart from the particulars listed under article 55(1) of the Act, also include the pharmaceutical forms of the products to be distributed, in particular any sterile products and

products requiring storage below 8 degrees Centigrade, and details of narcotic or psychotropic substances, blood, immunological medicinal products, or radiopharmaceuticals.

Granting of licence.

7. (1) A wholesale distribution licence shall only be granted if the Authority is satisfied that the applicant has at least -

(a) suitable and adequate premises, installations and equipment, so as to ensure proper conservation and distribution of the medicinal products;

(b) adequate staff, and in particular, a responsible person.

(2) A licence shall not be granted or renewed unless the applicant:

(a) makes the premises, installations and equipment accessible at all times for inspection;

(b) obtains the supplies of medicinal products from persons who are themselves in possession of a distribution licence, or who are exempt from obtaining such authorisation under the terms of regulation 3(4) of the Manufacturing and Importation of Medicinal Products for Human Use Regulations, 2005;

(c) supplies medicinal products to persons who are themselves in possession of a wholesale distribution licence or who are otherwise authorised or entitled to supply medicinal products to the public;

(d) has an emergency plan which ensures effective implementation of any recall of medicinal products from the market as ordered by the Authority or carried out in co-operation with the manufacturer or marketing authorization holder for the medicinal product concerned;

(e) keeps records available for inspection by the Authority, for a period of five years of any transaction in medicinal products received or dispatched, containing the following information:

(i) date;

(ii) name and pharmaceutical form of the medicinal product;

(iii) quantity received or supplied;

(iv) name and address of the supplier or consignee, as appropriate;

(f) complies with the principles and guidelines of good distribution practice for medicinal products as published by the Commission.

8. (1) It shall be the duty of the wholesale dealer, when supplying medicinal products to a person authorised or entitled to supply them to the public, to enclose a document thereby making it possible to ascertain the date, name and pharmaceutical form of the medicinal product, quantity supplied and the name and address of the supplier or consignee. Duty of wholesale dealer.

(2) In addition, the wholesale dealer shall, in respect of each product he is distributing in Malta, furnish to the Authority an authenticated copy of the marketing authorization together with a letter of access issued by the marketing authorization holder granting the wholesale dealer the use of such marketing authorisation:

Provided that a wholesale dealer may only engage in the wholesale distribution of medicinal products in Malta in respect of which no such authenticated copy of a valid marketing authorization and letter of access has been forwarded to the Authority, if he is in possession of a parallel import licence issued in terms of the law.

(3) Every wholesale dealer shall, within the limits of his responsibilities, ensure that an appropriate and continuous supply of medicinal products is furnished to pharmacies and persons authorized to supply medicinal products in order to satisfy the needs of patients.

9. It shall be the duty of the responsible person to: Duty of responsible person.

(a) ensure that the licence conditions are adhered to;

(b) ensure that the conditions for storage of medicinal products are in accordance with the requirements of the marketing authorisation and labelling;

(c) monitor all areas used for storage and distribution;

(d) maintain records as required by these regulations;

B 5532

(e) ensure that a quality system is maintained by the licensee in accordance with good distribution practice.

Homeopathic medicinal products.

10. The provisions of these regulations shall also apply to homeopathic medicinal products.

Repeal of L.N. 154 of 2004.

11. The Importation and Wholesale Distribution of Medicinal Products Regulations, 2004 are hereby being repealed.

