

A.L. 143 ta' l-2004**ATT DWAR IL-MEDICINI. (2003)
(ATT NRU. III TA' L -2003)****Regolamenti ta' l-2004 dwar il-Manifattura ta' Prodotti
Medicinali għall-Użu tal-Bniedem**

BIS-SAHHA tas-setghat mogħtija lilu bl-artiklu 106 ta' l-Att ta' l-2003 dwar il-Medicini, il-Ministru tas-Sahha, l-Anzjani u Kura fil-Kommunita' għamel ir-regolamenti li ġejjin:-

1. (1) It-titlu ta' dawn ir-regolamenti hu Regolamenti ta' l-2004 dwar il-Manifattura ta' Prodotti Medicinali għall-Użu tal-Bniedem. Titlu u bidu fis-sehh.

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

2. Għall-iskopijiet ta' dawn ir-regolamenti :- Tifsir.

“Kummissjoni” tfisser il-Kummissjoni skond id-deċiżjoni tal-Kunsill numru 1999/468/EC tat-28 ta' Gunju, 1999,

“Kommunita'” tfisser il-Kommunita' Ewropea jew iż-Żona Ekonomika Ewropea;

“prodotti medicinali importati” tfisser prodotti medicinali importati minn sorsi barra mill-Unjoni Ewropea jew iż-Żona Ekonomika Ewropea;

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

3. (1) (a) Ebda prodott medicinali ma jista' jiġi manifatturat f'Malta jekk dan il-prodott manifatturat ma jkollux il-liċenza biex jiġi manifatturat, hawn iżjed il-quddiem msejha “liċenza”. Liċenza tal-manifattura.

(b) liċenza għall-manifattura tkun mehtieġa minkejja li l-prodotti mediċinali manifatturati jkunu intiżi għall-esportazzjoni.

(2) (a) Tenhtieġ il-liċenza, li tibqa fis-sehħ għal perjodu li jiġi stabbilit mill-Awtorità, kemm għal manifattura totali, kemm għal dik parzjali u għad-diversi proċessi tat-taqsim fid-daqs, ippakkettjar jew preżentazzjoni.

(b) Ma tkunx mehtieġa liċenza għall-preparazzjoni, taqsim fid-daqs, bidla fl-ippakkettjar jew preżentazzjoni fejn dawk il-proċessi jsiru biss unikament għat-tqassim jew bejgh bl-imnut minn spizjara fl-ispizjeriji, jew minn persuni awtorizzati li jagħmlu dawk il-proċessi.

(3) Tenhtieġ wkoll, flimkien mal-liċenza msemmija taht is-subregolament(1) ta' dan ir-regolament, il-liċenza ta' l-importazzjoni għall-importazzjoni ta' prodotti mediċinali

(4) Liċenza għandha tkun tinkludi wkoll liċenza għat-tqassim bl-ingrossa ta' prodotti mediċinali li liċenza tkun inharġet għalihom.

Għotja jew tiġdid ta' liċenza.

4. L-Awtorità dwar Liċenzar, hawn iżjed 'il quddiem imsejja "l-Awtorita", għandha biss tagħti jew iġġedded liċenza jekk l-applikant:

(a) jispeċifika l-forom tal-prodotti mediċinali u farmaċewtiċi li jkunu ser jiġu manifatturati jew impurtati u l-post fejn dawn ikunu ser jiġu manifatturati u, jew ikkontrollati;

(b) ikollu għad-dispożizzjoni tiegħu biex jimmanifattura jew jimporta prodotti mediċinali, bini adattat u tajjeb biżżejjed, tagħmir tekniku u faċilitajiet ta' kontroll konformi mal-htigiet mitluba mill-Awtorità;

(ċ) ikollu għad-dispożizzjoni tiegħu almenu persuna waħda kwalifikata; u

(d) jippreżenta d-dokumenti kollha mehtieġa b'sostenn ta' l-applikazzjoni tiegħu.

Ipproċessar tal-liċenza.

5. (1) (a) L-Awtorità għandha tohroġ il-liċenza wara li tkun ivverifikat il-kontenut ta' l-applikazzjoni imma fl-ebda każ, mhux aktar tard minn disgħin ġurnata minn mindu tirċievi l-applikazzjoni.

(b) Dan il-perjodu ta' żmien ghandu jiġi sospiż meta l-Awtorità titlob aktar informazzjoni minn ghand l-applikant.

(ċ) L-Awtorità tista taghti liċenza kondizzjonali sakemm l-applikant jonora ċerti obbligazzjonijiet imposti fuqu.

(2) Il-Liċenza ghandha tapplika biss ghal postijiet fejn ikun hemm prodotti mediċinali, prodotti mediċinali, u forom farmaċewtiċi speċifikati fl-applikazzjoni .

6. Meta min ghandu l-liċenza tal-manifattura jitlob bidla f'xi partikolarità ta' l-applikazzjoni, il-proċess tal-verifika ta' dik l-informazzjoni ma ghandux jeċċedi t-tletin jum. Madankollu f'każijiet eċċezzjonali dan il-perjodu ta' żmien jista' jiġi estiż sa disgħin jum.

Tibdil fil-partikolaritajiet.

7. Il-persuna li ghandha il-liċenza barra li ghandha tikkonforma ma' l-obbligazzjonijiet kif jidhru fl-artikolu 44 ta' l-Att, ghandha tikkonforma wkoll mal-prinċipji u linji gwida tal-prattika tajba tal-manifattura u d-distribuzzjoni tajba fir-rigward ta' prodotti mediċinali kif pubblikati mill-Kummissjoni.

Obbligi ta' min ghandu l-liċenza.

8. Jekk min ghandu il-liċenza jippossjedi wkoll il-kwalifiki mnizzla fir-regolament 9 ta' dawn ir-regolamenti, allura dan jista' jassumi ir-responsabbiltà ta' persuna kwalifikata.

Min ghandu l-liċenza bhala persuna kwalifikata.

9. Biex persuna tiġi rikonoxxuta bhala persuna kwalifikata dik il-persuna ghandha ghal mill-anqas ikollha il-kwalifiki li ġejjin:—

Persuna kwalifikata.

(a) (i) ghandu jkollha diploma, ċertifikat, jew prova oħra ta' kwalifika formali ikkonferit lilha meta tlesti kors ta' studju, jew kors rikonoxxut bhala wiehed ekwivalenti, mifruq fuq perjodu ta' mill-anqas erba snin ta' studju teoretiku u prattiku f'xi waħda mid-dixxiplini xjentifiċi li ġejjin; farmaċija, mediċina, mediċna veterinarja, kimika, kimika farmaċewtika u teknoloġija, bijoloġija;

(ii) jekk il-kors ikun segwit minn perjodu ta' tahrig teoretiku u prattiku ta' mhux anqas minn sena u li fih jinkludi tahrig ghal perjodu ta' mhux anqas minn sitt xhur ġo spiżerija miftuha għall-pubbliku u dak il-perjodu jkun ikkorroborat b'eżami ta' livell universitarju, allura kors ta' l-universita jista bhala minimu jkun ta' tlett snin u nofs;

(iii) meta żewġ korsijiet universitarji jew żewġ korsijiet magħrufa bhala ekwivalenti ta' xulxin jkunu jeżistu fi Stat Membru, u meta wiehed minn dawn ikun jiehu erba' snin

skorruti u l-iehor tlitt snin skorruti, il-kors ta' tliet snin li jwassal ghal diploma, ċertifikat jew prova ohra ta' kwalifika formali, konferiti wara tmiem il-kors universitarju jew l-ekwivalenti rikonoxxut ta' dan, ghandu jitqies li jissodisfa l-kondizzjoni ta' tul ta' zmien hawn qabel msemmi, sakemm id-diploma, ċertifikat jew prova ohra ta' kwalifika formali konferiti fl-ahhar taż-żewġ korsijiet ikunu rikonoxxuti bhala ekwivalenti;

(b) il-kors ghandu jinkludi studji teoretiċi u prattiċi almenu ta' dawn is-sugġetti bażiċi li ġejjin:-

(i) fiżika applikata,

(ii) kimika ġenerali u organika,

(iii) kimika organika,

(iv) kimika analitika,

(v) kimika farmaċewtika, li tinkludi l-analizi ta' prodotti mediċinali,

(vi) biokimika ġenerali u applikata (medika),

(vii) fiżjoloġija,

(viii) mikrobijoloġija,

(ix) farmakoloġija,

(x) teknoloġija farmaċewtika,

(xi) tossikoloġija

(xii) farmakonjożi (istudju tal-kompożizzjoni u l-effetti ta' sustanzi attivi naturali ta' oriġini veġetali u mill-animali)

(ċ) l-istudju ta' dawn is-sugġetti ghandu jkun hekk bilanċjati li persuna kwalifikata tista tonora dawn l-obbligi li ġejjin:

(i) tiżgura li l-prodotti mediċinali jkunu ġew manifattuati u verifikati skond il-liċenza tal-bejgħ;

(ii) tiżgura fil-każ ta' prodotti li ġejjn minn pajjiżi li mhux Stati Membri kull konsenja ta' produzzjoni tkun sartilha analiżi kwalitattiva shiha kif ukoll analiżi kwantitattiva ta' almenu tlett elementi kostitwenti u t-testijiet l-oħra kollha li jistgħu jkunu meħtieġa biex jiżguraw li l-kwalità tal-prodott mediċinali jkun konformi mal-liċenza tal-bejgħ:

Iżda l-persuna kwaifikata tkun eżentata milli thares id-dmirijiet hawn qabel imsemmija fil-każ fejn il-Kommunità jkollha fethim mal-pajjiż li ma jkunx Stat Membru li jkun qed jesporta, li l-prodott mediċinali manifatturat, jkun skond il-livelli tal-prattika ta' manifattura tajba ekwivalenti għal dawk magħmula mill-Kommunità u li l-kontrolli jkunu saru fil-pajjiż esportatur:

Iżda wkoll jekk il-prodotti mediċinali jkollhom magħhom ċertifikati tal-kontroll li jkunu saru u ġew iffirmati minn persuna kwalifikata, jkunu eżentati minn dawk il-kontrolli jekk dawn jinbiegħu f'xi Stat Membru ieħor;

(d) f'dawk il-każijiet fejn id-diplomi, ċertifikati jew provi oħra ta' kwalifiki formali ma jkunux skond il-kriterji fuq imsemmija, l-Awtorità għandha tiżgura li l-persuna involuta tforni provi ta' tagħrif adegwat tas-suġġetti in kwistjoni;

(e) (i) il-persuna kwalifikata għandha tkun kisbet esperjenza Prattika ta' almenu sentejn, fl-attivitajiet ta' xi waħda jew aktar impriżi li jkunu awtorizzati jimmanifatturaw prodotti mediċinali fl-attivitajiet, ta' analiżi kwalitattiva ta' prodotti mediċinali, jew analiżi kwantitattiva ta' sustanzi attivi u fl-ittejtjar u verifika meħtieġa biex tiġi żgurata l-kwalità ta' prodotti mediċinali;

(ii) it-tul ta' żmien ta' l-esperjenza Prattika jista jitnaqqas b'sena meta l-kors universitarju idum almenu għal hames snin, u b'sena u nofs meta l-kors idum ta' lanqas sitt snin.

10. (1) Persuna li meta dawn ir-regolamenti jidhlu fis-seħh u sa sena minn dik il-data, kienet qed tagħmel ix-xogħol ta' persuna kwalifikata almenu għal sitt xhur, għandha tikkwalifika biex tkompli tagħmel dawk l-attivitajiet anke jekk ma tkunx ikkonformat mal-kondizzjonijiet miġjuba taht ir-regolament 9, sakemm dawk l-attivitajiet kienu saru għas-sodisfazzjon ta' l-Awtorità.

Riserva dwar persuna kwalifikata eżistenti.

(2) Il-possessur ta' diploma, ċertifikat, jew prova ta' kwalifika formali oħra konferiti fi tmiem ta' kors univertsitarju jew ta' kors f' dixeriplina xjentifika magħruf bħala ekwivalenti f' dik id-dixeriplina xjentifika, biex b'hekk ikun jista' jeżerċita d-doveri ta' persuna kwalifikata, jista, jekk ikun beda l-kors qabel il-21 ta' Mejju, 1975, jkun ikkonsidrat bħala kkwalifikat biex jaqdi d-dmirijiet ta' persuna kwalifikata, sakemm kien almenu għal sentejn qabel il-21 ta' Mejju 1985 involut f' xi impriza waħda jew aktar awtorizzati li jimmanifatturaw prodotti mediċinali u li jkun qeda dmirijietu taħt l-awtorita diretta ta' persuna kwalifikata in konnessjoni mal-produzzjoni, superviżjoni u , jew analiżi kwalitattiva u kwantitattiva ta' sostanzi attivi, u l-ittejtjar u l-vertifika meħtieġa sakemm tiġi żgurata l-kwalità tal-prodotti mediċinali.

(3) Jekk il-persuna in kwistjoni tkun kisbet l-esperjenza prattika msemmija fil-paragrafu ta' qabel qabel il-21 ta' Mejju, 1965, hija għandha tagħmel sena oħra ta' esperjenza prattika skond il-kondizzjonijiet msemmija fis-subregolament (2) minnufih qabel ma jkun jista' jagħmel xogħol f' dawk l-attivitatijiet.

Responsabbiltà ta'
persuna
kwalifikata.

11. Il-persuna responsabbli tkun responsabbli li tiżgura li:-

(a) kull konsenja ta' prodotti mediċinali tkun ġiet manifatturata fil-Kommunità u ġiet verifikata skond kull liġi fis-seħh u li tkun skond il-htigijiet ta' l-awtorizzazzjoni għat-tqegħid fis-suq;

(b) kull konsenja ta' produzzjoni ta' prodotti mediċinali ġejja minn pajjiżi li ma humiex Stati Membri, tkun saritilha, malli din tiġi importata, analiżi kwalitattiva u shiha u analiżi kwantitattiva almenu ta' l-elementi kostitwenti attivi kollha u l-eżamijiet u l-kontrolli l-oħra kollha meħtieġa biex jiżguraw il-kwalita tal-prodotti mediċinali skond il-kundizzjonijiet ta' l-awtorizzazzjoni għat-tqegħid fis-suq;

Iżda meta il-konsenji ta' prodotti mediċinali jkunu diġà sarulhom il-kontrolli hawn qabel msemmija, dawn ikunu eżentati minn aktar kontrolli jekk ikun hemm magħhom ir-rapporti tal-kontrolli ffirmati mill-persuna kwalifikata, u jkunu mibjugħa fil-Kommunità.

(ċ) Mhux meħtieġ li l-persuna kwalifikata tagħmel il-kontrolli hawn qabel msemmija fil-każ ta' prodotti mediċinali importati, meta qabel ikunu saru arrangamenti bejn il-Kommunità u l-pajjiż esportatur, li jobbligaw lil min ikun qed jimmanifatura l-prodotti mediċinali li japplika n-normi ta'

prattika ta' manifattura tajba almenu ekwivalenti ghal dawk stabbiliti mill-Kommunità u li jkunu jiżguraw li jkunu saru l-kontrolli msemmija hawn qabel fil-pajjiż esportatur.

12. (1) Il-persuna kwalifikata għandha d-dmir li żżomm reġistru fejn jiġi dokumentat u iċċertifikat li kull konsenja ta' produzzjoni tkun tissodisfa id-disposizzjonijiet ta' dawn ir-regolamenti. Għandu jinżamm reġistru.

(2) Dak ir-reġistru għandu jinżamm aġġornat, hekk kif isiru t-transazzjonijiet, u għandu jkun għad-disposizzjoni ta' l-Awtorità, biex tispezzjonah, almenu għal hames snin.

L.N.143 of 2004

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

**Manufacture of Medicinal Products for Human Use
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:-

Title and commencement.

1. (1) The title of these regulations is the Manufacture of Medicinal Products for Human Use Regulations, 2004.

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

Interpretation.

2. For the purposes of these regulations-

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

“the Community” means the European Community and the European Economic Area;

“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.

Manufacturing Licence.

3. (1) (a) No medicinal product may be manufactured in Malta unless there is in respect of such product a manufacturing licence, hereinafter referred to as “licence”.

(b) This manufacturing licence shall be required notwithstanding that the medicinal products manufactured are intended for export.

(2) (a) A licence, which shall remain in force for a period to be determined by the Authority, shall be required for both total and partial manufacture, and for the various processes of dividing up, packaging or presentation.

(b) A licence shall not be required for preparation, dividing up, changes in packaging or presentation where such processes are carried out solely for retail supply, by pharmacists, in pharmacies, or by persons authorised to carry out such processes.

(3) In addition to the licence referred to under subregulation (1) of this regulation an importer's licence shall also be required for the importation of medicinal products.

(4) A licence shall include a licence to distribute by wholesale the medicinal products in respect of which the licence has been issued.

4. The Licensing Authority, hereinafter referred to as the "Authority", shall only grant or renew an licence, if the applicant :

Grant or renewal of a licence.

(a) specifies the medicinal products and pharmaceutical forms which are to be manufactured or imported and the place where they are to be manufactured and, or controlled;

(b) has at his disposal, for the manufacture or import of medicinal products, suitable and sufficient premises, technical equipment and control facilities complying with requirements set by the Authority;

(c) has at his disposal the services of at least one qualified person; and

(d) provides all necessary documentation in support of his application.

5. (1) (a) The Authority shall issue the licence after verifying the contents of the application but in any case not later than ninety days of receipt of the application.

Processing of licence.

(b) This time period shall be suspended when the Authority requests additional information from the applicant.

(c) The Authority may grant a conditional licence subject to the carrying out of certain obligations imposed on the applicant.

(2) The licence shall apply only to the premises medicinal products and pharmaceutical forms specified in the application.

Change in particulars.

6. When the holder of the manufacturing licence requests a change in any of the particulars in the application, the process of verification of such information shall not exceed 30 days. However, in exceptional cases this period of time may be extended to 90 days.

Obligation of holder.

7. The holder of a manufacturing licence shall apart from his obligations under article 44 of the Act, comply with the principles and guidelines of good manufacturing practice and good distribution practice for medicinal products published by the Commission.

Holder as qualified person.

8. If the manufacturing licence holder personally has the qualifications laid down in the regulation 9 hereof, than he may himself assume the responsibility of a qualified person.

Qualified person.

9. For a person to be designated as qualified person such person he must at least possess the following qualifications as follows:

(a) (i) be in possession of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course of study, or a course recognised as equivalent, extending over a period of at least four years of theoretical and practical study in any of the following scientific disciplines; pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, biology ;

(ii) where the course is followed by a period of theoretical and practical training of a minimum duration of one year and including a training period of at least six months in a pharmacy open to the public, such period being corroborated by an examination at university level, then the minimum duration of the university course may be three and half years;

(iii) where two university courses or two courses recognised as equivalent co-exist in a Member State, and where one of these extends over four years and the other over three years, the three-year course leading to a diploma, certificate or other evidence of formal qualifications awards on completion of a university course or its recognised equivalent shall be considered to fulfil the condition of duration referred to above, in so far as the diplomas, certificates or other evidence of formal qualifications awarded on completion of both courses are recognised as equivalent;

(b) the course shall include theoretical and practical study on at least the following basic subjects:—

- (i) applied physics,
- (ii) general and inorganic chemistry,
- (iii) organic chemistry,
- (iv) analytical chemistry,
- (v) pharmaceutical chemistry, including analysis of medicinal products,
- (vi) general and applied biochemistry (medical),
- (vii) physiology,
- (viii) microbiology,
- (ix) pharmacology,
- (x) pharmaceutical technology,
- (xi) toxicology,
- (xii) pharmacognosy (study of the composition and effects of the natural active substances of plants and animal origin);

(c) studies in these subjects shall be so balanced as to enable the qualified person fulfil the following obligations:

- (i) ensure that medicinal products have been manufactured and checked in accordance with the marketing licence;
- (ii) ensure, in the case of medicinal products from non Member States, that each production batch has undergone a full qualitative analysis and a quantitative analysis of at least three constituents and all other tests as may be necessary to ensure that the quality of the medicinal product is in accordance with the marketing licence:

Provided that the qualified person shall be exempt from complying with the afore mentioned duty in those cases where the

Community has an agreement with the exporting non Member State that the manufactured medicinal product be manufactured in accordance with standards of good manufacturing practice equivalent to those laid down by the Community and that the controls be carried out in the exporting country:

Provided further that medicinal products which are accompanied by control reports drawn up and signed by a qualified person shall be exempt from such controls if they are marketed in another Member State;

(d) in those cases where diplomas, certificates or other evidence of formal qualifications do not fulfil the criteria above mentioned, the Authority shall ensure that the person concerned provides evidence of adequate knowledge of the subjects involved;

(e) (i) the qualified person shall have acquired practical experience over at least two years, in one or more undertakings which are authorised to manufacture medicinal products, in the activities of qualitative analysis of medicinal products, or quantitative analysis of any active substance and of the testing and checking necessary to ensure the quality of medicinal products;

(ii) the duration of practical experience may be reduced by one year where a university course lasts for at least five years, and by a year and a half where the course lasts for at least six years.

Saving about
existing qualified
person.

10. (1) A person who on the date of coming into force of these regulations and for a year thereafter, was carrying out the duties as a qualified person for a period of at least six months, shall be eligible to continue in those activities even though he does not fulfil the conditions set out under regulation 9, as long as such activities have been carried out to the satisfaction of the Authority.

(2) The holder of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course, or a course in a scientific discipline recognised as equivalent in a scientific discipline, thereby allowing him to perform the duties of a qualified person, may, if he began his course prior to 21st May 1975, be considered as qualified to carry out the duties of a qualified person, provided that he was, for at least two years before 21st May 1985, engaged with one or more undertakings authorised to manufacture and carried out his duties, under the direct authority of

a qualified person, in connection with production, supervision and, or qualitative and quantitative analysis of active substances, and the necessary testing and checking in order to ensure the quality of the medicinal products.

(3) If the person concerned has acquired the practical experience referred to in the preceding paragraph before the 21st May 1965, a further one year's practical experience in accordance with the conditions referred to in the sub-regulation (2) will be required to be completed immediately before he engages in such activities.

11. The qualified person shall be responsible to ensure that: Responsibility of qualified person.

(a) each batch of medicinal products has been manufactured and checked in terms of the laws in force and is in accordance with the requirements of the marketing authorisation;

(b) that each production batch of medicinal products coming from non Member States, has undergone, on importation, a full qualitative analysis and a quantitative analysis of at least all the active constituents and all the other tests or checks necessary to ensure the quality of medicinal products 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.

(c) The qualified person need not carry out the controls above mentioned in the case of imported medicinal products, 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 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.

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

(2) 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.