

A.L. 154 ta' l-2004**ATT TA' L-2003 DWAR IL-MEDICINI
(ATT NRU. III TA' L-2003)****Regolamenti ta' l-2004 dwar l-Importazzjoni u
d-Distribuzzjoni bl-Ingrossa ta' Prodotti Mediċinali**

BIS-SAHHA tas-setgħat mogħtija lilu bl-artiklu 106 ta' l-Att ta' l-2003 dwar il-Mediċini, il-Ministru tas-Sahħa, l-Anzjani u Kura fil-Kommunità għamel ir-regolamenti li ġejjin :-

1. (1) It-titolu ta' dawn ir-regolamenti hu Regolamenti ta' l-2004 dwar l-Importazzjoni u d-Distribuzzjoni bl-Ingrossa ta' Prodotti Mediċinali. Titolu u bidu fis-seħh.

(2) Dawn ir-regolamenti jidhlu fis-seħh fl-1 ta' Mejju, 2004.

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

Tifsir.

“applikant” tfisser min għandu liċenza;

“il-Kummissjoni” tfisser il-Kummissjoni kif imfissra fid-deċiżjoni tal-Kunsill ta' l-1999/468/EC tat-28 ta' Gunju, 1999;

“prodotti mediċinali impurtati” tfisser prodotti mediċinali li ġejjin minn sorsi barra l-Unjoni Ewropea jew iż-Zona Ekonomika Ewropea.

“persuna kwalifikata” tfisser dik il-persuna li tissodisfa l-kundizzjonijiet stabbiliti fir-Regolamenti ta' l-2004 dwar il-Manifattura ta' Prodotti Mediċinali għall-użu tal-Bniedem;

“persuna responsabbli” tfisser persuna reġistrata bhala spizjar mall-Kunsill ta' l-Ispiżjara u magħrufa bhala persuna adegwata u adatta mill-Awtorità tal-Mediċini għax għandha tagħrif adegwat tal-kundizzjonijiet rikjesti għall-ħażna u d-distribuzzjoni ta' prodotti mediċinali biex dawn la jiddeterjoraw u lanqas jiġri lhom hsara għax tkun taf b'mod adegwat ir-regolamenti li jikkonċernaw id-distribuzzjoni ta' prodotti mediċinali, u tkun taf u tifhem il-prattika ta' distribuzzjoni tajba.

“Stat Membru” tfisser Stat membru ta' l-Unjoni Ewropea u jinkludi wkoll l-Iżlanda, in-Norvegja, u l-Liechtenstein.

Liċenza ta' bejjiegh bl-ingrossa.

3. (1) L-ebda persuna ma tista' tqassam jew tiddistribwixxi bl-ingrossa prodotti mediċinali kemm il-darba ma jkollhiex liċenza ta' bejjiegh bl-ingrossa li minn hawn il-quddiem ser tkun imsejha "liċenza".

(2) L-ebda persuna ma tista tiddistribwixxi jew tqassam prodotti mediċinali impurtati bl-ingrossa kemm-il darba -

(a) minbarra l-liċenza ma jkollhiex ukoll awtorizzazzjoni ta' l-importazzjoni,

(b) ma tkunx impjegat magħha persuna kwalifikata.

Ispezzjoni tal-post.

4. (1) L-Awtorità dwar il-Liċenzar, hawn iżjed 'il quddiem msejha "l-Awtorità" tista' tispezzjona kull post u tiċċekja kull persuna awtorizzata li tkun qed tagħmilha ta' bejjiegh ta' prodotti mediċinali bl-ingrossa.

(2) L-Awtorità tista' tissospendi jew tirrevoka dik il-liċenza jekk tkun tal-fehma li xi wahda mill-kundizzjonijiet stabbiliti għall-hruġ tal-liċenza ma tkunx giet mharsa.

(3) Jekk l-Awtorità jidrilha, f'każ ta' liċenza li tkun ingħatat fi stat membru ieħor, li min għandu il-liċenza mhux qed iwettaq il-kundizzjonijiet imposti, l-Awtorità għandha tinforma lil Kummissjoni u lill-Istat Membru li jkun hareġ il-liċenza.

Iproċessar ta' applikazzjonijiet.

5. (1) L-Awtorità għandha tipproċessa l-applikazzjoni tal-bejjiegh bl-ingrossa fi żmien disghin jum minn meta tirċievi l-applikazzjoni. Dan il-perjodu ta' żmien għandu jiġi sospiż meta l-applikant jintalab jagħti aktar informazzjoni.

(2) L-applikazzjoni għandha tkun ukoll tinkludi, barra l-patrikolaritajiet li jinsabu fl-artikolu 55(1) ta' l-Att, il-forom farmaċewtiċi tal-prodotti li jkunu ser jitqassmu bl-ingrossa partikolarment dawk il-prodotti sterili u prodotti li jridu jinħażnu f' temperatura taħt it-8 gradi ċentigradi, kif ukoll dettalji ta' sustanzi narkotiċi jew psikotropiċi, demm, prodotti mediċinali immunoloġiċi, jew radjofarmaċewtiċi.

Għoti tal-liċenza.

6. (1) Il-liċenza għad-distribuzzjoni bl-ingrossa tingħata biss jekk l-Awtorità tkun sodisfatta li l-applikant għandu ta lanqas ikollu:

(a) post adattat u adegwat, istallazzjonijiet u tagħmir biex jiżgura l-konservazzjoni u d-distribuzzjoni kif imiss tal-prodotti mediċinali;

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

(2) il-liċenza ma ghandhiex tinghata jew tiġġeded kemm-il darba l-applikant:

(a) ma jhallix li l-post, l-istallazzjonijiet u t-tagħmir ikunu aċċessibbli għall- ispezzjon f'kull hin;

(b) ma jiksibx il-provvista ta' prodotti mediċinali minghand persuni li huma nfushom ikollhom il-liċenza għal distribuzzjoni jew li xort'ohra jkollhom liċenza tal-manifattura li tinkludi wkoll liċenza għal distribuzzjoni bl-ingrossa, jew li huma eżentati milli jiksbu dik l-awtorizzazzjoni;

(c) ma jfornix prodotti mediċinali lil persuni li diġa' huma nfushom għandhom il-liċenza għal distribuzzjoni bl-ingrossa jew li mill-banda l-oħra jinsabu awtorizzati jew intitolati li jissupplixxu prodotti mediċinali lill-pubbliku ;

(d) ma jkollux pjan ta' emerġenza li jiżgura b'mod effettiv l-implimentazzjoni tal-ġbir lura mis-suq ta' prodotti mediċinali jew skond ma jiġi ordnat jagħmel mill-Awtorità jew effettwat f'koperazzjoni mal-manifattur jew ma' min jkun awtorizzat li jbiegħ u jqiegħed fis-suq il-prodott mediċinali;

(e) ma jzommx lesti rekords għal ispezzjon ta' l-Awtorità, għal perjodu ta' hames snin dwar kull transazzjoni ta' prodotti mediċinali riċevuti jew mibjugħa u li għandu jkollu din l-informazzjoni li ġejja :-

(i) id-data,

(ii) l-isem u l-forma farmaċewtika tal-prodott mediċinali,

(iii) il-kwantità riċevuta jew fornita,

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

(f) ma jikkonformax ruhu mal prinċipji u linji gwida tal-prattika tajba tad-distribuzzjoni tal-prodotti mediċinali kif pubblikata mill-Kummissjoni.

7. Bejjiegħ bl-ingrossa għandu d-dmir li meta jissupplixxi prodotti mediċinali lil persuna awtorizzata jew intitolata li tissupplixxihom lill-pubbliku, huwa jipproduċi magħhom dokument li jkun jagħmilha possibbli li tiġi aċċertata d-data, l-isem tal-prodott mediċinali, il-kwantità kkonsenjata, l-isem u l-indirizz ta' min issupplixxa u tar-riċevitur.

Doveri ta' bejjiegħ bl-ingrossa.

Doveri tal-persuna
responsabbli.

8. Il-persuna responsabbli ghandha d-dmir li:

(a) taççerta ruhha li jinżammu l-kundizzjonijiet tal-licenza;

(b) tiżgura li l-kundizzjonijiet għall-ħażna ta' prodotti mediċinali ikunu skond il-htigijiet ta' l-awtorizzazzjoni għat-tqeghid fis-suq u dak li hemm fuq it-tikketta;

(c) tissorvelja kull post kemm tal-ħażna kif ukoll tad-distribuzzjoni;

(d) iżżomm rekords skond kif jitolbu dawn ir-regolamenti;

(e) tiżgura li tinżamm sistema kwalitattiva skond il-prattika tad-distribuzzjoni kif imiss, minn min ikollu il-licenza.

Responsabbiltà ta'
persuna
kwalifikata.

9. Il-persuna kwalifikata tkun responsabbli li tiżgura li :

(a) kull konsenja ta' prodotti mediċinali li tkun ġejja minn pajjiżi li mhumiex Stati Membri, tkun saritilha analiżi kwalitattiva shiha ta' almenu s-sustanzi attivi kollha u kull kontroll ieħor meħtieġ biex tiġi żgurata l-kwalita tal-prodotti mediċinali impurtati skond il-kundizzjonijiet ta' l-awtorizzazzjoni għal tqeghid fis-suq

Iżda meta daww il-prodotti mediċinali jkunu diġa' għaddew mill-kontrolli hawn msemmija dawn jkunu eżentati minn aktar kontrolli jekk magħhom ikun hemm ir-rapport tal-kontrolli ffirmat mill-persuna kwalifikata u dawn jinbiegħu fil-Kommunità;

(b) meta jkun hemm prodotti mediċinali impurtati ma jkunx hemm għalfejn il-persuna kwalifikata terġa' tagħmel il-kontrolli hawn qabel msemmija meta jkunu saru arranġamenti mill-Kommunita mal pajjiż li esportatur li bihom min jagħmel dawn il-prodotti mediċinali jiġi obligat li japplika normi tal-livelli ta' Prattika tal-manifattura tajba li jkunu mill-anqas ekwivalenti għal daww stabbiliti mill-Kommunità u li jiżgura li l-kontrolli hawn qabel msemmija saru fil-pajjiż esportatur.

Ghandu jinżamm
reġistru.

10. (a) Il-persuna kwalifikata għandha iżżomm reġistru u dokumenti li jiçcertifika li kull konsenja ta' produzzjoni tkun issodisfat id-disposizzjonijiet ta' dawn ir-regolamenti.

(b) Dan ir-reġistru għandu jkun aġġornat kull meta ssir transazzjoni u għandu jkun għad-dispożizzjoni ta' l-Awtorità biex tispezzjonah għal perjodu ta' mhux anqas minn hames snin.

L.N. 154 of 2004

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

**Importation and Wholesale Distribution of Medicinal
Products Regulations, 2004**

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:-

1. (1) The title of these regulations is the Importation and Wholesale Distribution of Medicinal Products Regulations, 2004. Title and commencement.

(2) These regulations shall come into force on the 1st May, 2004.

2. For the purposes of these regulations- Interpretation.

“applicant” includes a holder or licensee;

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

“imported medicinal products” means medicinal products obtained from a source outside the European Union or the European Economic Area;

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

“qualified person” means a person who fulfills the conditions set under the Manufacture of Medicinal Products for Human Use Regulations, 2004;

“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.

Wholesale dealer's licence.

3. (1) 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.

(2) No person shall engage in the wholesale distribution of imported medicinal products unless such person –

(a) apart from a license is also in possession of an import authorisation;

(b) employs a qualified person.

Inspection of premises.

4. (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.

Processing of applications.

5. (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.

6. (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 the distribution licence or who are otherwise in possession of a manufacturing licence, which includes a wholesale distribution licence, or who are exempt from obtaining such authorisation;

(c) supplies medicinal products to persons who are themselves in possession of the 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.

7. 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 of the medicinal product, quantity supplied and the name and address of the supplier or consignee.

Duty of wholesale dealer.

Duty of responsible person.

8. It shall be the duty of the responsible person to:

- (a) ensure that the licence conditions are adhered to;
- (b) ensure that the conditions for storage of medicinal products is 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.
- (e) ensure that a quality system is maintained by the licensee in accordance with good distribution practice.

Responsibility of qualified person.

9. The qualified person shall be responsible to ensure that:

- (a) each production batch of medicinal products coming from countries which are not Member States has, on importation, undergone a full qualitative analysis of at least all the active constituents and all the other tests or checks necessary to ensure that the quality of the medicinal products is in accordance with the conditions of the marketing authorisation:

Provided that when the batches of medicinal products have already undergone the controls above mentioned, they shall be exempt from further controls if they are accompanied by the control reports signed by the qualified person, and are marketed within the Community;

- (b) in the case of imported medicinal products, the qualified person need not carry out the controls above mentioned, where arrangements have been made by the Community with the exporting country obliging the manufacturer of the medicinal products to apply standards of good manufacturing practice which are at least equivalent to those laid down by the Community, and to ensure that the controls referred to above have been carried out in the exporting country.

Keeping of a register.

10. (a) It shall be the duty of the qualified person to keep a register and document that each production batch satisfies the provisions of these regulations.

- (b) The said register shall be kept up to date as operations are carried out and must be made available for inspection by the Authority for at least five years.