

A.L. 381 ta' l-2005

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

Regolamenti ta' l-2005 dwar il-Manifattura u l-Importazzjoni ta' Prodotti Mediċinali għall-Użu mill-Bniedem

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

1. (1) It-titolu ta' dawn ir-regolamenti hu Regolamenti ta' l-2005 dwar il-Manifattura u l-Importazzjoni ta' Prodotti Mediċinali għall-Użu mill-Bniedem. Titolu u bidu fis-seħh.

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

2. (1) Għall-għanijiet ta' dawn ir-regolamenti:- Tifsir.

“l-Aġenzija” tfisser l-Aġenzija Ewropea tal-Mediċini mwaqqfa bir-Regolament (KE) Nru 726/2004;

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

“il-Komunità” tfisser il-Komunità Ewropea u ż-żona Ekonomika Ewropea;

“il-Kummissjoni” tfisser il-Kummissjoni skond Deċiżjoni tal-Kumitat 1999/468/KE tat-28 ta' Ġunju, 1999;

“prodotti mediċinali importati” tfisser prodotti mediċinali miksuba minn sors barra mill-Unjoni Ewropea jew miż-żona Ekonomika Ewropea;

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

“sustanza attiva (API)” tfisser kull sustanza jew tahlita ta' sustanzi intenzjonata biex tiġi wżata fil-manifattura ta' prodott mediċinali, u illi meta tiġi użata fil- produzzjoni ta' prodott

medicinali, issir ingredjent attiv ta' dak il-prodott. Dawn is-sustanzi huma ntenzjonati biex ifornu attività farmakoloġika jew xi effett ieħor dirett fid-djanjosi, fejqan, tnaqqis, kura jew prevenzjoni tal-marda jew li tolgot l-istruttura jew il-funzjoni tal-ġisem.

(2) Il-provvedimenti ta' dawn ir-regoli ma għandhomx japplikaw għal:-

(a) prodott medicinali preparat ġo spizerija skond ricetta medika għal pazjent individwali (komunement magħrufa bħala l-formola maġistrali);

(b) prodott medicinali preparat fi spizerija skond ir-ricetti tal-farmakopea u li jkun intenzjonat li jiġi fornut direttament lill-pazjenti moqdiġa minn dik l-ispiżerija (komunement magħruf bħala l-formola officinali).

(c) prodotti medicinali intenzjonati għal tiftix u provi ta' żvilupp imma mingħajr preġudizzju għall-provvedimenti taht ir-Regolamenti ta' l-2004 dwar Provi Kliniċi, jew għad-Direttiva 2001/20/KEE tal-Parlament Ewropew u tal-Kunsill ta' l-4 ta' April, 2001 dwar l-approssimazzjoni tal-liġijiet, regolamenti u provvedimenti amministrattivi ta' l-Istati Membri li għandhom x'jaqsmu ma' l-implimentazzjoni ta' Prattika klinika tajba fit-tmexxija ta' provi kliniċi fuq prodotti medicinali biex jintużaw mill-bniedem;

(d) prodotti intermedjarji intenzjonati għal aktar proċessar minn manifattur awtorizzat;

(e) radjonuklidi f'għamla ta' sorsi sigillata;

(f) demm shih, plasma jew ċelluli tad-demm ġejjin mill-bniedem, minbarra plasma li hija preparata b'metodu li jinvolvi proess industrijali;

(g) prodotti medicinali fornuti wara ordni *bona fide* mhix mitluba, formolata skond l-ispeċifikazzjonijiet ta' professjonist tas-saħħa awtorizzat u għall-użu minn pazjent individwali li jkun jaqqa' direttament taht ir-responsabbiltà personali diretta tiegħu.

Liċenza tal-manifatturar.

3. (1) (a) l-ebda prodott medicinali, sustanza attiva bioloġika, jew sustanza attiva li tkun se tiġi użata bħala prodott medicinali investigattiv, ma jista' jiġi manifatturat f'Malta kemm-il darba ma jkunx hemm, rigward xi prodott jew sustanza bħal dawġ, liċenza tal-manifattura hawn iżjed 'l quddiem msejha "liċenza", għal dak l-għan.

Din il-liċenza tal-manifattura għandha tkun mehtieġa ukoll għall-proċessi ta' sterilizzazzjoni ta' sustanzi attivi.

(b) Il-liċenza tal-manifattura tkun mehtieġa ukoll minkejja li l-prodotti mediċinali manifatturati huma intenzjonati għall-esportazzjoni.

(2) (a) Tkun mehtieġa liċenza, li se tibqa' fis-sehh għal perjodu li jiġi determinat mill-Awtorità tal-Lienzjar, hawn iżjed il quddiem msejha "l-Awtorità", kemm għal manifattura totali kemm għal dik parzjali, u għall-proċessi varji ta' taqsim, ippakkettar jew preżentazzjoni.

(b) Ma għandhiex tkun mehtieġa liċenza għall-preparazzjoni, taqsim, bidliet fl-ippakkettar jew preżentazzjoni meta proċessi bħal dawk isiru biss għal skopijiet ta' bejgħ bl-imnut, minn spizjara fl-ispizeriji, jew minn persuni legalment awtorizzati biex imexxu dawk il-proċessi.

(3) Tkun mehtieġa liċenza ta' importatur, hawn iżjed il quddiem msejha wkoll "liċenza", għall-importazzjoni ta' prodotti mediċinali.

(4) Liċenza għandha tinkludi liċenza biex jitqassmu bl-ingrossa dawk il-prodotti mediċinali li dwarhom tkun għet mahruġa l-liċenza.

(5) L-Awtorità għandha tghaddi lill-Aġenzija kopja tal-liċenza msemmija fis-subregolament (1) ta' dan ir-regolament.

4. L-Awtorità għandha biss tagħti jew iġġedded liċenza jekk l-applikant:

Għoti jew tiġdid ta' liċenza.

(a) jispeċifika l-forom tal-prodotti mediċinali u farmaewtici li jkunu ser jiġu manifatturati jew importati u l-post fejn dawn ikunu ser jiġu manifatturati u, jew kontrollati;

(b) ikollu għad-disposizzjoni tiegħu, biex jimmanifattura jew jimporta prodotti mediċinali, bini adatt u tajjeb biżżejjed, tagħmir tekniku u facilitajiet ta' kontroll konformi mal-htigiet mitlubin mill-Awtorità;

(c) ikollu għad-disposizzjoni tiegħu s-servizzi ta' almenu persuna wahda kwalifikata inkluża fil-kuntest tar-regolament 8; u

(d) jipprezenta d-dokumenti kollha mehtiega biex isostni l-applikazzjoni li jagħmel.

Ipproċessar ta' licenza.

5. (1) (a) L-Awtorità għandha tohroġ il-liċenza wara li tivverifika il-kontenut ta' l-applikazzjoni, imma f'kull każ mhux aktar tard minn disghin jum minn meta tirċievi l-applikazzjoni.

(b) Iz-żmien mogħti għandu jiġi sospiż meta l-Awtorità titlob informazzjoni addizzjonali mingħand l-applikant.

(ċ) L-Awtorità tista' tagħti licenza taħt kondizzjoni biex issir l-eżekuzzjoni ta' ċerti obligazzjonijiet imposti fuq l-applikant.

(2) Il-liċenza għandha tapplika biss għall-postijiet, prodotti mediċinali u għamliet farmaewtiċi speifikati fl-applikazzjoni.

Bdil fid-dettalji.

6. Meta d-detentur tal-liċenza jitlob bidla fid-dettalji speifikati fir-regolament 4(a) u 4(b), il-proċess ta' verifika ta' dik l-informazzjoni m'għandux jeċċedi tletin jum. Madanakollu, f'każijiet eċċezzjonali, dan il-perjodu ta' żmien jista' jiġi estiż għal disghin jum.

Obligazzjonijiet tad-detentur ta' licenza.

7. (1) Id-detentur tal-liċenza għandu, minbarra l-obligazzjonijiet li għandu taħt l-artikolu 44 ta' l-Att, jikkonforma ruhu mal-prinċipji u linji-gwida ta' Prattika għal manifattura tajba fil-Komunità, u l-annessi kollha relattivi għal prodotti mediċinali, u juża biss, bhala materjal tal-bidu daww is-sustanzi attivi li jkunu ġew manifatturati skond il-linji-gwida dettaljati tal-Komunità dwar il-prattika ta' manifattura tajba għall-materjal tal-bidu.

(2) Għall-ghanijiet ta' dan ir-regolament, il-manifattura ta' sustanzi attivi użati bhala materjal tal-bidu għandha tinkludi l-manifattura, sew totali sew parzjali, jew l-importazzjoni ta' sustanza attiva użata bhala materjal tal-bidu kif definit fil-Parti I, punt 3.2.1.1 (b) Anness I mad-Direttiva 2001/83, u l-proċessi varji ta' taqsim, ippakkettar jew prezentazzjoni qabel ma tiġi inkorporata fi prodott mediċinali, u dan jinkludi l-ippakkettar mill-ġdid jew it-tikkettjar mill-ġdid, kif isir mid-distributori ta' materjal tal-bidu.

Htieġa ta' persuna kwalifikata u detentur bhala persuna kwalifikata.

8. (1) Id-detentur tal-liċenza għandu jkollu permanentement u kostantement għad-disposizzjoni tiegħu, is-servizzi ta' mill-anqas persuna wahda kwalifikata, skond il-kundizzjonijiet imniżżlin fir-regolament 9 ta' dawn ir-regolamenti, li jkun speċjalment responsabbli biex jesegwixxi d-dmirijiet speċifikati fir-regolament 11.

(2) Jekk id-detentur tal-liċenza ta' manifattura innifsu jkollu l-kwalifiki imnizzlin fir-regolament 9, allura jkun jista' hu stess jassumi r-responsabbiltà ta' persuna kwalifikata.

9. Biex persuna tistemma bhala persuna kwalifikata, hija għandu jkollha dawn il-kwalifiki li ġejjin: Persuna kwalifikata.

(a) (i) ikollha diploma, ċertifikat jew xi evidenza oħra ta' kwalifiki formali moghtijin lilha wara li ttejjem kors ta' studju f'Università jew kors rikonoxxut bhala ekwivalenti, mifruq fuq mill-anqas perjodu ta' erba' snin ta' studju prattiku u teoretiku f'xi wahda minn dawn id-dixxiplini xjentifiċi li ġejjin: farmaġja, mediċina, mediċina veterinarja, kimika, kimika farmaċewtika, teknoloġija farmaċewtika, bioloġija;

(ii) meta l-kors ikun segwit minn perijodu ta' tahrig fit-teorija u l-prattika li jdum mill-inqas sena u jkun jinkludi żmien ta' tahrig ta' mhux anqas minn sitt xhur fi spiżerija miftuha għall-pubbliku, u dak iż-żmien ikun korroborat minn eżami f'livell universitarju, allura l-kors universitarju jista' mill-inqas idum għal tliet snin u nofs;

(iii) meta żewġ korsijiet universitarji jew żewġ korsijiet rikonoxxuti bhala ekwivalenti ikunu jeżistu fi Stat Membru, u meta wiehed minn dawn jifirex fuq erba' snin u l-iehor fuq tliet snin, il-kors ta' tliet snin li jwassal għal diploma, ċertifikat jew xi prova oħra ta' kwalifika formali moghtija mat-tlestija tal-kors universitarju jew l-ekwivalenti rikonoxxut tiegħu, jitqies bhala li jissodisfa l-kundizzjoni tat-tul tiegħu kif imsemmi hawn aktar qabel, għaladarba d-diplomi, ċertifikati u prova oħra ta' kwalifika formali moghtija mat-tlestija taż-żewġ korsijiet ikunu rikonoxxuti bhala li huma ekwivalenti;

(b) il-korsijiet għandhom jinkludu studju teoretiku u prattiku dwar ta' l-anqas wiehed minn dawn is-sugġetti bażiċi li ġejjin:

- (i) fiżika esperimentali;
- (ii) kimika ġenerali u inorganika;
- (iii) kimika organika;
- (iv) kimika analitika;

(v) kimika farmaċewtika li tinkludi analisi ta' prodotti mediċinali;

(vi) biokimika (medika) ġenerali u applikata;

(vii) fiżjoloġija;

(viii) mikrobioloġija;

(ix) farmakoloġija;

(x) teknoloġija farmaċewtika;

(xi) tossikoloġija;

(xii) farmakonjosi (l-istudju tal-komposizzjoni u l-effetti ta' sustanzi naturali attivi ġejjin minn pjanti u animali);

(ċ) studji f' dawn is-sugġetti għandhom ikunu hekk bilanjati li jghinu lill-persuna kwalifikata biex tissodisfa l-obbligazzjonijiet speċifikati fir-regolament 11;

(d) f' dawk il-kazijiet fejn diplomi, ċertifikati u evidenza ohra ta' kwalifiki formali ma jissodisfawx il-kriterji msemmijin hawn qabel, l-Awtorità għandha tiżgura li l-persuna konċernata ġġib provi ta' taġlim adegwat fis-sugġetti involuti.

(e) (i) Il-persuna kwalifikata għandha tkun akkwistat esperjenza Prattika ta' mill-anqas sentejn, f' xi wiehed jew aktar mill-imprizi li jkunu awtorizzati jimmanifatturaw prodotti mediċinali, fl-attivitajiet ta' analisi kwalitattiva ta' prodotti mediċinali, ta' analisi kwantitattiva ta' sustanzi attivi, u fl-ittestjar u l-għamil ta' verifiki neċessarji biex tiġi żgurata l-kwalità tal-prodotti mediċinali;

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

Eżenzjonijiet għal persuni kwalifikati, eżistenti.

10. (1) Id-detentur ta' diploma, ċertifikat jew prova ohra ta' kwalifiki formali mogħtija mat-tlestija ta' kors universitarju, jew kors rikonoxxut bhala ekwivalenti, f' dixxiplina xjentifika li tippermetti li jeseġwixxi d-dmirijiet tiegħu ta' persuna kwalifikata, jista', jekk ikun beda l-kors qabel il-21 ta' Mejju, 1975, jiġi kunsidrat bhala li kien kwalifikat biex jaqdi d-dmirijiet tiegħu ta' persuna kwalifikata, sakemm kien, għal ta' l-anqas sentejn qabel il-21 ta' Mejju, 1985, jahdem ma' xi

impriza wahda jew aktar awtorizzati biex jimmanifatturaw, u li jkun qeda d-dmirijiet ta' supervizjoni tal-produzzjoni u, jew ta' analisi kwalitattiva u kwantitattiva ta' sustanzi attivi, u ghamel l-ittestjar u l-verifiki mehtieġa taht l-awtorità diretta ta' persuna kwalifikata sabiex tiġi żgurata l-kwalità ta' l-prodotti mediċinali.

(2) Jekk dik il-persuna tkun akkwistat l-esperjenza Prattika msemija fis-subregolament (1) qabel il-21 ta' Mejju, 1965, tkun mehtieġa li ssir sena oħra ta' esperjenza Prattika skond il-kundizzjonijiet imsemija fis-subregolament (1) immedjatament qabel ma jibda dawk l-attivitajiet.

(3) Persuna li tkun qeghda taghmel l-attivitajiet ta' persuna kwalifikata minn meta tiġi applikata d-Direttiva 75/319/KE fi Stat Membru minghajr ma tikkonforma ruħha mad-disposizzjonijiet tar-regolament 9 tkun eliġibbli biex tkompli ttwettaq dawk l-attivitajiet fi hdan il-Komunità.

11. (1) Il-persuna kwalifikata, minghajr preġudizzju ghar-relazzjoni taghha mad-detentur tal-liċenza, ghandha tkun responsabbli biex tiżgura li:

Responsabilità ta' persuna kwalifikata.

(a) kull konsenja ta' prodotti mediċinali manifatturati f'Malta tkun giet manifatturata u verifikata skond il-liġijiet fis-sehh li tkun skond il-htigijiet ta' l-awtorizzazzjoni ghat-tqeghid fis-suq;

(b) fil-każ ta' prodotti mediċinali li jkunu ġejjin minn pajjiżi terzi, irrISPettivament jekk il-prodott kienx ġie manifatturat fil-Komunità, kull konsenja tal-produzzjoni ghandha tkun għaddiet fi Stat Membru minn analisi kwalitattiva shiha, analisi kwantitattiva ta' mill-anqas is-sustanzi attivi kollha u t-testijiet u kull test jew verifika oħra neċessarji biex tiġi żgurata l-kwalità tal-prodott mediċinali skond il-htigijiet ta' l-awtorizzazzjoni ghat-tqeghid fis-suq;

Iżda meta l-konsenji ta' prodotti mediċinali jkunu diġà għaddew mill-kontrolli hawn qabel imsemmijin fi Stat Membru, dawn għandhom ikunu eżenti minn aktar kontrolli jekk ikun hemm anness maghhom ir-rapporti ta' kull kontroll li jkun sar iffirmat mill-persuna kwalifikata, u jitqeghdu fis-suq fi hdan il-Komunità.

(2) Il-persuna kwalifikata m'għandhiex għalfejn tesegwixxi l-kontrolli msemmin hawn qabel fil-każ ta' prodotti mediċinali impurtati, meta jkunu saru arrangamenti mill-Komunità mal-pajjiż li jkun qed jesporthom biex jiżgura li l-manifattur tal-prodotti mediċinali

japplika *standards* ta' prattika ta' manifattura tajba li tkun ta' l-anqas ekwivalenti għal dawk stabbiliti mill-Komunità, u biex jiġi żgurat li l-kontrolli msemmijin hawn aktar qabel ikunu ġew esegwiti fil-pajjiż li jesporta.

Registri li
għandhom
jinżammu.

12. (1) Ikun id-dmir tal-persuna kwalifikata li żżomm registru biex tiddokumenta fih u tiċċertifika li kull konsenja li tkun ġiet prodotta tkun tissodisfa l-provvedimenti ta' dawn ir-regolamenti.

(2) Ir-registru msemmi għandu jinżamm aġġornat ma' kull biċċa xogħol li ssir u għandu jkun disponibbli għal spezzjonijiet mill-Awtorità għal mhux anqas minn hames snin.

Ihassar A.L. 143 ta'
l-2004.

13. Ir-Regolamenti ta' l-2004 dwar il-Manifattura ta' Prodotti Mediċinali għall-Użu mill-Bniedem, huma b'dawn imhassrin.

L.N. 381 of 2005

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

**Manufacture and Importation of Medicinal Products for Human
Use 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:-

1. (1) The title of these regulations is the Manufacture and Importation of Medicinal Products for Human Use Regulations, 2005. Title and commencement.

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

2. (1) For the purposes of these regulations- Interpretation.

“the Act” means the Medicines Act;

“active substance (API)” means any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that when used in the production of a medicinal product, becomes an active ingredient of the said product. These substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body;

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

“the 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 includes Iceland, Norway and Liechtenstein.

(2) The provisions of these regulations shall not apply to:

(a) any medicinal product prepared in a pharmacy in accordance with a medical prescription for an individual patient (commonly known as the magistral formula);

(b) any medicinal product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by the pharmacy in question, (commonly known as the officinal formula);

(c) medicinal products intended for research and development trials but without prejudice to the provisions of the Clinical Trials Regulations, 2004 or Directive 2001/20/EEC of the European Parliament and of the Council of the 4th April, 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products on human use;

(d) intermediate products intended for further processing by an authorised manufacturer;

(e) any radionuclides in the form of sealed sources;

(f) whole blood, plasma or blood cells of human origin, except for plasma which is prepared by a method involving an industrial process;

(g) medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised health-care professional and for use by an individual patient under his direct personal responsibility.

Manufacturing
licence.

3. (1) (a) No medicinal product, biological active substance, or active substance to be used directly as an investigational medicinal product, may be manufactured in Malta unless there is, in respect of such product or substance, a manufacturing licence, hereinafter referred to as “licence”, to that effect. This manufacturing licence shall also be required for the processes of sterilisation of active substances.

(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 Licensing Authority, hereinafter referred to as “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 legally authorised to carry out such processes.

(3) An importer’s licence, hereinafter also referred to as “licence”, shall 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.

(5) The Authority shall forward to the Agency a copy of the licence referred to in sub-regulation (1) hereof.

4. The Authority, shall only grant or renew a 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 within the meaning of regulation 8; 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 from 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 licence requests a change in the particulars specified in regulation 4(a) and (b), the process of verification of such information shall not exceed thirty days. However, in exceptional cases, this period of time may be extended to ninety days.

Obligation of licence holder.

7. (1) The holder of a licence shall apart from his obligations under article 44 of the Act, comply with Community principles and guidelines of good manufacturing practice and any annexes thereof for medicinal products, and use as starting materials only active substances, which have been manufactured in accordance with the detailed Community guidelines on good manufacturing practice for starting materials.

(2) For the purposes of this regulation, manufacture of active substances used as starting materials shall include both total and partial manufacture or import of an active substance used as a starting material as defined in Part I, point 3.2.1.1 (b) Annex I of Directive 2001/83, and the various processes of dividing up, packaging or presentation prior to its incorporation into a medicinal product, including repackaging or re-labelling, such as are carried out by a distributor of starting materials.

Requirement for qualified person and holder as qualified person.

8. (1) The holder of the licence shall have permanently and continuously at his disposal the services of at least one qualified person, in accordance with the conditions laid down in regulation 9 hereof, responsible in particular for carrying out the duties specified in regulation 11.

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

Qualified person.

9. For a person to be designated as qualified person, he must possess the following qualifications:

(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 awarded 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) experimental 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 to fulfil the obligations specified in regulation 11 hereof;

(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, of quantitative analysis of active substances, 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.

Exemptions for
existing qualified
person.

10. (1) The holder of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course, or a course recognised as equivalent, in a scientific discipline allowing him to perform the duties of a qualified person, may, if he began his course prior to the 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 the 21st May, 1985, engaged with one or more undertakings authorised to manufacture, and as having carried out the duties of production supervision and, or qualitative and quantitative analysis of active substances, and the necessary testing and checking under the direct authority of a qualified person in order to ensure the quality of the medicinal products.

(2) If the person concerned has acquired the practical experience referred to in sub-regulation (1) before the 21st May, 1965, a further one year's practical experience in accordance with the conditions referred to in sub-regulation (1) will be required to be completed immediately before he engages in such activities.

(3) A person engaging in the activities of a qualified person from the time of the application of Directive 75/319/EEC in a Member State without complying with the provisions of regulation 9 shall be eligible to continue to engage in those activities within the Community.

11. (1) The qualified person, without prejudice to his relationship with the holder of the licence, shall be responsible to ensure that:

Responsibility of qualified person.

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

(b) in the case of medicinal products coming from third countries, irrespective of whether the product has been manufactured in the Community, each production batch has undergone in a Member State a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of the medicinal product in accordance with the requirements of the marketing authorisation:

Provided that when the batches of medicinal products have already undergone the controls above mentioned in a Member State, 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.

(2) 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 to ensure that the manufacturer of the medicinal products applies 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.

Keeping of registers.

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.

Repeals L.N. 143 of 2004.

13. The Manufacture of Medicinal Products for Human Use Regulations, 2004, are hereby repealed.