# MALTA

**ATT Nru. III ta' l-2003**

ATT maħruġ b'liġi mill-Parlament ta' Malta.

**ATT biex jipprovdi dwar ħwejjeġ li għandhom x'jaqsmu mal-manifattura, il-preparazzjoni u l-assemblaġġ, id-distribuzzjoni bl-ingrossa, il-ħżin, il-qirda, it-tneħħija, ir-reklamar u l-awtorizzazzjoni ta' prodotti mediċinali u ta' kull attività li għandha x'taqsam ma' dan u r-regolament tal-bejgħ ta' prodotti mediċinali, spiżeriji u attivitajiet farmaċewtiċi relatati u dwar ħwejjeġ oħra anċillari għal dawn jew li għandhom x'jaqsmu magħhom.**

**ACT No. III of 2003**

AN ACT enacted by the Parliament of Malta.

**AN ACT to make provision for matters connected with the manufacture, preparation and assembly, wholesale distribution, storage, destruction, disposal, advertising and authorisation of medical products and any activity connected therewith and the regulation of the sale of medicinal products, pharmacies and related pharmaceutical activities and for any other matters ancillary thereto or connected therewith.**

# ATT TA L-2003 DWAR IL-MEDIĊINI

Arranġament ta l-artikoli

TAQSIMA III - DISPOSIZZJONIJIET ĠENERALI

*TITOLU I - Awtorizzazzjoni għat-Tqegħid fis-Suq Ta' Prodotti Mediċi*



*TITOLU II - Manifattura ta Prodotti Mediċinali għall-Użu tal-Bniedem*

Nagħti l-kunsens tiegħi.

**(L.S.)** GUIDO DE MARCO
President

5 ta Marzu, 2003

**ATT Nru. III ta l-2003**

*ATT biex jipprovdi dwar ħwejjeġ li ghandhom x jaqsmu mal-manifattura, l-preparazzjoni u l-assemblaġġ, id-distribuzzjoni bl-ingrossa, il-ħżin, il-qirda, t-tneħħija, r-reklamar u l-awtorizzazzjoni ta prodotti medicinali u ta kull attività li ghandha x taqsam ma dan u r-regolament tal-bejgh ta prodotti medicinali, spiżeriji u attivitajiet farmaċewtici relatati u dwar ħwejjeġ oħra anċillari ghal dawn jew li ghandhom x jaqsmu magħhom.*

IL-PRESIDENT bil-parir u l-kunsens tal-Kamra tad-Deputati, imlaqqgħa f dan il-Parlament, u bl-awtorità ta l-istess, ħareġ b liġi dan li ġej:-

Titolu fil-qosor u bidu fis-seħħ.

**1.** (1) It-titolu fil-qosor ta dan l-Att huwa l-Att ta l-2003 dwar il-Mediċini.

(2) Dan l-Att jibda jseħħ f dik id-data li l-Ministru responsabbli mis-saħħa jista b avviż fil-Gazzetta jistabbilixxi, u dati differenti jistgħu jiġu hekk stabbiliti għal disposizzjonijiet differenti jew għal għanijiet differenti ta dan l-Att.

**TAQSIMA I**

PRELIMINARI

Tifsir.

**2.** F dan l-Att, kemm-il darba r-rabta tal-kliem ma tkunx teħtieġ xort oħra -

"analisi" tinkludi l-ittestjar ta xi prodott mediċinali jew ta xi kostitwenti tiegħu, kemm attivi kemm mhux attivi, dwar il-proprjetajiet kimiċi, fiżiċi, farmaċewtiċi, bioloġiċi, tossikoloġiċi jew farmakoloġiċi tagħhom;

"apparat mediku" tfisser strument, apparat, tagħmir, materjal jew xi oġġett ieħor, sew jekk użat waħdu jew f kombinazzjoni, inkluż kull *software* meħtieġ għall-applikazzjoni tiegħu adatta kif intiża mill-manifattur li jkun użat għall-bnedmin għall-fini ta :

(a) dijanjosi, prevenzjoni, sorveljar, kura jew allevjazzjoni ta marda;

(b) dijanjosi, sorveljar, kura, allevjazzjoni jew kumpens għal feriment jew diżabilità;

(ċ) investigazzjoni, sostituzzjoni jew modifikazzjoni ta l-anatomija jew ta xi proċess fiżjoloġiku; u

(d) kontroll tal-konċepiment u li ma jiksibx l-azzjoni intiża prinċipali tiegħu fi jew fuq il-ġisem tal-bniedem b mezzi farmakoloġiċi, immunoloġiċi jew metaboliċi, imma li jista jkun assistit fil-funzjoni tiegħu b dawk il-mezzi;

"apparat ta radjonuklidi" tfisser preparazzjoni li għandha terġa tiġi mwaqqfa jew kombinata ma radjonuklidi fir-radjofarmaċewtiku finali, soltu qabel l-amministrazzjoni tiegħu;

"Awtorità dwar il-Mediċini" tfisser l- Awtorità mwaqqfa taħt l-artikolu 4;

"Bord ta Reviżjoni dwar il-Mediċini" tfisser il-Bord imwaqqaf taħt l-artikolu 14;

"dentist" tfisser persuna li tkun awtorizzata teżerċita dik il-professjoni taħt l-Ordinanza dwar il-Professjoni Medika u l-Professjonijiet li għandhom x jaqsmu magħha jew xi liġi oħra li tissostiwixxi dik l-Ordinanza;

Kap. 31.

"detentur ta liċenza" tfisser persuna li tkun id-detentur ta liċenza għal xi attività partikolari u mogħtija taħt dan l-Att;

"dispensa" tinkludi bejgħ jew forniment ta prodotti mediċinali;

"distribuzzjoni bl-ingrossa" dwar prodott mediċinali, tinkludi dawk l-attivitajiet kollha li jikkonsistu fl-akkwist, it-tiżmim, il-forniment, id-distribuzzjoni, esportazzjoni jew importazzjoni ta prodotti mediċinali ħlief għall-bejgħ bl-imnut jew għal użu personali;

"esperiment kliniku" tfisser investigazzjoni li ssir fuq bnedmin u li tkun intiża li tiskopri jew tivverifika l-effetti kliniċi, farmakoloġiċi jew farmakodinamiċi oħra ta xi prodott mediċinali wieħed jew aktar li jkun qed jiġi investigat, jew biex jiġu identifikati reazzjonijiet

kuntrarji ta xi prodott mediċinali wieħed jew aktar li jkun qed jiġi investigat jew biex isir studju ta l-assorbiment, d-distribuzzjoni, l-metaboliżmu u t-tneħħija minn ġol-ġisem ta xi prodott mediċinali wieħed jew aktar li jkun qed jiġi investigat bil-għan li jiġi aċċertat kemm dak il-prodott ikun wieħed sigur jew effikaċi; u tinkludi esperiment kliniċi li jsiru f xi post wieħed jew f diversi postijiet, sew lokalment sew f xi stat wieħed jew aktar rikonoxxuti mill- Awtorità dwar il-Liċenzjar;

"farmakopeia rikonoxxuta" tfisser farmakopeia rikonoxxuta b regoli għall-fini ta dan l-Att;

"formola maġistrali" tfisser prodott mediċinali ppreparat fi spiżerija skond riċetta li ssir għal pazjent individwali;

"formola uffiċjali" tfisser prodott mediċinali li jkun imħejji fi spiżerija skond istruzzjonijiet li jkun hemm f riċetta ta farmakopoeia rikonoxxuta u li jkun intiż li jiġi fornut direttament lil pazjent li jmur biex jinqeda minn dik l-ispiżerija;

"ingredient" dwar il-manifattura jew il-preparazzjoni ta xi sustanza, tinkludi kull ma jkun l-uniku ingredjent attiv tas-sustanza kif din tkun manifatturata jew preparata;

"ippakkettjar fuq barra" tfisser l-ippakkettjar li fih jitqiegħed l-ippakkettjar immedjat;

"ippakkettjar immedjat" tfisser il-kontenitur jew forma oħra ta ippakkettjar immedjat li jkun f kuntatt mal-prodott mediċinali;

"ippakkettjar minn qabel" tfisser l-għemil li bih spiżjar jaqsam prodott mediċinali fi kwantitajiet aktar adatti għall-użu ta pazjent individwali, billi hekk jibdel l-ippakkettjar fuq barra ta dan il-prodott biex ikun jista jeffettwa l-bejgħ;

"ittikkettjar" tfisser informazzjoni li tkun qegħda fuq l-ippakkettjar immedjat jew fuq barra;

"kirurgu veterinarju" tfisser persuna li tkun awtorizzata teżerċita dik il- professjoni taħt l-Att dwar is-Servizz Veterinarju, jew xi liġi oħra li tissostiwixxi dak l-Att;

"kompożizzjoni" dwar prodott mediċinali, tfisser l-ingredjenti li jikkostitwuh u l-proporzjonijiet, u l-gradi ta qawwa, l-kwalità u l-purezza, li bihom dawk l-ingredjenti jkunu rispettivament jinsabu fih u skond ma jista jiġi stabbilit fil-farmakopoeia rikonoxxuta;

"kontenitur" dwar prodott mediċinali, tfisser l-ippakkettjar

immedjat jew l-ippakkettjar fuq barra;

"kummerċ" tfisser attività ekonomika ġestita sew minn individwu sew minn korp ta persuni, kemm b mod korporat kemm mhux korporat, u tinkludi l-eżerċizzju ta xi professjoni;

"laboratorju rikonoxxut" tfisser laboratorju rikonoxxut bħala tali mill-Awtorità dwar il-Liċenzjar għall-finijiet ta dan l-Att;

"*leaflets* ġo pakkett" tfisser *leaflet* li jkun fiha informazzjoni għall-utent u li tkun tinsab flimkien mal-prodott mediċinali;

"liċenza" tfisser liċenza maħruġa taħt id-disposizzjonijiet ta dan l-Att;

"manifattura", dwar prodott mediċinali, tinkludi proċess li jsir fil-kors tal-manifattura ta prodott, imma ma tinkludix it-tidwib jew it-tifrix ta prodott fi, jew id-dilwizzjoni jew it-taħlit tiegħu ma xi sustanza oħra użata bħala vettura għall-fini li din tiġi amministrata;

"marda" tinkludi kull feriment, uġigħ jew kondizzjoni ħażina, sew jekk tal-ġisem jew tal-moħħ;

"Ministru" tfisser il-Ministru responsabbli għas-saħħa pubblika;

"oġġetti ta l-ikel" għandha l-istess tifsira bħalma għandha taħt l-Att dwar is-Sigurtà fl-Ikel;

"pakkett", dwar prodott mediċinali, tfisser kaxxa, pakkett jew oġġett ieħor li jingħalqu fih, jew ikunu intiżi li jingħalqu fih, xi kontenitur tal-prodott wieħed jew aktar u, meta tali kaxxa, pakkett jew oġġett ieħor ikun, jew ikollu hu nnifsu jingħalaq f xi kaxxa, pakkett jew oġġett ieħor wieħed jew aktar, tinkludi kull tali kaxxa, pakkett jew oġġett ieħor;

"persuna kwalifikata" tfisser li tkun persuna kwalifikata għar-rigward ta liċenza ta manifattur kif provdut fl-artikolu 31(1)(e);

"persuna responsabbli" tfisser persuna li tkun responsabbli fir-rigward ta liċenza ta negozjant bl-ingrossa kif provdut fl-artikolu 55(1)(d);

"*pharmacy technician*" tfisser persuna awtorizzata biex taġixxi bħala tali taħt l-Ordinanza dwar il-Professjoni Medika u l-Professjonijiet li għandhom x jaqsmu magħha, jew xi liġi oħra li tissostitwixxi dik l-Ordinanza;

"preparati erbali" tfisser preparati rizultat ta sustanzi erbali li

ġew soġġetti għal proċessi ta trattament bħala estrazzjoni, distillazzjoni, espressjoni, frazzazzjoni, purifikazzjoni, konċentrazzjoni u fermentazzjoni. Dawn jinkludu sustanzi erbali li ġew trasformati fi trab, mkissra f biċċiet, żjut essenzjali, tinturi, estratti, meraq magħsur u ċertu materjal likwidu u li jnixxi li ġie proċessat;

"prattika tajba" dwar il-prattika tal-manifattura, il-prattika tal-laboratorju, il-prattika tad-distribuzzjoni u l-prattika tal-bejgħ minn spiżerija tfisser *standards* għall-eżekuzzjoni kif imiss ta l- attività relattiva stabbilita minn jew taħt dan l-Att;

"prekursur ta radjonuklidi" tfisser radjonuklidi li ma jkunx radjofarmaċewtiku, radjonuklidi ġeneratur jew apparat ta radjonuklidi li jkun prodott għal radjo-ittikkettjar ta xi sustanza oħra qabel l-amministrazzjoni;

"preskritt" tfisser preskritt b regolamenti magħmulin mill-Ministru taħt dan l-Att;

"prodott kosmetiku" għandha l-istess tifsira bħalma għandha taħt l-Att dwar is-Sigurezza tal-Prodotti;

"prodott mediċinali" tfisser kull sustanza jew kombinazzjoni ta sustanzi ppreżentati għall-kura jew il-prevenzjoni ta marda fil-bniedem, kif ukoll kull sustanza jew kombinazzjoni ta sustanzi li jistgħu jiġu amministrati lill-bniedem sabiex issir dijanjosi medika jew jiġu restawrati, korretti jew modifikati funzjonijiet fiżjoloġiċi fil-bniedem;

"prodott mediċinali erbali" tfisser kull prodott mediċinali li jkollu fih wieħed jew aktar minn wieħed ingredjenti erbali bħala ingredjent attiv, jew wieħed jew iżjed minn wieħed preparati erbali, jew wieħed jew iżjed minn wieħed sustanzi erbali flimkien ma' wieħed jew iżjed minn wieħed preparati erbali;

"prodott mediċinali immunoloġiku" tfisser xi prodott mediċinali li jikkonsisti f vaċċin, tossin, serum jew prodott ta allerġen hekk li:

(a) vaċċin, tossin u serum għandhom jinkludu:

(i) aġenti użati biex jipproduċu immunità attiva;

(ii) aġenti użati għad-djanjosi ta l-immunità;

(iii) aġenti użati biex jipproduċu immunità passiva; u

(b) "prodott ta allerġen" tfisser prodott mediċinali li jkun intiż biex jidentifika jew iġib alterazzjoni miksuba speċifika fir-rispons immunoloġiku għal aġent allerġizzanti;

"prodott mediċinali investigattiv" tfisser forma farmaċewtika ta sustanza attiva jew plaċebo li jiġi ttestjat jew użat bħala riferenza f xi esperiment kliniku, u tinkludi prodotti li diġà jkollhom awtorizzazzjoni ta tqegħid fis-suq imma li l-użu jew l-assemblaġġ tagħhom (formulat jew ippakkettjat) b mod differenti mill-forma awtorizzata, jew meta jintużaw għal xi indikazzjoni mhux awtorizzata, jew meta jintużaw għall-ksib ta informazzjoni ulterjuri dwar il-forma awtorizzata;

"prodott mediċinali omeopatiku" tfisser xi prodott mediċinali preparat minn prodotti, sustanzi jew kompożizzjonijiet imsejjħa ħażniet omeopatiċi skond proċedura ta manifattura omeopatika deskritta f xi farmakopoeia rikonoxxuta;

"radjofarmaċewtiku" tfisser prodott mediċinali li, meta jkun lest għall-użu, jkun fih xi radjonuklidi wieħed jew aktar inklużi għal skop mediċinali;

"radjonuklidi ġeneratur" tfisser sistema li tkun tinkorpora fiha radjonuklidi ġenitur fiss li minnu tkun prodotta radjonuklidi filjali li għandha titneħħa b eluzzjoni jew b xi metodu ieħor u tintuża f radjofarmaċewtiku;

"regoli" tfisser regoli magħmula mill-Awtorità dwar il-Liċenzjar taħt id-disposizzjonijiet ta dan l-Att;

"reklamar" dwar prodotti mediċinali tinkludi xi forma ta informazzjoni li tingħata minn dar għall-oħra, attività ta kkanvassjar jew tħajjir intiżi biex iġibu l quddiem il-ħruġ ta riċetti, il-forniment, il-bejgħ jew il-konsum ta prodotti mediċinali u mingħajr preġudizzju għall-ġeneralità ta dak imsemmi hawn qabel tinkludi b mod partikolari:

(a) ir-reklamar ta prodotti mediċinali lill-pubbliku ġenerali;

(b) ir-reklamar ta prodotti mediċinali lil persuni kwalifikati li jippreskrivuhom jew jipprovduhom;

(ċ) viżti minn rappreżentanti mediċi jew bejjiegħa lil persuni kwalifikati li jippreskrivu prodotti mediċinali;

(d) l-għoti ta kampjuni;

(e) it-tħajjir li jiġu preskritti jew provduti prodotti mediċinali, b rigal, offerta jew wegħda ta xi benefiċċju jew bonus, sew fi flus sew għal xi korrispettiv, ħlief meta l-valur intrinsiku ta dak it-tħajjir ikun wieħed minimu;

(f) l-isponsorjar ta laqgħat promozzjonali li għalihom jattendu persuni kwalifikati li jippreskrivu jew jipprovdu prodotti mediċinali;

(g) l-isponsorjar ta xi kungress xjentifiku li għalih jattendu persuni kwalifikati li jippreskrivu jew jipprovdu prodotti mediċinali u b mod partikolari meta jiġi offrut il-ħlas ta l-ispejjeż tagħhom ta l-ivvjaġġar u għall-akkomodazzjoni f konnessjoni ma dan;

iżda għandha teskludi:

(i) l-ittikkettjar u *leaflets* li jitqassmu mal-pakkett, kif jista' jiġi stabbilit skond id-disposizzjonijiet tat-Taqsima III, Titolu I ta dan l-Att;

(ii) korrispondenza, ukoll jekk din ikollha magħha materjal ta xorta mhux promozzjonali, li tingħata b risposta għal xi mistoqsija speċifika dwar xi prodott mediċinali partikolari;

(iii) materjal fattwali u informattiv fil-forma ta tħabbira jew materjal ta riferenza li jirrigwarda tibdil fl-ippakkettjar, twissijiet ta reazzjonijiet kuntrarji bħala parti minn prekawzjonijiet ġenerali dwar mediċinali, katalogi kummerċjali, listi ta prezzijiet u materjal ieħor ta xorta simili sakemm dak il-materjal ma jkunx jinkludi xi pretensjoni dwar prodott;

(iv) kull dikjarazzjoni li tirrigwarda s-saħħa jew xi marda tal-bniedem, sakemm ma jkun hemm ebda riferenza, sew diretta sew mhux diretta, għal xi prodott mediċinali.

"riċetta mediċinali" tfisser riċetta maħruġa minn persuna professjonali kwalifikata biex tippreskrivi prodotti mediċinali b dan l-Att jew taħtu;

"skop mediċinali" tinkludi xi wieħed jew aktar mill-għanijiet li ġejjin:

(a) il-kura jew il-prevenzjoni ta marda;

(b) id-dijanjosi ta marda jew l-aċċertament ta l-eżistenza, il-grad jew l-estent ta xi kondizzjoni fiżjoloġika;

(ċ) il-kontraċezzjoni;

(d) l-anestesija;

(e) il-prevenzjoni jew l-indħil fl-operazzjoni normali ta funzjoni fiżjoloġika, sew jekk permanentement jew temporanjament, u sew jekk bit-terminazzjoni, riduzzjoni jew postponiment jew biż-żjieda jew l-aċċelerazzjoni tat-tħaddim ta dik il-funzjoni jew b xi mod ieħor;

"spiżjar" tfisser persuna li tkun awtorizzata teżerċita dik il-professjoni taħt l-Ordinanza dwar il-Professjoni Medika u l-Professjonijiet li għandhom x jaqsmu magħha, jew xi liġi oħra li tissostitwixxi dik l-Ordinanza;

"Suprintendent tas-Saħħa Pubblika" għandha l-istess tifsira bħalma hu mogħti lilha bl-artikolu 4 ta l-Ordinanza dwar l-Organizzazzjoni tad-Dipartiment tas-Saħħa;

"sustanza" tfisser xi ħaġa irrispettivament mill-oriġini li jista jkun mill-bniedem (inkluż demm tal-bniedem u prodotti ġejjin mid-demm tal-bniedem), mill-annimali (inklużi mikro-organiżmi, annimali sħaħ, partijiet ta organi, tnixxija minn annimali, estratti), mill-ħaxix (inklużi mikro-organiżmi, pjanti, partijiet minn pjanti, tnixxija minn ħxejjex, estratti), jew mill-kimika (inklużi elementi, materjal kimiku li jinsab b mod naturali jew prodotti kimiċi miksuba b tibdil kimiku jew sintesi kimika);

"sustanzi erbali" tfisser kull pjanta forma ta biċċiet, imqatta jew kważi sħiħa, partijiet ta pjanti, algi, fungi, *lichens* mhux proċessati, ġeneralment niexfa imma kultant friski; ċertu materjal jew likwidu li jnixxi mill-pjanti li jkun għadu ma ġiex soġġett għal xi proċess ta trattament partikolari wkoll;

"tabib" tfisser persuna li tkun awtorizzata teżerċita dik il-professjoni taħt l-Ordinanza dwar il-Professjoni Medika u l-Professjonijiet li għandhom x jaqsmu magħha jew xi liġi oħra li tissostitwixxi dik l-Ordinanza;

"tagħmel assemblaġġ", dwar prodott mediċinali, tfisser li tagħlaq il-prodott f kontenitur li jingħata tikketta qabel ma jinbiegħ jew jiġi fornut il-prodott, jew, meta l-prodott ikun diġà magħluq fil-kontenitur li għandu jinbiegħ jew jiġi fornut fih, l-ittikkettjar tal-kontenitur qabel ma jinbiegħ jew jiġi fornut il-prodott fih, u għandha

wkoll tinkludi l-għemil ta introduzzjoni ta informazzjoni approvata fil-kontenitur jew fuqu, u "assemblaġġ" għandha tiftiehem skond hekk;

"uffiċjal awtorizzat" dwar l-Awtorità dwar il-Mediċini tfisser xi uffiċjal jew impjegat ta l-Awtorità jew persuna oħra awtorizzata mill-Awtorità biex taġixxi f isimha u għar-rigward ta l-Awtorità dwar il-Liċenzjar tfisser uffiċjal jew impjegat tad-Dipartiment kif imsemmi fl-artikolu 5 ta l-Ordinanza dwar l-Organizzazzjoni tad-Dipartiment tas-Saħħa, li jkun awtorizzat mill-Awtorità dwar il-Liċenzjar biex jaġixxi f isimha. Kap. 94.

## TAQSIMA II

## AMMINISTRAZZJONI

### *Titolu I - Awtorità dwar il-Liċenzjar*

Funzjonijiet ta l-Awtorità dwar il-Liċenzjar.

**3.** (1) Is-Suprintendent għas-Saħħa Pubblika jkun l-Awtorità dwar il-Liċenzjar għall-għanijiet ta' dan l-Att.

(2) L-Awtorità dwar il-Liċenzjar ikollha dawn il-funzjonijiet li ġejjin:

(a) li tistabbilixxi *standards* biex tiżgura l-kwalità, s-sigurezza u l-effikaċja ta prodotti mediċinali;

(b) li tistabbilixxi *standards* għall-operazzjoni ta spiżeriji;

(ċ) li tistabbilixxi *standards* għall-manifattura, preparazzjoni, assemblaġġ, ippakkjar, ippakkettjar jew ippakkjar mill-ġdid u ttikkettjar ta prodotti mediċinali jew ta xi sustanza li tintuża jew hi intiża li tintuża f dawk il-prodotti;

(d) li tistabbilixxi *standards* għall-operazzjoni ta distribuzzjoni bl-ingrossa;

(e) li tistabbilixxi *standards* għall-ittestjar jew l-analisi ta prodotti mediċinali jew ta xi sustanza li tintuża jew hi intiża li tintuża f dawk il-prodotti;

(f) li tistabbilixxi *standards* għat-twettiq ta esperimenti kliniċi;

(g) li tistabbilixxi *standards* għar-rapportar ta reazzjonijiet avversi, reazzjonijiet avversi serji jew reazzjonijiet avversi mhux mistennija suspetti u jipprovdi għall-ġbir jew il-

preżentazzjoni ta informazzjoni relatata mill-persuna jew l-attività regolati b dan l-Att jew taħtu;

(h) li tistabbilixxi *standards* dwar ir-reklamar ta prodotti mediċinali;

(i) li tagħti pariri lill-Ministru fl-għemil ta' regolamenti dwar il-klassifikazzjoni ta prodotti mediċinali;

(j) li toħroġ, iġġedded, temenda, tibdel, tissospendi jew tjirrevoka awtorizzazzjonijiet ta tqegħid fis-suq għal prodotti mediċinali;

(k) li tirtira jew tiġbor lura prodotti mediċinali mis-suq fl-interess tas-saħħa pubblika; u

(l) li tiżgura konformità ma l-obbligi internazzjonali li l-Gvern ta Malta jkollu dwar xi ħaġa regolata minn jew taħt dan l-Att;

(m) li toħroġ, iġġedded, temenda, tibdel, tissospendi jew tirrevoka xi awtorizzazzjoni jew liċenza li tista tkun meħtieġa b dan l-Att jew taħtu;

(n) li tagħmel ispezzjonijiet fuq kull attività, servizz jew proċeduri dwar prodotti mediċinali u li tagħmel dak kollu li jista jkun meħtieġ għall-fini li tiġi żgurata konformità ma kull disposizzjoni ta' dan l-Att jew magħmula taħtu;

(o) li tawtorizza r-reklamar u l-promozzjoni ta prodotti mediċinali;

(p) li tagħmel kull attività oħra li tista tiġi ordnata;

(q) li tagħti parir lill-Ministru dwar xi ħaġa konnessa mal-funzjonijiet tagħha jew ma xi disposizzjoni oħra ta dan l-Att.

(3) L-Awtorità dwar il-Liċenzjar tista b ordni tiddelega xi funzjoni minn dawk imsemmija fis-subartikolu (2)(m), (n) u (o) lill-Awtorità dwar il-Mediċini.

(4) L-Awtorità dwar il-Liċenzjar għandha tiġbor dawk id-drittijiet li jistgħu jkunu preskritti għall-fini ta dan l-Att:

Iżda dawn ir-regolamenti jistgħu jipprovdu għat-twarrib mill-ħlas ta' dawk id-drittijiet f'dawk iċ-ċirkostanzi li jistgħu jiġu preskritti.

(5) Sabiex isir l-eżerċizzju kif imiss tal-funzjonijiet tagħha, l-Awtorità dwar il-Liċenzjar tista tistabbilixxi kumitati konsultattivi kif tista tqis li jkun meħtieġ.

*Titolu II - L-Awtorità dwar il-Mediċini*

Twaqqif ta l-Awtorità dwar il-Mediċini.

**4.** Għandu jkun hemm Awtorità dwar il-Mediċini, li titmexxa minn Uffiċjal Eżekuttiv Ewlieni.

Personalità ġuridika ta l-Awtorità dwar il-Mediċini.

**5.** (1) L-Awtorità dwar il-Mediċini għandha tkun korp magħqud li jkollu personalità ġuridika separata u distinta u li tkun tista , soġġetta biss għad-disposizzjonijiet ta dan l-Att, tagħmel kuntratti, tikseb, ikollha f idejha u tiddisponi minn kull xorta ta proprjetà kemm mobbli kemm immobbli, li timpjega persunal għall-finijiet ta l-operazzjonijiet tagħha, u li tħarrek u tiġi mħarrka, u li lilha ġiet assenjat jew tista tiġi assenjata kull funzjoni jew operazzjoni tal-gvern taħt din il-liġi jew kull liġi oħra.

(2) Ir-rappreżentanza legali u ġuridika ta l-Awtorità dwar il-Mediċini tkun vestita fl-Uffiċjal Eżekuttiv Ewlieni:

Iżda l-Awtorità dwar il-Mediċini tista taħtar lil xi wieħed jew aktar mill-uffiċjali jew impjegati tagħha biex jidher minflokha u f isimha fi proċedimenti ġudizzjarji jew fuq xi att, kuntratt, istrument jew dokument ieħor li jkun.

Funzjonijiet ta l-Awtorità dwar il-Mediċini.

**6.** (1) L-Awtorità dwar il-Mediċini jkollha dawn il-funzjonijiet li ġejjin:

(a) li taqdi dawk dawk il-funzjonijiet li jistgħu jiġu lilha delegati mill-Awtorità dwar il-Liċenzjar skond l-artikolu 3(3);

(b) li tassisti u tagħti pariri lill-Awtorità dwar il-Liċenzjar fuq kull ma jirrigwarda r-regolament ta prodotti mediċinali u attivitajiet relatati;

(ċ) li tidħol għal dawk l- attivitajiet u proġetti li jistgħu jkunu meħtieġa jew spedjenti għall-eżerċizzju kif imiss tal-funzjonijiet tagħha;

(d) li tistabbilixxi dawk il-proċeduri li jistgħu jkunu meħtieġa biex tikseb u tivvaluta informazzjoni dwar is-sigurezza, il-kwalità u l-effikaċja ta prodotti mediċinali biex dawn jitqegħdu fis-suq f Malta;

(e) li tistabbilixxi dawk il-proċeduri li jistgħu jkunu meħtieġa biex tagħmel dawk il-valutazzjonijiet dwar is-sigurezza, l-kwalità u l-effikaċja ta prodott mediċinali kif tista

tqis li jkun meħtieġ biex dawk il-prodotti jitqegħdu fis-suq f Malta;

(f) li tistabbilixxi dawk il-proċeduri li jistgħu jkunu meħtieġa għas-sorveljar u l-ksib ta rapporti fuq il-kwalità, is-sigurtà jew l-effikaċja ta prodotti mediċinali;

(g) li tagħmel rakkomandazzjonijiet lill-Awtorità dwar il-Liċenzjar fuq *standards* u liċenzjar;

(h) li tagħti parir lill-Awtorità dwar il-Liċenzjar fuq il-prekawzjonijiet jew restrizzjonijiet li prodotti mediċinali jistgħu jkunu soġġetti għalihom għat-tqegħid tagħhom fis-suq jew għall-użu kontinwat tagħhom f Malta; u

(i) li tagħti, kull meta jkun hekk jidhrilha adatt jew hekk tintalab tagħmel mill-Awtorità dwar il-Liċenzjar, pariri jew tagħmel rakkomandazzjonijiet lill-Awtorità dwar il-Liċenzjar dwar xi ħaġa li jkollha x taqsam mal-funzjonijiet tagħha.

(2) Sabiex twettaq il-funzjonijiet tagħha sew, l-Awtorità dwar il-Mediċini tista titlob il-produzzjoni ta' dik l-informazzjoni jew dokumenti li jenħtieġu għal xi waħda mill-funzjonijiet tagħha, u tista' tikseb il-parir ta espert minn kull persuna, li ma tkunx membru tal-Bord ta Reviżjoni dwar il-Mediċini, li jkollha l-kwalifiki u l-esperjenza meħtieġa fl-oqsma elenkati fl-Ewwel Skeda, u tista wkoll tistabbilixxi dawk il-kumitati konsultattivi kif tista tqis li jkun meħtieġ; u dan għal għanijiet kemm ġenerali kemm speċifiċi.

(3) L-Awtorità dwar il-Mediċini għandha tiġbor dawk id-drittijiet li jistgħu jkunu preskritti għall-fini ta dan l-Att:

Iżda dawn ir-regolamenti jistgħu jipprovdu għat-twarrib mill-ħlas ta' dawk id-drittijiet f'dawk iċ-ċirkostanzi eċċezzjonali li jistgħu jiġu preskritti.

Organizzazzjoni ta l-Awtorità dwar il-Mediċini.

**7.** L-Awtorità għandha twaqqaf dawk id-Direttorati li jkunu meħtieġa, u għandha tassenja lil kull Direttorat dawk il-funzjonijiet li jidhrilha spedjenti għall-eżerċizzju tajjeb tal-funzjonijiet tagħha.

L-Uffiċjal Eżekuttiv Ewlieni ta l-Awtorità dwar il-Mediċini.

**8.** (1) L-Uffiċjal Eżekuttiv Ewlieni għandu jinħatar mill-Ministru minn fost persuni li jkunu kwalifikati kif imiss u li jkollhom esperjenza f settur mediku, farmaċewtiku jew xjenza medika.

(2) L-Uffiċjal Eżekuttiv Ewlieni jkun responsabbli għall-amministrazzjoni ġenerali u l-prestazzjoni ta' l-Awtorità, inkluża l-amministrazzjoni tal-ħidmiet ta kull jum li jsiru mill-Awtorità.

(3) Persuna ma għandhiex tkun eliġibbli li tinħatar jew li jkollha il-kariga ta Direttur jew Uffiċjal Eżekuttiv Ewlieni ta l-Awtorità jekk:

(i) tkun membru tal-Kamra tad-Deputati; jew

(ii) tkun Imħallef jew Maġistrat; jew

(iii) tkun, skond il-liġi, inabilita; jew

(iv) tkun ġiet dikjarata falluta jew tkun għamlet kompożizzjoni jew arranġament mal-krediturі tagħha; jew

(v) ġiet misjuba ħatja ta' frodi jew ta' xi reat reat ieħor kontra l-fiduċja pubblika, jew tkun mod ieħor ġiet kundannata għal ħabs għal żmien ta' mhux anqqas minn tliet xhur; jew

(vi) ikollha xi interessi finanzjarji jew oħra, diretti jew indiretti f xi intrapriża jew attività li x aktarx jolqtu t-twettiq tal-funzjonijiet tagħha bħala membru ta l-Awtorità.

(4) (a) L-Uffiċjal Eżekuttiv Ewlieni ta l-Awtorità għandu jibqa f dik il-kariga għal perjodu mhux iżjed minn ħames snin imma huwa jkun eliġibbli li jerġa jinħatar għal perjodi oħra li kull wieħed minnhom ma jistax jeċċedi ħames snin.

(b) L-Uffiċjal Eżekuttiv Ewlieni ta l-Awtorità jista jitneħħa mill-kariga mill-Ministru qabel l-iskadenza taż-żmien ta l-kariga tiegħu meta, fil-fehma tal-Ministru, jkun ħati ta tmexxija mhux kif imiss jew minħabba fl-inkapaċità tiegħu li jkompli jwettaq il-funzjonijiet tal-kariga tiegħu, sew jekk minħabba f inkapaċità tal-moħħ jew tal-ġisem, jew għal xi raġuni oħra, jew minħabba fi mġieba mhux kif imiss.

Impjegati ta l-Awtorità dwar il-Mediċini.

**9.** (1) Bla ħsara għad-disposizzjonijiet tal-Kostituzzjoni u ta xi liġi oħra li tapplika dwar dan, u mingħajr preġudizzju għad-disposizzjonijiet l-oħra ta dan l-Att, il-ħatra ta uffiċjali jew impjegati ta l-Awtorità għandha ssir mill-Awtorità. Il-pattijiet u l-kondizzjonijiet ta impjieg għandhom jiġu stabbiliti mill-Awtorità bi ftehim mal-Ministru, mogħti wara konsultazzjoni mal-Ministru tal-finanzi.

(2) Il-Prim Ministru jista , fuq talba ta l-Awtorità, wara li din tikkonsulta mal-Ministru, minn żmien għal żmien u b ordni jingaġġa uffiċjal pubbliku jagħmel xogħol ma l-Awtorità f dik il-kapaċità u għal dak iż-żmien u taħt dawk il-kondizzjonijiet li jistgħu jiġu

stabbiliti dwar dak l-uffiċjal hekk ingaġġat.

(3) Il-Prim Ministru jista f kull waqt jirrevoka ordni bħal dak mogħti taħt is-subartikolu (2).

(4) Meta uffiċjal jiġi ingaġġat biex jaqdi dmirijietu ma l-Awtorità dak l-uffiċjal għandu, matul iż-żmien li dak l-ordni jibqa jseħħ, ikun taħt id-direzzjoni amministrativa u l-kontroll ta l-Uffiċjal Eżekuttiv Ewlieni u għandu xort oħra jibqa u jżomm kull dritt u dmir li jkollu bħala uffiċjal pubbliku u għall-finijiet ta xi liġi li tirrigwarda l-pensjoni għas-servizz mal-gvern, is-servizz li jingħata ma l-Awtorità għandu jitqies bħala servizz mal-Gvern:

Iżda ma għandu jittieħed ebda qies, fl-evalwazzjoni ta emolumenti pensjonabbli ta dak l-uffiċjal għall-finijiet ta xi liġi li tirrigwarda l-pensjonijiet għas-servizz mal-gvern, ta kull *allowance*, bonus jew gratwità mħallsa lil dak l-uffiċjal mill-Awtorità b żjieda ma dak li jkollu jedd għalih bħala uffiċjal pubbliku:

Iżda wkoll waqt dak iż-żmien li dwaru huwa jkun hekk ingaġġat biex iwettaq dmirijiet ma l-Awtorità il-pattijiet u l-kondizzjonijiet tas-servizz tiegħu ma għandhomx ikunu inqas favorevoli minn dawk marbuta mal-ħatra tiegħu taħt il-Gvern matul il-perjodu hawn qabel imsemmi. Dawk il-pattijiet u l-kondizzjonijiet ma għandhomx jitqiesu bħala inqas favorevoli unikament minħabba f li ma jkunux għalkollox identiċi ma jew superjuri għal dawk li l-uffiċjal involut ikun igawdi fid-data meta ssir dik l-offerta, jekk dawk il-pattijiet u l-kondizzjonijiet, meħudin ilkoll flimkien, fil-fehma tal-Prim Ministru jkunu sostanzjalment joffru benefiċċji ekwivalenti jew akbar.

Kontijiet ta l-Awtorità dwar il-Mediċini.

**10.** (1) L-Awtorità għandha żżomm kotba tal-kontijiet kif imiss b dak il-mod li l-Ministru responsabbli għall-finanzi jista minn żmien għal żmien jordna. Dawk il-kontijiet għandhom ikunu verifikati minn awditur li jinħatar għal dan il-fini mill-Awtorità u għandhom iktar minn hekk ikunu soġġetti għall-verifika ta l-Awditur Ġenerali.

(2) L-Awtorità għandha, mhux aktar tard minn sitt ġimgħat wara tmiem kull sena finanzjarja, tippreżenta lill-Ministru u lis-segretarju permanenti l-kontijiet verifikati flimkien ma rapport fuq il-ħidma ta l-aġenzija liema rapport għandu jiddikjara l-mod li bih tkun operat l-aġenzija biex twettaq il-funzjonijiet tagħha u l-pjanijiet li jkollha għall-futur.

(3) Ir-rapporti msemmija fis-subartikolu (2) għandhom jitqegħdu fuq il-Mejda tal-Kamra tad-Deputati mill-Ministru mhux

iżjed tard minn sitt ġimgħat wara li dawn jaslu, jew meta matul dak il-perjodu ma jkunx hemm sessjoni tal-Kamra mhux iżjed tard mit-tieni ġimgħa wara li l-Kamra tkompli bis-seduti tagħha.

Akkwisti mill-Awtorità dwar il-Mediċini.

**11.** Hlief bl-approvazzjoni tal-Ministru, l-Awtorità ma għandha tagħmel ebda kuntratt għall-forniment ta merkanzija jew materjal jew għall-esekuzzjoni ta xogħlijiet jew għall-għoti ta servizzi, lil jew għall-benefiċċju ta l-Awtorità, li jkun stmat mill-Awtorità li jinvolvi spiża li tkun teċċedi il-mitt elf lira jew kull ammont ieħor li l-Ministru jista minn żmien għal żmien jordna bil-miktub, ħlief wara li jkun ġie ppubblikat avviż tal-ħsieb li l-Awtorità jkollha li tagħmel dak il-kuntratt u jkunu nħarġu sejħiet għal offerti kompetittivi.

Kif japplika l-Kodiċi ta Etika.

**12.** L-Uffiċjal Eżekuttiv Ewlieni u kull uffiċjal eżekuttiv u impjegat ieħor ta l-Awtorità għandhom jikkonformaw ruħhom ma u jħarsu kull valur tas-servizz pubbliku u tal-Kodiċi ta Etika li jista jkun fis-seħħ minn żmien għal żmien dwar l-uffiċjali pubbliċi.

Eżenzjoni mit-taxxa, eċċ.

**13.** L-Awtorità għandha tkun eżenti minn kull responsabbiltà għall-ħlas ta taxxa fuq l-*income* jew taxxa fuq id-dokumenti li f dak il-waqt ikunu fis-seħħ f Malta.

*Titolu III - Bord ta Reviżjoni dwar il-Mediċini*

Twaqqif ta Bord ta Reviżjoni dwar il-Mediċini.

**14.** (1) Ikun hemm Bord ta Reviżjoni dwar il-Mediċini li jkun magħmul minn tliet membri u minn tliet membri sostituti li jinħatru mill-Ministru, kif ġej:

(a) persuna li tkun persuna li tipprattika l-professjoni legali u li jkollha mill-anqas seba snin esperjenza legali u li tkun *chairperson*; u

(b) mill-anqas żewg persuni li jkollhom il-kwalifiki u l-esperjenza teknika u xjentifika fil-qasam regolatorju tal-mediċini.

(2) Il-Ministru għandu jaħtar uffiċjal pubbliku biex jagħmilha ta segretarju tal-Bord ta Reviżjoni dwar il-Mediċini.

(3) Il-membri tal-Bord ta Reviżjoni dwar il-Mediċini għandhom jiġu maħtura mill-Ministru għal żmien tliet snin, u taħt dawk il-pattijiet u l-kondizzjonijiet li jistgħu jiġu speċifikati fil-ħatra tagħhom. Membri li jiġu hekk maħtura jistgħu jerġgħu jinħatru mill-ġdid meta jiskadi ż-żmien tagħhom fil-kariga.

(4) Meta xi membru tal-Bord ta Reviżjoni dwar il-Mediċini ma jkunx jista jaġixxi, l-membru sostitut li jkollu l-istess kwalifiki

għandu jaġixxi minfloku.

(5) Persuna ma tkunx kwalifikata li tibqa fil-kariga bħala membru tal-Bord ta Reviżjoni dwar il-Mediċini jekk:

(i) tkun membru tal-Kamra tad-Deputati; jew

(ii) tkun Imħallef jew Maġistrat; jew

(iii) tkun, skond il-liġi, inabilita; jew

(iv) tkun ġiet dikjarata falluta jew tkun għamlet kompożizzjoni jew arranġament mal-krediturі tagħha; jew

(v) ġiet misjuba ħatja ta' frodi jew ta' xi reat reat ieħor kontra l-fiduċja pubblika, jew tkun mod ieħor ġiet kundannata għal ħabs għal żmien ta' mhux anqqas minn tliet xhur; jew

(vi) ikollha xi interessi finanzjarji jew oħra, diretti jew indiretti, f xi intrapriża jew attività li x aktarx jolqtu t-twettiq tal-funzjonijiet tagħha bħala membru tal-Bord.

(6) Id-disposizzjonijiet tas-Subtitolu II tat-Titolu II tat-Tielet Ktieb tal-Kodiċi ta' Organizzazzjoni u Proċedura Ċivili għandhom jgħoddu, *mutatis mutandis*, għall-membri tal-Bord ta' Reviżjoni dwar il-Mediċini li jistgħu jiġu rikużati jew jistgħu jastjenu milli joqgħodu fuq dak il-Bord waqt is-smigħ ta' xi appell.

Kap. 12.

(7) Persuna ttemm milli tibqa membru tal-Bord ta Reviżjoni dwar il-Mediċini meta jiskadi ż-żmien tal-kariga tagħha, jew jekk ikun hemm ċirkostanzi illi, li kieku ma tkunx membru tal-Bord ta Reviżjoni dwar il-Mediċini, ittemm milli tkun kwalifikata għal ħatra bħal dik.

(8) Membru tal-Bord ta Reviżjoni dwar il-Mediċini jista jitneħħa mill-kariga mill-Ministru jekk, fil-fehma tiegħu, dak il-membru ma jibqax iżjed idoneu biex ikompli f dik il-kariga jew ma jkunx baqa aktar kapaċi li jwettaq kif imiss id-dmirijiet tiegħu bħala membru.

Bord ta Reviżjoni dwar il-Mediċini jista jaħtar konsulenti.

**15.** (1) Fl-esekuzzjoni tal-funzjonijiet tiegħu, il-Bord ta Reviżjoni dwar il-Mediċini jista jitlob il-parir ta kull persuna b għarfien fil-materja li jkun sar appell dwarha.

(2) Il-Bord jista wkoll jeħtieġ lil xi dipartiment u, jew awtorità tal-gvern jipprovdilu dik l-informazzjoni jew dak il-parir li

jista jqis li jkunu meħtieġa għall-qadi kif imiss tal-funzjonijiet tiegħu.

Funzjonijiet tal-Bord ta Reviżjoni dwar il-Mediċini.

**16.** (1) Tkun il-funzjoni tal-Bord ta Reviżjoni dwar il-Mediċini:

(a) li jisma kull appell magħmul minn persuna aggravata minn xi rakkomandazzjoni ta l-Awtorità dwar il-Mediċini dwar is-sigurezza, l-kwalità u l-effikaċja ta xi prodott mediċinali wara li tkun saret applikazzjoni għal awtorizzazzjoni ta tqegħid fis-suq li tiġi ppreżentata mill-appellant;

(b) li jagħti kull parir u jagħmel ir-rakkomandazzjonijiet tiegħu lill-Awtorità dwar il-Liċenzjar dwar appell jew talba li jsirulha.

(2) Flimkien mal-preżentazzjoni tar-rakkomandazzjonijiet tiegħu lill-Awtorità dwar il-Liċenzjar, il-Bord għandu wkoll jippreżenta kopja ta dawk ir-rakkomandazzjonijiet lill-appellant u lill-Awtorità dwar il-Mediċini.

(3) Kull appoġġ amministrativ u finanzjarju meħtieġ mill-Bord ta Reviżjoni dwar il-Mediċini għat-twettiq tal-funzjonijiet tiegħu għandu jingħata mill-Awtorità dwar il-Liċenzjar.

(4) Bla ħsara għad-disposizzjonijiet hawn qabel imsemmija l-affarijiet tal-Bord ta Reviżjoni dwar il-Mediċini għandhom jitmmexxu skond ir-regoli li hemm fit-Tieni Skeda u l-Bord jista xort oħra jirregola l-proċedura tiegħu nnifsu.

Proċedura dwar l-appelli.

**17.** (1) Meta applikant għal xi awtorizzazzjoni ta tqegħid fis-suq iħoss ruġu aggravat bir-riżultanzi u r-rakkomandazzjonijiet magħmula mill-Awtorità dwar il-Mediċini li jsiru lill-Awtorità dwar il-Liċenzjar, huwa jista , fi żmien erbatax-il ġurnata minn meta tasallu kopja ta dawk ir-riżultanzi u rakkomandazzjonijiet, jippreżenta appell quddiem il-Bord ta Reviżjoni dwar il-Mediċini.

(2) L-Awtorità dwar il-Liċenzjar tista , jekk tqis li jkun hekk meħtieġ, fi żmien erbatax-il ġurnata minn meta jaslu r-riżultanzi u r-rakkomandazzjonijiet ta l-Awtorità dwar il-Mediċini fuq is-sigurezza, l-kwalità u l-effikaċja ta xi prodott mediċinali, titlob lill-Bord ta Reviżjoni dwar il-Mediċini jipprovdilha fehma ulterjuri fuq il-każ.

(3) Appell jew talba għal reviżjoni għandhom isiru bil-miktub u għandu jkollhom magħhom id-dritt preskritt.

(4) Ir-rikors ta l-appell jew talba għal reviżjoni għandu jkun

fihom b mod ċar u komprensiv il-fatti li jikkostitwixxu l-appell jew ir-reviżjoni u għandu jkun fihom kull prova u dokumentazzjoni biex isostnu l-pretensjoni li tkun qegħda ssir u li tista tkun meħtieġa sabiex il-Bord jasal biex jiddeċiedi dwar il-każ:

Iżda l-Bord ta Reviżjoni dwar il-Mediċini jista jitlob li jiġu ppreżentati kull tali informazzjoni jew dokumentazzjoni ulterjuri skond ma jista jitqies li jkun meħtieġ:

Iżda wkoll il-Bord ta Reviżjoni dwar il-Mediċini għandu wara li jikseb l-informazzjoni rilevanti kollha, jipproċessa r-rikors fi żmien speċifikat skond regolamenti li jsiru taħt dan l-Att.

Smigħ fil-pubbliku.

**18.** (1) Il-Bord ta Reviżjoni dwar il-Mediċini għandu jappunta s-smigħ ta' l-appell fil-pubbliku fi żmien tletin ġurnata mill-ġurnata tal-preżentata ta l-appell jew talba għal reviżjoni u għandu jiddeċiedi dwar il-kwistjoni mill-aktar fis possibbli.

(2) Il-Bord ta Reviżjoni dwar il-Mediċini għandu jinforma lill-appellant, lill-Awtorità dwar il-Liċenzjar u lill-Awtorità dwar il-Mediċini bl-opinjoni tiegħu bil-miktub malli jkun hekk prattikkabbli li jagħmel.

## TAQSIMA III

## DISPOSIZZJONIJIET ĠENERALI

### *Titolu I - Awtorizzazzjoni ta Tqegħid fis-Suq dwar Prodotti Mediċinali*

Kif japplikaw ċerti disposizzjonijiet

**19.** (1) Id-disposizzjonijiet ta' l-artikoli 20 sa 36 għandhom japplikaw għal prodotti mediċinali li jiġu manifatturati b mod industrjali għall-użu tal-bniedem u li jkunu intiżi li jitqegħdu fis-suq f Malta.

(2) L-artikoli 20 sa 36 ma għandhomx japplikaw għal:

(a) prodott mediċinali ppreparat skond xi formula maġistrali;

(b) prodott mediċinali ppreparat skond formola uffiċjali;

(ċ) prodotti mediċinali maħsuba għal riċerka u provi għall-iżvilupp tagħhom;

(d) prodotti intermedji intiżi għall-ipproċessar ulterjuri li jsir minn manifattur awtorizzat;

(e) radjonuklidi fl-għamla ta sorsi siġillati.

Awtorizzazzjoni biex jitqiegħdu prodotti mediċinali fis-suq.

**20.** (1) Ħadd ma għandu jqiegħed prodott mediċinali fis-suq f Malta kemm-il darba ma jkollux awtorizzazzjoni ta tqegħid fis-suq mill-Awtorità dwar il-Liċenzjar, skond id-disposizzjonijiet ta dan l-Att jew ta xi regolamenti jew regoli magħmulin taħtu:

Iżda l-Awtorità dwar il-Liċenzjar tista , f każijiet eċċezzjonali, tippermetti l-użu ta xi prodott mediċinali mingħajr l-awtorizzazzjoni ta tqegħid fis-suq bla ħsara għal dawk il-kondizzjonijiet li tista torbot ma dan:

Iżda wkoll prodott mediċinali li jkun essenzjalment identiku ma prodott mediċinali li dwaru tkun diġà ngħatat awtorizzazzjoni għat-tqegħid fis-suq, għandu biss ikun soġġett għal kondizzjonijiet li jistgħu jiġu stabbiliti mill-Awtorità dwar il-Liċenzjar.

(2) Applikazzjoni għall-għoti ta awtorizzazzjoni għat-tqegħid fis-suq għandha ssir lill-Awtorità dwar il-Liċenzjar u għandu jkun hemm id-dritt preskritt.

(3) L-applikazzjoni għandu jkun fiha l-informazzjoni u d-dokumenti kollha meħtieġa għall-valutazzjoni tas-sigurezza, l-kwalità u l-effikaċja tal-prodott mediċinali u għandha tkun ippreżentata f dik il-forma u b dak il-mod hekk kif l-Awtorità dwar il-Liċenzjar tista b regoli teħtieġ.

(4) L-Awtorità dwar il-Liċenzjar għandha tressaq l-applikazzjoni li tkun ġiet ippreżentata lilha, quddiem l-Awtorità dwar il-Mediċini mill-aktar fis possibbli.

(5) Meta applikazzjoni għall-ħruġ ta awtorizzazzjoni ta tqegħid fis-suq tiġi riċevuta mill-Awtorità dwar il-Mediċini, l-Awtorità tista :

(a) tirrifjuta li tipproċessa l-applikazzjoni jekk dik l-applikazzjoni ma tkunx ġiet ippreżentata skond id-disposizzjonijiet ta' dan l-Att;

(b) titlob lill-applikant jipprovdiha b dik l-informazzjoni ulterjuri li tirrigwarda l-applikazzjoni li hija tista tqis meħtieġa; u meta ssir xi talba bħal dik, l-Awtorità dwar il-Mediċini ma għandhiex tkun meħtieġa tiddeċiedi dwar l-applikazzjoni sakemm ma tiġix hekk lilha ppreżentata l-informazzjoni hekk mitluba;

(ċ) tevalwa l-applikazzjoni dwar is-sigurezza, il-kwalità

u l-effikaċja ta prodott mediċinali b dak il-mod u f dak il-perjodu li jista jiġi ordnat b dan l-Att jew taħtu;

(d) twettaq kull attività oħra li tista tiġi ordnata mill-Ministru minn żmien għal żmien.

(6) L-Awtorità dwar il-Mediċini għandha tirrapporta r-riżultanzi tagħha u tagħmel ir-rakkomandazzjonijiet tagħha lill-Awtorità dwar il-Liċenzjar, u tippreżenta kopja ta dawn lill-applikant, b dak il-mod u f dak il-perjodu li jista jiġi preskritt.

Reviżjoni jew appell.

**21.** Meta l-Awtorità dwar il-Liċenzjar jew l-applikant ma jaqblux mar-riżultanzi jew mar-rakkomandazzjonijiet ta l-Awtorità dwar il-Mediċini, kull parti tista tappella lill-Bord ta Reviżjoni dwar il-Mediċini bil-mod stabbilit b dan l-Att jew taħtu.

Għoti ta awtorizzazzjoni ta tqegħid fis-suq.

**22.** (1) Meta tirċievi r-riżultanzi u r-rakkomandazzjonijiet ta l-Awtorità dwar il-Mediċini, jew wara appell jew talba għal reviżjoni mill-Bord ta' Reviżjoni dwar il-Mediċini, l-Awtorità dwar il-Liċenzjar tista tirrifjuta jew xort oħra toħroġ awtorizzazzjoni ta tqegħid fis-suq jew skond ma jiġi rakkomandat mill-Awtorità dwar il-Mediċini jew soġġetta għal kull tali kondizzjoni jew obbligu li tista tqis li jkunu meħtieġa.

(2) Id-deċiżjoni ta l-Awtorità dwar il-Liċenzjar għandha tkun waħda finali, u għandha flimkien mar-raġunijiet dettaljati li fuqhom tkun ibbażata dik id-deċiżjoni tiġi komunikata lill-Bord ta Reviżjoni dwar il-Mediċini, lill-Awtorità dwar il-Mediċini u lill-applikant kif meħtieġ.

Notifikazzjoni ta awtorizzazzjoni ta tqegħid fis-suq.

**23.** (1) Sew meta tingħata sew jekk xort oħra ma tingħatax awtorizzazzjoni ta tqegħid fis-suq, l-Awtorità dwar il-Liċenzjar għandha wkoll tgħarraf lill-Awtorità dwar il-Mediċini b dik id-deċiżjoni.

(2) Awtorizzazzjoni ta tqegħid fis-suq għandha tispeċifika:

(a) is-sommarju tal-karatteristiċi tal-prodott kif approvat;

(b) l-ittikkettjar u l-ippakkettjar approvat;

(ċ) kull kondizzjoni li tista tkun marbuta ma l-għoti ta l-awtorizzazzjoni ta tqegħid fis-suq;

(d) il-klassifikazzjoni tal-prodott mediċinali;

(e) iż-żmien ta validità ta l-awtorizzazzjoni ta tqegħid

fis-suq;

(f) kull speċifikazzjoni oħra li l-Awtorità dwar il-Liċenzjar tista tqis li tkun meħtieġa.

Validità ta awtorizzazzjoni ta tqegħid fis-suq.

**24.** (1) Kull awtorizzazzjoni ta tqegħid fis-suq mogħtija taħt dan l-Att għandha, kemm-il darba ma tkunx ġiet revokata qabel, tiskadi fi tmiem il-validità tagħha.

(2) Kull awtorizzazzjoni ta tqegħid fis-suq hekk mogħtija taħt dan l-Att, kemm-il darba ma tkunx ġiet revokata qabel, tkun tista tiġġedded wara li ssir applikazzjoni mid-detentur mill-anqas tliet xhur qabel l-iskadenza tal-perjodu ta validità.

Applikazzjoni għal tiġdid.

**25.** (1) Meta applikazzjoni għat-tiġdid ta xi awtorizzazzjoni ta tqegħid fis-suq taħt dan l-Att tkun saret kif imiss, il-validità ta l-awtorizzazzjoni ta tqegħid fis-suq għandha titqies bħala li tkun għadha effettiva sakemm l-Awtorità dwar il-Liċenzjar tiddeċiedi dwar l-applikazzjoni.

(2) Minkejja d-disposizzjonijiet ta' kull liġi oħra, l-ebda qorti ma tista' toħroġ mandat ta' inibizzjoni li jwaqqaf l-Awtorità dwar il-Liċenzjar milli tiddeċiedi dwar dik l-applikazzjoni.

Notifikazzjoni ta rifjut ta tiġdid.

**26.** L-Awtorità dwar il-Liċenzjar għandha tgħaddi l-applikazzjoni għal tiġdid ta awtorizzazzjoni ta tqegħid fis-suq lill-Awtorità dwar il-Mediċini u f kull każ bħal dan għandhom jgħoddu, *mutatis mutandis*, id-disposizzjonijiet ta l-artikolu 20(4), (5), (6) u ta l-artikolu 21.

Meta awtorizzazzjoni ta tqegħid fis-suq ma tiġġeddidx.

**27.** (1) L-Awtorità dwar il-Liċenzjar tista tirrifjuta li tagħti jew iġġedded l-awtorizzazzjoni tat-tqegħid fis-suq abbażi ta nuqqas ta kwalità, sigurezza jew effikaċja tal-prodott mediċinali jew fl-interess tas-saħħa pubblika jew għal xi raġuni oħra li normalment tkun raġuni valida għas-sospensjoni, ir-revoka, ir-rifjut jew ta xi awtorizzazzjoni xort oħra ta tqegħid fis-suq:

Iżda meta tagħmel dan l-Awtorità tal-Liċenzjar għandha tinnotifika lill-Awtorità tal-Mediċini u lill-applikant bid-deċiżjoni tagħha u tagħti r-raġunijiet dettaljati li fuqhom tkun motivata dik id-deċiżjoni.

(2) Awtorizzazzjoni ta tqegħid fis-suq mġeddha għandha tispeċifika:

(a) is-sommarju tal-karatteristiċi tal-prodott kif approvat;

(b) l-ittikkettjar u l-ippakkettjar approvat;

(ċ) kull kondizzjoni li tista tkun marbuta ma l-għoti ta l-awtorizzazzjoni ta tqegħid fis-suq;

(d) il-klassifikazzjoni tal-prodott mediċinali;

(e) iż-żmien ta validità ta l-awtorizzazzjoni ta tqegħid fis-suq;

(f) kull speċifikazzjoni oħra li l-Awtorità dwar il-Liċenzjar tista tqis li tkun meħtieġa.

Sospensjoni jew revoka ta awtorizzazzjoni ta tqegħid fis-suq.

**28.** (1) L-Awtorità dwar il-Liċenzjar għandha tissospendi jew tirrevoka awtorizzazzjoni ta tqegħid fis-suq ta xi prodott mediċinali meta dak il-prodott jirriżulta li jkun dannuż fil-kondizzjonijiet ta użu normali tiegħu, jew meta ma jkollux effikaċja terapewtika, jew meta l-kompożizzjonijiet tiegħu kemm kwalitattivi kemm kwantitattivi ma jkunux dawk dikjarati. Għall-fini ta dan l-artikolu jitqies li jkun hemm nuqqas ta effikaċja terapewtika meta jiġi stabbilit li ma jkunux jistgħu normalment jinkisbu riżultati terapewtiċi mill-prodott mediċinali.

(2) Awtorizzazzjoni tkun ukoll sospiża jew revokata meta jirriżulta li l-partikolaritajiet b'sostenn ta l-applikazzjoni kif provdut dwarhom f dan l-Att ma jkunux korretti jew ikunu ġew emendati mingħajr awtorizzazzjoni jew meta l-kontrolli meħtieġa b dan l-Att jew taħtu ma jkunux ġew imwettqa.

(3) Meta l-ippakkettjar, ittikkettjar jew *leaflet* ġo pakkett tal-prodott mediċinali inkwistjoni ma jkunux konformi mal-ħtiġiet speċifikati b dan l-Att jew taħtu, l-Awtorità dwar il-Liċenzjar tista tissospendi l-awtorizzazzjoni ta tqegħid fis-suq b avviż li jiġi notifikat lid-detentur ta' l-awtorizzazzjoni għat-tqegħid fis-suq u s-sospensjoni għandu jibqa jkollha effett sakemm l-Awtorità dwar il-Liċenzjar tkun sodisfatta li l-ħtiġiet ikunu twettqu.

(4) Jekk l-Awtorità dwar il-Liċenzjar tissospendi jew tirrevoka awtorizzazzjoni ta tqegħid fis-suq, din għandha tavża lid-detentur ta l-awtorizzazzjoni ta tqegħid fis-suq u lill-Awtorità dwar il-Mediċini b dik id-deċiżjoni fejn tagħti b mod dettaljat ir-raġunijiet li fuqhom tkun motivata dik id-deċiżjoni.

(5) Id-detentur ta' awtorizzazzjoni ta' tqegħid fis-suq jista, fi żmien erbatax-il ġurnata minn dik in-notifika, jitlob lill-Bord ta' Reviżjoni dwar il-Mediċini biex jeżamina ċ-ċirkostanzi li wasslu għas-sospensjoni jew revoka ta' l-awtorizzazzjoni għat-tqegħid fis-suq, u l-Bord ta' Reviżjoni dwar il-Mediċini għandu jagħti r-

rakkomandazzjoni tiegħu lill-Awtorità dwar il-Liċenzjar:

Iżda din it-talba ma għandhiex tissospendi l-effetti tad-deċiżjoni ta' l-Awtorità dwar il-Liċenzjar u l-Awtorità dwar il-Liċenzjar ma tkunx marbuta bir-rakkomandazzjonijiet magħmula mill-Bord ta' Reviżjoni dwar il-Mediċini.

Klassifikazzjoni ta prodotti mediċinali.

**29.** (1) Meta tingħata jew tiġi mġedda awtorizzazzjoni ta tqegħid fis-suq, l-Awtorità dwar il-Liċenzjar għandha tispeċifika l-klassifikazzjoni tal-prodott mediċinali skond id-disposizzjonijiet ta dan l-Att, imma b mod ġenerali:

(a) fi prodott mediċinali soġġett għal riċetta mediċinali; jew

(b) fi prodott mediċinali mhux soġġett għal riċetta mediċinali, meta dak il-prodott mediċinali jitqies li jista jinbiegħ jew jiġi fornut b sigurezza raġonevoli minn xi spiżjar jew taħt is-superviżjoni tiegħu sakemm ma jkunx provdut b dan l-Att li prodott mediċinali taħt paragrafu (b) ta subartikolu (1) jiġi klassifikat taħt paragrafu (a) ta subartikolu (1).

(2) L-Awtorità dwar il-Liċenzjar tista b regoli tistabbilixxi t-tip, il-kontenut u l-preżentazzjoni jew xort oħra ta xi riċetta u min ikun awtorizzat li joħroġ dik ir-riċetta li tista tkun meħtieġa għal xi prodott mediċinali jew klassi ta prodotti mediċinali.

Lista ta mediċini li għandhom awtorizzazzjoni ta tqegħid fis-suq.

**30.** (1) L-Awtorità dwar il-Liċenzjar għandha, mill-anqas ta kull sena, tippubblika fil-Gazzetta lista li tispeċifika:

(a) il-prodotti mediċinali li jkollhom awtorizzazzjoni valida ta tqegħid fis-suq;

(b) il-prodotti mediċinali li jistgħu jinbiegħu biss b'riċetta; u

(ċ) meta dan ikun japplika, t-tip ta riċetta meħtieġa u l-persuna jew persuni awtorizzati li joħorġu dik ir-riċetta.

(2) Kull meta tkun inħarġet awtorizzazzjoni ta tqegħid fis-suq dwar xi prodott mediċinali, l-Awtorità dwar il-Liċenzjar għandha tippublika fil-Gazzetta l-informazzjoni speċifikata fis-subartikolu (1)(a), (b) u (ċ) u dik il-pubblikazzjoni għandha titqies li tkun qegħda temenda l-lista ta prodotti mediċinali maħruġa taħt is-subartikolu (1).

(3) L-Awtorità dwar il-Liċenzjar għandha tippublika fil-Gazzetta, malli jkun hekk prattikabbli li jsir, il-lista ta' prodotti mediċinali li dwarhom tkun ġiet sospiża jew revokata l-

awtorizzazzjoni ta tqegħid fis-suq u dik il-pubblikazzjoni għandha titqies li tkun qegħda temenda l-lista ta prodotti mediċinali maħruġa taħt is-subartikolu (1).

Reklamar ta prodotti mediċinali.

**31.** Prodott mediċinali jista biss jiġi reklamat skond dawk il-kondizzjonijiet li jistgħu jiġu stabbiliti b dan l-Att jew taħtu.

Prodotti mediċinali omeopatiċi.

**32.** Id-disposizzjonijiet ta din it-Taqsima għandhom jgħaddu għal prodotti mediċinali omeopatiċi għall-użu tal-bniedem ħlief għal prodotti mediċinali omeopatiċi li:

(a) jiġu amministrati mill-ħalq u esternament, bla ħsara għal dawk ir-regolamenti li jistgħu jsiru mill-Ministru dwarhom;

(b) ma jkollhom ebda indikazzjoni terapewtika speċifika li tidher fuq l-ittikkettjar tal-prodott mediċinali jew f xi informazzjoni li jkollha x taqsam ma dan; u

(ċ) jkollhom grad biżżejjed ta dilwizzjoni biex jiggarantixxi s-sigurezza tal-prodott mediċinali, b mod partikolari, il-prodott mediċinali ma jistax ikun fih jew aktar minn taqsima waħda minn kull 10,000 tat-tintura prinċipali jew aktar minn wieħed minn kull mija ta l-anqas doża li tintuża fl-allopatija għar-rigward ta elementi prinċipali li l-preżenza tagħhom fi prodott mediċinali allopatiku tirriżulta fl-obbligu li tiġi ppreżentata riċetta għall-mediċina.

Prodotti li jinkisbu mid-demm tal-bniedem jew plasma tal-bniedem.

**33.** Id-disposizzjonijiet ta din it-Taqsima għandhom japplikaw għal prodotti mediċinali bbażati fuq kostitwenti tad-demm li jiġu mħejjija industrijalment minn stabbiliment privat jew pubbliku, imma ma għandhomx japplikaw għal demm, plasma jew ċelluli tad-demm li joriġinaw mill-bniedem.

Prodotti mediċinali radjofarmaċewtiċi.

**34.** L-awtorizzazzjoni ta tqegħid fis-suq imsemmija fl-artikolu 20 għandha tkun meħtieġa għal ġeneraturi, apparat, prekursuri ta radjofarmaċewtiċi u radjofarmaċewtiċi ppreparati industrijalment, ħlief għal prodotti radjofarmaċewtiċi li jiġu ppreparati fil-waqt ta l-użu tagħhom minn persuna jew minn stabbiliment awtorizzat, taħt dan l-Att, biex juża dawk il-prodotti mediċinali fi stabbiliment approvat għall-kura tas-saħħa esklużivament minn ġeneraturi, apparat jew prekursuri ta radjofarmaċewtiċi awtorizzati skond l-istruzzjonijiet tal-manifattur.

Prodotti mediċinali immunoloġiċi.

**35.** (1) Id-disposizzjonijiet ta din it-Taqsima għandhom jgħoddu għal prodotti mediċinali immunoloġiċi.

(2) L-Awtorità dwar il-Liċenzjar tista tippreskrivi regoli biex

tirregola l-ħruġ jew xort oħra ta xi awtorizzazzjoni ta tqegħid fis-suq għal prodotti mediċinali immunoloġiċi.

Prodotti mediċinali erbali.

**36.** (1) Id-disposizzjonijiet ta din it-Taqsima għandhom jgħoddu għal prodotti mediċinali erbali minbarra prodotti mediċinali erbali ppreparati skond formola maġistrali jew uffiċjali.

(2) L-Awtorità dwar il-Liċenzjar tista tippreskrivi regoli biex tirregola l-ħruġ jew xort oħra ta xi awtorizzazzjoni ta tqegħid fis-suq għal prodotti mediċinali erbali.

*Titolu II - Manifattura ta Prodotti Mediċinali għall-Użu tal-Bniedem*

Liċenza ta manifattur.

**37.** Mingħajr preġudizzju għal kull eżenzjoni li tista tiġi mogħtija taħt dan l-Att, ħadd ma għandu jimmanifattura, jagħmel assemblaġġ jew b xi mod jibdel xi prodott mediċinali ħlief skond liċenza ta manifattur maħruġa skond id-disposizzjonijiet ta dan l-Att jew regolamenti jew regoli magħmulin taħtu:

Iżda tali liċenza ma għandhiex tkun meħtieġa għall-preparazzjoni, qsim, tibdil fl-ippakkettjar jew fil-preżentazzjoni meta dawn il-proċessi jiġu mwettqa għall-fini ta bejgħ jew amministrazzjoni skond ma hu pprovdut taħt dan l-Att.

Applikazzjoni għal liċenza ta manifattur.

**38.** (1) Applikazzjoni għall-għoti ta liċenza għall-manifattura, assemblaġġ jew tibdil ta prodott mediċinali għandha ssir lill-Awtorità dwar il-Liċenzjar u għandu jkun fiha dik l-informazzjoni, dokumenti, kampjuni u materjal ieħor li jista jkun provdut b dan l-Att jew taħtu:

Iżda dik l-applikazzjoni għandha tindika dan li ġej:

(a) l-isem tal-prodott mediċinali u l-forma jew il-forom farmaċewtiċi, li jkun se jiġi manifatturat, isir l-assemblaġġ tiegħu jew b xi mod isirlu tibdil;

(b) il-post fejn tkun se ssir dik l-attività, u dik l-informazzjoni u dokumentazzjoni li jkunu meħtieġa sabiex jintwera li dak il-post ikun wieħed adatt u suffiċjenti għal dak l-għan;

(ċ) it-tagħmir u l-faċilitajiet ta kontroll li huma meħtieġa b dan l-Att jew taħtu;

(d) l-isem u indirizz ta l-applikant;

(e) l-isem ta mill-inqas persuna kwalifikata waħda li għandha tkun professjonalment responsabbli għall-attività, u dik

il-persuna għandu jkollha l-kwalifiki li jiġu preskritti:

Iżda meta tiġi nominata aktar minn persuna kwalifikata waħda, l-applikazzjoni għandha turi b mod ċar ir-responsabbiltajiet speċifiċi ta kull persuna;

(f) kull informazzjoni, dokumentazzjoni jew prova oħra li tista tintalab mill-Awtorità dwar il-Liċenzjar skond jew taħt dan l-Att.

(2) L-Awtorità dwar il-Liċenzjar għandha tiddeċiedi dwar l-applikazzjoni fil-perjodu ta żmien li jista jiġi stabbilit taħt dan l-Att:

Iżda dan il-perjodu jista' jiġi sospiż sakemm tingħata l-informazzjoni rilevanti.

Għoti ta liċenza ta manifattur.

**39.** (1) L-Awtorità dwar il-Liċenzjar għandha, qabel ma tiddeċiedi dwar applikazzjoni, tispezzjona l-fond indikat fi-applikazzjoni u ma għandhiex toħroġ liċenza kemm-il darba ma tkunx sodisfatta li dak il-fond jkun konformi mal-ħtiġiet stabbiliti b dan l-Att jew taħtu:

Iżda liċenza tista tingħata bil-kondizzjoni li jitwettqu dawk l-obbligi li jistgħu jiġu imposti fiha.

(2) Il-liċenza ta manifattur għandha tispeċifika l-fond u l-prodotti mediċinali u l-forma jew forom farmaċewtiċi li għalihom tirreferi.

(3) Id-detentur ta liċenza għandu jiżgura li l-attività tiġi mwettqa skond id-disposizzjonijiet ta dan l-Att u ta regolamenti magħmulin taħtu.

Avviż dwar informazzjoni ulterjuri.

**40.** Meta l-Awtorità dwar il-Liċenzjar jidhrilha li jistgħu jeżistu ċirkostanzi li jirrendu meħtieġa l-konsiderazzjoni ta jekk għandhiex tiġi mibdula, sospiża jew revokata l-liċenza, l-Awtorità dwar il-Liċenzjar tista tinnotifika lid-detentur ta liċenza ta manifattur avviż li jkun jeħtieġu biex, fi żmien li jista jiġi speċifikat fl-avviż, jipprovdiha b kull informazzjoni speċifikata fl-avviż.

Sospensjoni jew revoka ta liċenza ta manifattur.

**41.** (1) L-Awtorità dwar il-Liċenzjar tista tissospendi liċenza ta manifattur taħt dan l-Att għal dak il-perjodu li tista tistabbilixxi, jew tista tirrevoka, jew tibdel id-disposizzjonijiet ta xi tali liċenza.

(2) Il-poteri vestiti fis-subartikolu (1) għandhom jiġu biss eżerċitati f xi ċirkostanzi minn dawn li ġejjin:

(a) meta l-ħwejjeġ dikjarati fl-applikazzjoni li abbażi tagħha tkun ingħatat il-liċenza kienu foloz jew inkompleti f xi dettal partikolari;

(b) meta jkun ġara bdil materjali ta ċirkostanzi dwar xi ħaġa minn dawk il-ħwejjeġ;

(ċ) meta tkun inkisret xi kondizzjoni tal-liċenza;

(d) meta ma jkunux tħarsu l-ħtiġiet dwar il-liċenzi kif stabbiliti b dan l-Att jew taħtu;

(e) meta l-proċessi ta manifattura jew assemblaġġ ta xi prodott mediċinali jitwettqu b mod mhux konformi mad-disposizzjonijiet ta l-awtorizzazzjoni ta tqegħid fis-suq ta dak il-prodott mediċinali;

(f) ma jkunux qegħdin jitħarsu l-kondizzjonijiet dwar prattika ta manifattura kif dovuta; u

(g) f xi ċirkostanza oħra li tista tiġi stabbilita b dan l-Att jew taħtu.

Spezzjoni fir-rigward ta manifattur, eċċ.

**42.** (1) L-Awtorità dwar il-Liċenzjar għandha twettaq spezzjonijiet regolari biex tiżgura li jiġu mħarsa l-ħtiġiet stabbiliti b dan l-Att jew taħtu dwar il-manifattura, l-assemblaġġ jew il-modifikazzjoni ta xi prodott mediċinali.

(2) L-Awtorità dwar il-Liċenzjar jew persuna li tkun qed tagħmel spezzjoni għandha:

(a) tispezzjona l-istabbiliment ta manifattura u kull post ieħor skond ma jista jkun meħtieġ;

(b) teżamina kull dokument rilevanti;

(ċ) tieħu kampjuni skond ma jista jkun meħtieġ;

(d) tabbozza rapport tar-riżultanzi, u tikkomunika l-kontenut ta dak ir- rapport lid-detentur ta liċenza jew lil applikant għal liċenza dwar dak l-ispezzjoni u lil-persuna kwalifikata;

(e) twettaq kull attività oħra li tista tqis li tkun adatta għall-eżekuzzjoni ta dmirijietha u r-responsabbiltajiet tagħha kif imiss u kif provdut b dan l-Att jew taħtu.

(3) Hlief f'każijiet urġenti, kull spezzjoni għandha tiġi

mwettqa fil-preżenza ta persuna kwalifikata jew ir-rappreżentant tiegħu, jekk ikun hemm.

Għal kemm żmien iddum u tiġdid ta liċenza ta manifattur.

**43.** (1) Bla ħsara għad-disposizzjonijiet ta dan l-Att, kull liċenza mogħtija taħt din it-Taqsima għandha, kemm-il darba ma tkunx ġiet qabel imġedda jew revokata, tiskadi fi tmiem il-validità tagħha.

(2) Kull liċenza hekk mogħtija għandha, kemm-il darba ma tkunx ġiet revokata qabel, tiġġedded billi ssir applikazzjoni mid-detentur ta liċenza mill-anqas tliet xhur qabel l-iskadenza tal-perjodu ta validità.

(3) L-Awtorità dwar il-Liċenzjar tista b regoli tistabbilixxi l-perjodu ta validità ta liċenza maħruġa taħt din it-Taqsima.

(4) Meta ssir applikazzjoni lill-Awtorità dwar il-Liċenzjar għat-tiġdid ta liċenza taħt din it-Taqsima, l-Awtorità dwar il-Liċenzjar:

(a) tista ġġedded il-liċenza, kemm b modifikazzjonijiet kemm mingħajrhom, għal dak il-perjodu ulterjuri li jista jkun speċifikat; jew

(b) jekk, wara li tqis id-disposizzjonijiet ta dan l-Att, tqis li jkun meħtieġ jew spedjenti li hekk isir, tista tirrifjuta li ġġedded il-liċenza.

(5) Id-disposizzjonijiet ta' l-artikoli 25, 39 u 40 għandhom jgħoddu għal applikazzjonijiet bħal dawn.

Responsabbil-tajiet ta detentur ta liċenza ta manifattur.

**44.** Ikun id-dmir ta detentur ta liċenza ta manifattur -

(a) li minnufih jinforma lill-Awtorità dwar il-Liċenzjar dwar kull tibdil tal-persuna kwalifikata;

(b) li jipprovdi lil uffiċjali awtorizzati b aċċess għall-fond tiegħu f kull ħin raġonevoli;

(ċ) li jagħmel possibbli li l-persuna kwalifikata tkun tista taqdi dmirijietha kif stabbilit minn jew taħt dan l-Att;

(d) li jżomm dawk ir-*records* għal kull operazzjoni li ssir fi prodotti mediċinali bħalma jista jiġi stabbilit b dan l-Att jew taħtu u jara li dawk ir-*records* ikunu disponibbli għall-ispezzjon minn kull uffiċjal awtorizzat għal dak il-perjodu ta żmien skond ma jkun jenħtieġ b dan l-Att jew taħtu;

(e) li jkollu għad-disposizzjoni tiegħu s-servizzi ta impjegati sabiex jissodisfa il-ħtiġiet stabbiliti minn jew taħt dan l-Att rigward manifattura, *assembly* jew modifikazzjoni ta prodotti mediċinali;

(f) li japplika lill-Awtorità dwar il-Liċenzjar dwar kull tibdil propost jew modifikazzjoni rigward il-liċenza;

(g) illi josserva r-regolamenti jew Ordnijiet dwar il-prattika tajba ta manifattura stabbiliti minn jew taħt dan l-Att jew taħt xi ligi oħra;

(h) li jiddisponi minn prodotti mediċinali kif stabbilit minn jew taħt dan l-Att jew taħt xi liġi oħra;

(i) responsabbiltajiet oħra li jistgħu jkunu stabbiliti minn żmien għal żmien minn jew taħt dan l-Att.

Responsabbiltajiet tal-persuna kwalifikata.

**45.** (1) Ir-responsabbiltajiet ta persuna kwalifikata jkunu:

(a) li tiżgura li *standards* ta prattika tajba fil-manifattura jiġu mħarsa f kull waqt;

(b) li tiżgura li kull lott ta' prodotti mediċinali jkun ġie manifatturat, ittestjat u jkun konformi f kull rigward ma kull ħtieġa stabbilita b dan l-Att jew taħtu; u

(ċ) li tiżgura li kull lott ta' prodotti mediċinali jkun ġie manifatturat skond il-ħtiġiet ta l-awtorizzazzjoni ta tqegħid fis-suq.

(2) Il-persuna kwalifikata għandha tkun preżenti fil-fond f kull waqt meta tkun qegħda ssir l-attività:

Iżda l-persuna kwalifikata tista tinnomina persuna li tkun kwalifikata bħalha biex taġixxi bħala r-rappreżentant tagħha.

(3) Meta l-persuna kwalifikata tkun innominat rappreżentant kif hawn qabel imsemmi, hi għandha minnufih tinforma lill-Awtorità dwar il-Liċenzjar b dik in-nomina.

Sospensjoni ta attività ta persuna kwalifikata.

**46.** L-Awtorità dwar il-Liċenzjar, tista jekk ikollha suspett raġonevoli li xi persuna kwalifikata tkun qed taġixxi bi ksur ta xi disposizzjoni ta dan l-Att, tissospendi l-attività ta dik il-persuna kwalifikata b'avviż bil-miktub fejn tispeċifika r-raġunijiet għal dik is-sospensjoni sakemm dik il-persuna tkun irrimedjat kull nuqqas li ġie indikat lilha mill-Awtorità dwar il-Liċenzjar.

Bdil fil-kondizzjonijiet ta liċenza ta manifattur.

**47.** L-Awtorità dwar il-Liċenzjar tista , wara li ssir applikazzjoni mid-detentur ta' liċenza għal hekk, tibdel il-kondizzjonijiet tal-liċenza jekk din tkun sodisfatta li dik il-varjazzjoni ma tkunx se tolqot avversment *standards* ta prattika tajba fil-manifattura skond kif jista jiġi preskritt.

Obbligi ta l-Awtorità dwar il-Liċenzjar.

**48.** L-Awtorità dwar il-Liċenzjar tista' tvarja, tissospendi, tirrevoka jew tirrifjuta milli ġġedded liċenza ta manifattur, jew tista' tgħaddi l-kwistjoni lill-Awtorità dwar il-Mediċini u f'kull każ bħal dan għandhom jgħoddu, *mutatis mutandis*, id-disposizzjonijiet ta' l-artikolu 20(4), (5) u (6) u ta' l-artikolu 21.

Manifattura ta prodotti mediċinali omeopatiċi.

**49.** Mingħajr preġudizzju għall-artikolu 32, id-disposizzjonijiet ta l-artikoli 37 sa 48 għandhom jgħoddu għall-manifattura u l-assemblaġġ ta prodotti mediċinali omeopatiċi, minbarra l-prodotti elenkati fl-artikolu 32(a), (b) u (ċ).

Manifattura ta prodotti mediċinali li jinkisbu mid-demm tal-bniedem u plasma tal-bniedem, eċċ.

**50.** Mingħajr preġudizzju għall-artikolu 33, id-disposizzjonijiet ta l-artikoli 37 sa 48 u ta regolamenti magħmulin taħthom għandhom jgħoddu għall-manifattura u l-assemblaġġ ta prodotti mediċinali li jinkisbu mid-demm tal-bniedem u plasma tal-bniedem, minbarra l-prodotti elenkati fl-artikolu 32(a), (b) u (ċ).

Manifattura ta radjofarmaċewtiċi.

**51.** Mingħajr preġudizzju għall-artikolu 34, id-disposizzjonijiet ta l-artikoli 37 sa 48 u ta regolamenti magħmulin taħthom għandhom jgħoddu għall-manifattura u l-assemblaġġ ta prodotti radjofarmaċewtiċi, minbarra l-prodotti elenkati fl-artikolu 32(a), (b) u (ċ).

Prodotti mediċinali immunoloġiċi.

**52.** Mingħajr preġudizzju għall-artikolu 35, id-disposizzjonijiet ta l-artikoli 37 sa 48 u ta regolamenti magħmulin taħthom għandhom jgħoddu għall-manifattura u l-assemblaġġ ta prodotti mediċinali immunoloġiċi, minbarra l-prodotti elenkati fl-artikolu 32(a), (b) u (ċ).

Prodotti mediċinali erbali.

**53.** Mingħajr preġudizzju għall-artikolu 36**,** id-disposizzjonijiet ta l-artikoli 37 sa 48 u ta regolamenti magħmulin taħthom għandhom jgħoddu għall-manifattura u l-assemblaġġta prodotti mediċinali erbali, minbarra l-prodotti elenkati fl-artikolu 32(a), (b) u (ċ).

*Titolu III - Distribuzzjoni bl-Ingrossa ta Prodotti Mediċinali għall-Użu tal-Bniedem*

Negozju bl-ingrossa.

**54.** (1) Mingħajr preġudizzju għal kull eżenzjoni li tista tkun mogħtija b dan l-Att jew taħtu, ħadd ma għandu jħaddem negozju bl-ingrossa f'xi prodott mediċinali ħlief jekk ikun id-detentur ta' liċenza ta negozjant bl-ingrossa maħruġa skond id-disposizzjonijiet ta dan l-Att u ħlief jekk il-prodott mediċinali jkun

ingħata awtorizzazzjoni ta tqegħid fis-suq mill-Awtorità dwar il-Liċenzjar.

(2) Id-distribuzzjoni bl-ingrossa ta prodott mediċinali permezz ta negozju bl-ingrossa għandha ssir biss mill-post speċifikat fil-liċenza u skond il-kondizzjonijiet ta l-istess liċenza.

Applikazzjoni għal liċenza ta negozjant bl-ingrossa.

**55.** (1) Applikazzjoni għall-għoti ta liċenza ta' negozjant bl-ingrossa għandha ssir lill-Awtorità dwar il-Liċenzjar u għandu jkun fiha dik l-informazzjoni, dokumenti, kampjuni u materjal ieħor li jista jkun provdut b dan l-Att jew taħtu:

Iżda dik l-applikazzjoni għandha tindika dan li ġej:

(a) l-isem u indirizz ta l-applikant;

(b) l-indirizz tal-post li se jintuża għall-għanijiet tad-distribuzzjoni bl-ingrossa;

(ċ) it-tagħmir u l-faċilitajiet ta kontroll li huma meħtieġa b dan l-Att jew taħtu;

(d) l-informazzjoni, d-dokumentazzjoni u l-prova biex jiġi ppruvat li l-post hu adatt u adegwat, u li hemm faċilitajiet, installazzjonijiet u tagħmir adatti, biex tiġi żgurata l-konservazzjoni u d-distribuzzjoni xierqa ta' prodotti mediċinali;

(e) l-isem ta mill-anqas persuna waħda responsabbli jew kwalifikata li għandha tkun professjonalment responsabbli għall-attività, u dik il-persuna għandu jkollha l-kwalifiki li jiġu perskritti:

Iżda meta tiġi nominata aktar minn persuna responsabbli jew kwalifikata waħda, l-applikazzjoni għandha turi b mod ċar ir-responsabbiltajiet speċifiċi ta kull persuna;

(f) kull informazzjoni, dokumentazzjoni jew prova oħra li tista tintalab mill-Awtorità dwar il-Liċenzjar skond jew taħt dan l-Att.

(2) L-Awtorità dwar il-Liċenzjar għandha tiddeċiedi dwar l-applikazzjoni fil-perjodu ta żmien li jista jiġi stabbilit taħt dan l-Att:

Iżda dan il-perjodu jista' jiġi sospiż sakemm tingħata l-informazzjoni rilevanti.

Għoti ta liċenza ta negozjant bl-ingrossa.

**56.** (1) L-Awtorità dwar il-Liċenzjar għandha, qabel ma tiddeċiedi dwar applikazzjoni, tispezzjona l-fond indikat fi-

applikazzjoni u ma għandhiex toħroġ liċenza kemm-il darba ma tkunx sodisfatta li dak il-fond jkun konformi mal-ħtiġiet stabbiliti b dan l-Att jew taħtu:

Iżda liċenza tista tingħata bil-kondizzjoni li jitwettqu dawk l-obbligi li jistgħu jiġu imposti fiha.

(2) Il-liċenza ta negozjant bl-ingrossa għandha tispeċifika l-fond u l-attivitajiet li għalihom tirreferi.

(3) Id-detentur ta liċenza għandu jiżgura li l-attività tiġi mwettqa skond id-disposizzjonijiet ta dan l-Att u ta regolamenti magħmulin taħtu.

Avviż dwar informazzjoni ulterjuri.

**57.** Meta l-Awtorità dwar il-Liċenzjar jidhrilha li jistgħu jeżistu ċirkostanzi li jirrendu meħtieġa l-konsiderazzjoni ta jekk għandhiex tiġi mibdula, sospiża jew revokata l-liċenza, l-Awtorità dwar il-Liċenzjar tista tinnotifika lid-detentur ta liċenza ta negozjant bl-ingrossa avviż li jkun jeħtieġu biex, fi żmien li jista jiġi speċifikat fl-avviż, jipprovdiha b kull informazzjoni speċifikata fl-avviż.

Għal kemm żmien iddum u tiġdid ta liċenza ta negozjant bl-ingrossa.

**58.** (1) Bla ħsara għad-disposizzjonijiet ta dan l-Att, kull liċenza mogħtija taħt din it-Taqsima għandha, kemm-il darba ma tkunx ġiet qabel imġedda jew revokata, tiskadi fi tmiem il-validità tagħha.

(2) Kull liċenza hekk mogħtija għandha, kemm-il darba ma tkunx ġiet revokata qabel, tiġġedded billi ssir applikazzjoni mid-detentur ta liċenza mill-anqas tliet xhur qabel l-iskadenza tal-perjodu ta validità.

(3) L-Awtorità dwar il-Liċenzjar tista b regoli tistabbilixxi l-perjodu ta validità ta liċenza maħruġa taħt din it-Taqsima.

(4) Meta ssir applikazzjoni lill-Awtorità dwar il-Liċenzjar għat-tiġdid ta liċenza taħt din it-Taqsima, l-Awtorità dwar il-Liċenzjar:

(a) tista ġġedded il-liċenza, kemm b modifikazzjonijiet kemm mingħajrhom, għal dak il-perjodu ulterjuri li jista jkun speċifikat; jew

(b) jekk, wara li tqis id-disposizzjonijiet ta dan l-Att, tqis li jkun meħtieġ jew spedjenti li hekk isir, tista tirrifjuta li ġġedded il-liċenza.

(5) Id-disposizzjonijiet ta' l-artikoli 25, 39 u 40 għandhom

jgħoddu għal applikazzjonijiet bħal dawn.

Obbligi ta detentur ta liċenza ta negozjant bl-ingrossa.

**59.** Ikun id-dmir ta detentur ta liċenza ta negozjant bl-ingrossa -

(a) li minnufih jinforma lill-Awtorità dwar il-Liċenzjar dwar kull tibdil tal-persuna kwalifikata jew responsabbli;

(b) li jipprovdi lil uffiċjali awtorizzati b aċċess għall-fond tiegħu f kull ħin raġonevoli;

(ċ) li jagħmel possibbli li l-Awtorità dwar il-Liċenzjar tkun tista taqdi dmirijietha kif stabbiliti b dan l-Att jew taħtu;

(d) li jżomm dawk ir-*records* għal kull operazzjoni li ssir fi prodotti mediċinali bħalma jista jiġi stabbilit b dan l-Att jew taħtu u jara li dawk ir-*records* ikunu disponibbli għall-ispezzjon minn kull uffiċjal awtorizzat għal dak il-perjodu ta żmien skond ma jkun jenħtieġ b dan l-Att jew taħtu.

Ir-responsabbiltà li għandhom il-persuni responsabbli.

**60.** (1) Il-persuna responsabbli għandha tiżgura li jiġu mħarsa f kull waqt *standards* ta prattika tajba fid-distribuzzjoni bl-ingrossa skond kif jista jiġi preskritt.

(2) Il-persuna kwalifikata jew responsabbli għandha tkun preżenti fil-fond f kull waqt meta tkun qiegħda ssir l-attività liċenzjata:

Iżda l-persuna kwalifikata jew responsabbli tista tinnomina persuna oħra biex taġixxi bħala r-rappreżentant tagħha.

(3) Meta l-persuna kwalifikata jew responsabbli tkun innominat rappreżentant kif hawn qabel imsemmi, hi għandha minnufih tinforma lill-Awtorità dwar il-Liċenzjar b dik in-nomina.

Sospensjoni jew revoka ta liċenza ta negozjant bl-ingrossa.

**61.** L-Awtorità dwar il-Liċenzjar tista tissospendi il-liċenza ta negozjant bl-ingrossa mogħtija taħt dan l-Att għal dak l- perjodu li din tista tistabbilixxi, jew tista tirrevoka, jew tibdel id-disposizzjonijiet ta xi liċenza bħal dik f'kull wieħed mill-każijiet li ġejjin:

(a) meta l-ħwejjeġ dikjarati fl-applikazzjoni li abbażi tagħha tkun inħarġet il-liċenza kienu foloz jew inkompleti f xi materjal partikolari;

(b) meta jkun hemm bdil materjali ta ċirkostanzi dwar xi ħaġa minn dawk;

(ċ) meta tkun inkisret xi kondizzjoni tal-liċenza;

(d) meta ma jkunux tħarsu l-ħtiġiet dwar il-liċenza kif stabbiliti b dan l-Att jew taħtu;

(e) meta ma jkunux qegħdin jitħarsu l-kondizzjonijiet ta prattika tajba dwar id-distribuzzjoni bl-ingrossa; u

(f) f kull ċirkostanza oħra li tista tiġi stabbilita b dan l-Att jew taħtu.

Bdil fil-kondizzjonijiet ta liċenza ta negozjant bl-ingrossa.

**62.** L-Awtorità dwar il-Liċenzjar tista , wara li ssir applikazzjoni mid-detentur ta' liċenza għal hekk, tibdel il-kondizzjonijiet tal-liċenza jekk din tkun sodisfatta li dik il-varjazzjoni ma tkunx se tolqot avversment standards ta prattika tajba fid-distribuzzjoni bl-ingrossa.

Obbligi ta l-Awtorità dwar il-Liċenzjar.

**63.** L-Awtorità dwar il-Liċenzjar tista' tvarja, tissospendi, tirrevoka jew tirrifjuta milli ġġedded liċenza ta negozjant bl-ingrossa, jew tista' tgħaddi l-kwistjoni lill-Awtorità dwar il-Mediċini u f'kull każ bħal dan għandhom jgħoddu, mutatis mutandis, id-disposizzjonijiet ta' l-artikolu 20(4), (5) u (6) u ta' l-artikolu 21.

Spezzjonar dwar bejgħ bl-ingrossa.

**64.** (1) L-Awtorità dwar il-Liċenzjar għandha tiżgura li jiġu mħarsa l-ħtiġiet stabbiliti b dan l-Att jew taħtu dwar in-negozju bl-ingrossa ta xi prodott mediċinali.

(2) L-Awtorità dwar il-Liċenzjar għandha:

(a) tispezzjona l-istabbiliment tan-negozju bl-ingrossa u kull imkien ieħor li tista tqies li jkun meħtieġ;

(b) teżamina kull dokument li jirrigwarda l-ispezzjon;

(ċ) tieħu kull kampjun li tista tqies li jkun meħtieġ;

(d) tagħmel rapport dwar ir-riżultanzi, li għandu jitwassal kemm lid-detentur ta liċenza jew lill-applikant għal liċenza dwar dik l-ispezzjon kemm lill-persuna responsabbli;

(e) tagħmel kull attività oħra li tista titqies adatta għall-eżekuzzjoni ta dmirijietha u r-responsabbiltajiet tagħha kif imiss u kif provdut b dan l-Att jew taħtu.

Disposizzjonijiet speċjali.

**65.** Mingħajr preġudizzju għad-disposizzjonijiet ta din it-Taqsima, l-Awtorità dwar il-Liċenzjar tista b regoli tistabbilixxi ħtiġiet addizzjonali għad-distribuzzjoni bl-ingrossa ta :

(a) sustanzi narkotiċi jew psikotropiċi;

(b) prodotti mediċinali li jinkisbu mid-demm;

(ċ) prodotti mediċinali immunoloġiċi;

(d) radjofarmaċewtiċi;

(e) dawk il-prodotti mediċinali l-oħra jew klassi jew klassijiet ta prodotti mediċinali li l-Ministru jista jordna.

*Titolu IV - Spiżeriji u Attività Farmaċewtika relatata*

Liċenza biex tinfetaħ spiżerija.

**66.** (1) Ħadd ma jista jiftaħ jew iżomm spiżerija kemm-il darba ma jkollux liċenza ta spiżerija maħruġa skond id-disposizzjonijiet ta dan l-Att jew regolamenti magħmulin taħtu.

(2) Liċenzi ta spiżeriji għandhom jinħarġu skond kriterji ġeo-demografiċi stabbiliti permezz ta regolamenti taħt dan l-Att.

(3) Regolamenti taħt dan l-artikolu m għandhomx isiru kemm-il darba l-Ministru ma jkunx qabel ippubblika l-abbozz tagħhom fil-Gazzetta tal-Gvern fejn jippermetti lil kull persuna perjodu ta mill-anqas erba ġimgħat biex tagħmel rappreżentazzjoni bil-miktub lill-Ministru.

(4) Il-Ministru għandu jitlob lill-Awtorità tal-Liċenzjar sabiex tagħmel rapport dwar ir-rappreżentazzjonijiet imsemmija fis-subartikolu preċedenti wara li tisma lil dawk il-persuni jew tieħu dak il-parir espert li tikkonsidra spedjenti, flimkien ma kull opinjoni oħra li jista jkollha dwar l-abbozz ippubblikat taħt is-subartikolu (2), u l-Ministru jista meta jirċievi r-rapport mingħand l-Awtorità jipproċedi biex jirrevedi l-abbozz tar-regolamenti u jippromulga dawk ir-regolamenti skond dik ir-reviżjoni.

(5) Mingħajr preġudizzju għal kull eżenzjoni li tista tkun mogħtija b dan l-Att jew taħtu, ħadd ma għandu jbiegħ bl-imnut xi prodott mediċinali ħlief skond liċenza ta spiżerija maħruġa skond id-disposizzjonijiet ta dan l-Att jew regolamenti jew xi regoli magħmulin taħtu.

(6) Id-detentur ta liċenza jkun responsabbli biex iħares il-kondizzjonijiet tal-liċenza li jistgħu jiġu stabbiliti b dan l-Att jew taħtu.

Applikazzjoni għal liċenza ta spiżerija.

**67.** (1) Applikazzjoni għall-għoti ta liċenza ta' spiżerija għandha ssir lill-Awtorità dwar il-Liċenzjar u għandu jkun fiha dik l-informazzjoni, dokumenti, kampjuni u materjal ieħor li jista jkun provdut b dan l-Att jew taħtu:

Iżda dik l-applikazzjoni għandha tindika dan li ġej:

(a) l-isem u indirizz ta l-applikant;

(b) l-indirizz tal-fond li għandu jintuża għall-fini tal-bejgħ bl-imnut ta prodotti mediċinali;

(ċ) it-tagħmir u l-faċilitajiet ta kontroll li huma meħtieġa b dan l-Att jew taħtu;

(d) l-informazzjoni, id-dokumentazzjoni u l-prova biex jiġi ppruvat li l-post hu adatt u adegwat, u li hemm faċilitajiet, installazzjonijiet u tagħmir adatti, biex tiġi żgurata l-konservazzjoni u dispensa ta prodotti mediċinali;

(e) l-isem ta spiżjar responsabbli li għandu jkun professjonalment responsabbli għall-attivitajiet kollha;

(f) kull informazzjoni, dokumentazzjoni jew prova oħra li tista tintalab mill-Awtorità dwar il-Liċenzjar skond jew taħt dan l-Att.

(2) L-Awtorità dwar il-Liċenzjar għandha tiddeċiedi dwar l-applikazzjoni fil-perjodu ta żmien li jista jiġi stabbilit taħt dan l-Att:

Iżda dan il-perjodu jista' jiġi sospiż sakemm tingħata l-informazzjoni rilevanti.

Għoti ta liċenza ta spiżerija.

**68.** (1) L-Awtorità dwar il-Liċenzjar għandha, qabel ma tiddeċiedi dwar applikazzjoni, tispezzjona l-fond indikat fi-applikazzjoni u ma għandhiex toħroġ liċenza kemm-il darba ma tkunx sodisfatta li dak il-fond jkun konformi mal-ħtiġiet stabbiliti b dan l-Att jew taħtu:

Iżda liċenza tista tingħata bil-kondizzjoni li jitwettqu dawk l-obbligi li jistgħu jiġu imposti fiha.

(2) Il-liċenza ta spiżerija għandha tispeċifika l-fond u l-attivitajiet li għalihom tirreferi:

Iżda l-Awtorità dwar il-Liċenzjar tista , meta ssirilha applikazzjoni, tagħti liċenza addizzjonali għall-użu ta xi fond identifikat li jkun se jintuża bħala maħżen għall-finijiet ta l-ispiżerija u wara li tkun sodisfatta li dak il- fond ikun konformi mal-ħtiġiet stabbiliti b dan l-Att jew taħtu.

Avviż dwar informazzjoni ulterjuri.

**69.** Meta l-Awtorità dwar il-Liċenzjar jidhrilha li jistgħu jeżistu ċirkostanzi li jirrendu meħtieġa l-konsiderazzjoni ta jekk għandhiex tiġi mibdula, sospiża jew revokata l-liċenza, l-Awtorità dwar il-Liċenzjar tista tinnotifika lid-detentur ta liċenza ta spiżerija

b avviż biex, fi żmien li jista jiġi speċifikat fl-avviż, jipprovdiha b kull informazzjoni speċifikata fl-avviż.

Għal kemm żmien iddum u tiġdid ta liċenza ta spiżerija.

**70.** (1) Bla ħsara għad-disposizzjonijiet ta dan l-Att, kull liċenza mogħtija taħt din it-Taqsima għandha, kemm-il darba ma tkunx ġiet qabel imġedda jew revokata, tiskadi fi tmiem il-validità tagħha.

(2) Kull liċenza hekk mogħtija għandha, kemm-il darba ma tkunx ġiet revokata qabel, tiġġedded billi ssir applikazzjoni mid-detentur ta liċenza mill-anqas tliet xhur qabel l-iskadenza tal-perjodu ta validità.

(3) L-Awtorità dwar il-Liċenzjar tista b regoli tistabbilixxi l-perjodu ta validità ta liċenza maħruġa taħt din it-Taqsima.

(4) Meta ssir applikazzjoni lill-Awtorità dwar il-Liċenzjar għat-tiġdid ta liċenza taħt din it-Taqsima, l-Awtorità dwar il-Liċenzjar:

(a) għandha ġġedded il-liċenza, kemm b modifikazzjonijiet kemm mingħajrhom, għal dak il-perjodu ulterjuri li jista jkun speċifikat; jew

(b) jekk, wara li tqis id-disposizzjonijiet ta dan l-Att, tqis li jkun meħtieġ jew spedjenti li hekk isir, tista tirrifjuta li ġġedded il-liċenza.

(5) Id-disposizzjonijiet ta l-artikoli 25 u 39 għandhom jgħoddu għal applikazzjonijiet bħal dawn.

Trasferiment ta liċenza ta spiżerija.

**71.** Hadd ma jista jittrasferixxi liċenza kemm-il darba ma jkunx awtorizzat mill-Awtorità dwar il-Liċenzjar, liema awtorizzazzjoni ma tingħatax jekk l-Awtorità dwar il-Liċenzjar ma tkunx sodisfatta li d-detentur ġdid tal-liċenza jkun ħares kull ħtieġa stabbilita b dan l-Att jew taħtu u sakemm ma jitħallas id-dritt preskritt.

Sospensjoni jew revoka ta liċenza ta spiżerija.

**72.** L-Awtorità dwar il-Liċenzjar tista tissospendi liċenza ta spiżerija mogħtija taħt dan l-Att għal dak il-perjodu li tista tistabbilixxi jew tista tirrevoka, jew tibdel id-disposizzjonijiet ta xi tali liċenza f'kull wieħed mill-każijiet li ġejjin:

(a) meta xi ħaġa li tingħad fl-applikazzjoni li l-liċenza tkun ġiet maħruġa abbażi tagħha tkun falza jew inkompleta;

(b) meta kien hemm bdil materjali ta' ċirkostanzi dwar xi ħaġa minn dawk;

(ċ) meta jkunu inkisru d-disposizzjonijiet tal-liċenza mid-detentur ta liċenza; jew

(d) f'kull ċirkostanza oħra li tista tiġi stabbilita b dan l-Att jew taħtu:

Iżda meta tagħmel dan l-Awtorità tal-Liċenzjar għandha tinnotifika lid-detentur ta liċenza bid-deċiżjoni tagħha u tagħti r-raġunijiet dettaljati li fuqhom tkun motivata dik id-deċiżjoni.

Għeluq temporanju ta spiżerija.

**73.** (1) Id-detentur ta liċenza ta xi spiżerija ma għandux jagħlaq spiżerija, temporanjament jew xort oħra, kemm-il darba ma jkunx ta mill-anqas erbgħa w għoxrin siegħa avviż lil, u dak l-għeluq ikun ġie hekk awtorizzat minn, l- Awtorità dwar il-Liċenzjar:

Iżda dak l-għeluq temporanju ma għandux jinfitiehem bħala li jinkludi l-għeluq ta spiżerija kif jirriżulta mill-assenza mhux prevista jew mistennija ta xi spiżjar, forza maġġuri li tirriżulta f li l-fond ma jkunx jista jinfetaħ, jew l-għeluq barra mill-ħinijiet tan-negozju stabbiliti għall-ispiżeriji b regoli magħmulin mill-Awtorità dwar il-Liċenzjar.

(2) Bla ħsara għad-disposizzjonijiet tas-subartikolu (1), il-liċenza ta spiżerija li tkun baqgħet magħluqa għal perjodu ta ħamest ijiem konsekuttivi mingħajr l-awtorizzazzjoni ta l-Awtorità dwar il-Liċenzjar, għandha titqies li tkun ġiet awtomatikament revokata.

(3) L-Awtorità dwar il-Liċenzjar tista , meta tirċievi xi avviż kif hemm imsemmi fis-subartikolu (1), jew meta ssir taf li spiżerija tkun inżammet magħluqa, tissiġilla l-prodotti mediċinali kollha, kull fejn dawn ikunu qed jinżammu mid-detentur ta liċenza skond id-disposizzjonijiet ta dan l-Att, u televa kull reġistru meħtieġ li jinżamm mid-detentur ta liċenza skond il-liġi jew xi liġi oħra.

Obbligi ta detentur ta liċenza ta spiżerija.

**74.** Detentur ta liċenza ta spiżerija għandu -

(a) minnufih jinforma lill-Awtorità dwar il-Liċenzjar dwar kull tibdil ta' l- ispiżjar responsabbli qabel ma ssir dik il-bidla;

(b) jipprovdi lil uffiċjali awtorizzati b aċċess għall-fond tiegħu f kull ħin raġonevoli;

(ċ) jagħmel possibbli li l-Awtorità dwar il-Liċenzjar tkun tista taqdi dmirijietha kif stabbiliti b dan l-Att jew taħtu;

(d) jżomm dawk ir-*records* għal kull operazzjoni li ssir fi prodotti mediċinali bħalma jista jiġi stabbilit b dan l-Att jew

taħtu u jara li dawk ir-*records* ikunu disponibbli għall-ispezzjon minn kull uffiċjal awtorizzat għal dak il-perjodu ta żmien skond ma jkun jenħtieġ b dan l-Att jew taħtu;

(e) jħares kull regolament jew Ordnijiet li jkunu jirrigwardaw kull prattika stabbilita fil-bejgħ bl-imnut ta prodotti mediċinali li tista tiġi stabbilita minn jew taħt dan l-Att;

(f) jiddisponi minn prodotti mediċinali kif stabbilit minn jew taħt dan l-Att jew taħt xi liġi oħra;

(g) responsabbilitajiet oħra li jistgħu jiġu stabbiliti minn żmien għal żmien minn jew taħt dan l-Att.

Spiżjar responsabbli.

**75.** (1) Kull spiżerija għandha tkun maniġġata minn spiżjar hawn iżjed il quddiem imsejjaħ "spiżjar responsabbli".

(2) L-ispiżjar responsabbli għandu:

(a) jaġixxi bħala l-ispiżjar responsabbli ta spiżerija li jkollha liċenza inkluż kull fond ieħor użat bħala maħżen mill-imsemmija spiżerija skond l-artikolu 68(2);

(b) jiżgura li jew hu jew spiżjar ieħor ibigħ jew jissorvelja l-bejgħ ta prodotti mediċinali fl-ispiżerija u jżomm *records* ta l-ispiżjar li kien preżenti fl-ispiżerija matul il-ħin li din damet miftuħa;

(ċ) jżomm kull dokument, informazzjoni jew prova bil-mod skond ma jkun meħtieġ li jinżamm b dan l-Att jew taħtu;

(d) jaqdi daw l-obbligi relatati ma spiżjar responsabbli skond ma jistgħu jiġu stabbiliti b dan l-Att jew taħtu;

(e) jinnomina spiżjar responsabbli sostitut meta ma jkunx jista jwettaq dmirijietu għal perjodu ta ħamest ijiem jew aktar konsekuttivi u javża lill-Awtorità dwar il-Liċenzjar b tali sostituzzjoni:

Iżda f każijiet eċċezjonali d-detentur ta liċenza jista' jinnomina sostitut u javża b dan lill-Awtorità dwar il-Liċenzjar;

(f) jħares kull regolament jew regola li tkun tirrigwarda kull prattika kif imiss fid-dispensa ta prodotti mediċinali li tista tiġi stabbilita minn jew taħt dan l-Att;

(g) jiddisponi minn prodotti mediċinali kif stabbilit b dan l-Att jew taħtu jew b xi liġi oħra.

(3) Ebda spiżjar ma jista , mingħajr l-awtorità bil-miktub ta l-Awtorità dwar il-Liċenzjar, jagħmilha ta spiżjar responsabbli ta żewġ spiżeriji jew aktar:

Iżda l-Awtorità dwar il-Liċenzjar ma għandhiex tagħti dik l- awtorità kemm-il darba ma tkunx sodisfatta li dak l-ispiżjar jkun jista raġonevolment iwettaq id-dmirijiet ta spiżjar responsabbli għal aktar minn spiżerija waħda.

(4) Ebda spiżjar ma għandu jibda jaqdi jew jabbanduna dmirijietu bħala spiżjar responsabbli ta spiżerija mingħajr ma qabel jagħti avviż bil-miktub għaldaqstant lill-Awtorità dwar il-Liċenzjar.

Dmirijiet ta spiżjar.

**76.** (1) Kemm-il darba ma jiġix xort oħra provdut b dan l-Att jew taħtu, prodott mediċinali għandu jiġi biss ippreparat jew mibjugħ minn spiżerija minn spiżjar:

Iżda spiżjar jista jippermetti li prodotti mediċinali jiġu ppreparati jew mibjugħin minn *pharmacy technician* taħt is-superviżjoni personali tiegħu skond ma hemm regolat minn jew taħt dan l-Att.

(2) Fit-twettiq tal-funzjonijiet tiegħu fil-preparazzjoni, dispensa u t-tqassim ta prodotti mediċinali minn spizerija, spiżjar għandu jagixxi skond tali *standards* li jistgħu jiġu stabbiliti minn jew taħt dan l-Att jew taħt xi liġi oħra.

Interess fi spiżerija.

**77.** Il-kondizzjonijiet u kriterji li jistabbilixxu jekk persuna għandha jew m għandhiex interess dirett jew indirett fi spiżerija għandhom jiġu stabbiliti fit-Tielet Skeda ta dan l-Att.

Detentur ta liċenza jista jimpjega spiżjar wieħed jew aktar .

**78.** Id-detentur ta liċenza għandu jimpjega spiżjar sabiex jaqdi r-responsabbiltajiet ta spiżjar responsabbli u għandu jipprovdilu l-appoġġ tiegħu kollu u b ebda mod ma għandu jindaħal fir-responsabbiltajiet ta l-ispiżjar jew fir-responsabbiltajiet professjonali ta spiżjar fit-twettiq ta dmirijietu kif imfissra b dan l-Att jew taħtu jew taħt xi oħra liġi.

Prodotti mediċinali li għandhom jinbiegħu minn spiżerija.

**79.** (1) Fi spiżerija għandu jsir biss dispensa ta prodotti mediċinali u kummerċ ta prodotti jew gruppi jew klassijiet ta prodotti li jistgħu minn żmien għal żmien jiġu preskritti b regoli maħruġa mill-Awtorità dwar il-Liċenzjar.

(2) Kemm-il darba ma jiġix xort oħra provdut b dan l-Att jew taħtu, prodott mediċinali għandu biss jinbiegħ minn spiżerija:

Iżda l-Awtorità dwar il-Liċenzjar tista f ċirkostanzi speċjali relatati mal-għoti ta servizzi lill-pubbliku, b regoli tippreskrivi li prodott mediċinali jew klassi jew klassijiet ta prodotti mediċinali li jiġu hemm speċifikati jistgħu jinbiegħu minn xi fond li ma jkunx spiżerija liema fond ma jistax ikun fond minn fejn oġġetti jinbiegħu bl-imnut:

Iżda wkoll, l-Awtorità dwar il-Liċenzjar tista fl-istess ċirkostanzi b regoli tippreskrivi li prodott mediċinali jew klassi jew klassijiet ta prodotti mediċinali li jiġu hemm speċifikati jistgħu jinbiegħu, jiġu preparati jew provduti lil pazjent minn xi persuna, li ma tkunx spiżjar li jkollha kwalifika kif imiss għal dan il-għan:

Iżda wkoll, dawk ir-regoli għandhom jipprovdu dwar iċ-ċirkostanzi li taħthom jistgħu jsiru l-bejgħ, il-preparazzjoni jew it-tqassim filwaqt li tqiegħed dawk ir-restrizzjonijiet li jistgħu jiġu provduti.

(3) L-Awtorità dwar il-Liċenzjar tista b regoli tistabbilixxi lista ta prodotti mediċinali li mill-anqas għandhom ikunu disponibbli fi spiżerija f kull waqt:

Iżda din il-ħtieġa tista tkun temporanjament imwarrba għar-rigward ta xi prodott mediċinali jew klassi ta prodott mediċinali partikolari f ċirkostanzi eċċezjonali, jekk l-Awtorità dwar il-Liċenzjar tkun sodisfatta li n-nuqqas ta disponibbiltà ta dak il-prodott mediċinali jew klassi ta prodott mediċinali minn spiżerija ma jkunx jaqa taħt il-kontroll ta l-ispiżjar responsabbli.

Bejgħ ta prodott mediċinali.

**80.** (1) Spiżjar għandu jipprepara jew ibigħ prodott mediċinali meħtieġ minn persuna li tippreżenta riċetta kemm-il darba huwa ma jkollux raġuni ġustifikata jissuspetta li r-riċetta tkun falza, li l-persuna tkun qed tagħmel użu ħażin mill-prodott mediċinali ordnat, jew li l-prodott mediċinali ma jkunx disponibbli jew jekk ikollu raġunijiet professjonali għaliex ma għandux jipprepara jew ibigħ skond ma jkollu fir-riċetta.

(2) Meta tiġi ppreżentata lil spiżjar riċetta għal prodott mediċinali, kemm-il darba min joħroġ ir-riċetta ma jindikax prodott ta ditta partikolari billi jikteb "tad-ditta" jew "®" fuq ir-riċetta, huwa jista jbiegħ kemm il-prodott mediċinali ordnat kemm prodott mediċinali ekwivalenti li jkollu l-istess entità, doża, forma ta' dożaġġ, formulazzjoni u frekwenza ta dożaġġ kimiċi bħalma jkollu l-prodott mediċinali indikat fuq ir-riċetta.

(3) Meta, fil-bejgħ ta xi prodott mediċinali, spiżjar jiskopri li jkun hemm raġunijiet il-għaliex il-prodott mediċinali ma għandux

jinbiegħ lill-pazjent jew li l-amministrazzjoni tad-dożaġġ indikata fil-ħruġ ta riċetta jkun joltrepassa dik li tista titqies bħala doża terapewtiku sigura, l-ispiżjar għandu d-dmir jinforma b dan lil min ikun qed joħroġ ir-riċetta u jista jitlob lil dik il-persuna tiktiblu bil-inka jew b xi mod ieħor li ma jitħassarx fuq ir-riċetta dikjarazzjoni fejn jassumi r-responsabbiltà għal dik ir-riċetta.

(4) L-ispiżjar għandu jassumi kull responsabbiltà għall-bejgħ ta prodotti mediċinali li ma jkunux jeħtieġu riċetta biex jinbiegħu lill-pazjenti.

Bejgħ b riċetta.

**81.** (1) Ebda spiżjar ma jista jbigħ prodott mediċinali ħlief bir-riċetta ta tabib, dentist jew kirurgu veterinarju jew persuna oħra awtorizzata li toħroġ riċetta taħt dan l-Att jew xi Att ieħor, kemm-il darba l-prodott mediċinali ma jitqiesx mill-Awtorità dwar il-Liċenzjar li ma jeħtieġx riċetta mediċinali.

(2) Id-disposizzjonijiet tas-subartikolu (1) għandhom ukoll jgħoddu għal prodotti jew sustanzi li mhux klassifikati bħala prodotti mediċinali imma li jitqiesu bħala li jeħtieġu riċetta mediċinali għall-użu tagħhom mill-awtorità kompetenti rilevanti.

Meta tiġi ppreżentata riċetta.

**82.** L-Awtorità dwar il-Liċenzjar tista b regoli tippreskrivi l-format, il-kontenut u kif tiġi ppreżentata riċetta li tkun meħtieġa b dan l-Att jew taħtu.

Ittikkettjar ta prodotti mibjugħa.

**83.** L-ispiżjar għandu jwaħħal tikketta fuq kull prodott mediċinali jew formola maġistrali li jinbiegħu skond dawk ir-regolamenti jew regoli magħmula taħt dan l-Att.

Bejgħ ta prodotti skaduti, mgħarrqa jew mhux perfetti.

**84.** Ebda spiżjar responsabbli ma għandu jbigħ, jippermetti l-bejgħ, it-tqassim jew il-forniment xort oħra ta xi -

(a) sustanza mhux perfetta, mgħarrqa jew dannuża;

(b) prodott mediċinali li jkollu data ta użu li tkun skaduta;

(ċ) ikel mhux skond id-disposizzjonijiet ta l-Att ta' l-2002 dwar is-Sigurezza ta l-Ikel jew regolamenti magħmulin taħtu:

Iżda dawk is-sustanzi jew prodotti mediċinali mhux perfetti, mgħarrqa jew skaduti għandhom biss jiġu miżmuma f dak il-post u b dak il-mod skond ma l-Awtorità dwar il-Liċenzjar tista minn żmien għal żmien b regoli tistabbilixxi.

Ħżin ta prodotti mediċinali fi spiżerija.

**85.** (1) Ebda spiżjar responsabbli ma jista jżomm x imkien fl-ispiżerija prodott mediċinali f kontenitur jew taħt dawk il-kondizzjonijiet li ma jkunux adatti għax-xorta tiegħu u li ma jkunux tali li jħarsuh ninn kull alterazzjoni, deterjorazzjoni jew kontaminazzjoni.

(2) Ebda spiżjar responsabbli ma jista jippermetti li prodott mediċinali jinżamm taħt ir-responsabbiltà tiegħu jew li jinħażen barra mill-ispiżerija taħt it-tmexxija tiegħu, u jkun id-dmir tiegħu li jiżgura li l-ispiżerija jkollha l-faċilitajiet li tiżgura li l-prodotti mediċinali jinħażnu skond rakkomandazzjonijiet ta ħżin:

Iżda fil-każ meta l-Awtorità dwar il-Liċenzjar tkun ħarġet liċenza biex jinżammu jew jinħażnu prodotti mediċinali f xi fond li ma jkunx spiżerija, r-responsabbiltajiet ta l-ispiżjar responsabbli għandhom ikunu wkoll japplikaw għal dak il-fond.

Il-fond, eċċ., skond il-ħtiġiet u *standards*.

**86.** Il-fond, il-faċilitajiet, ir-*records* u t-tagħmir użat għall-ħżin, preparazzjoni u bejgħ ta prodotti mediċinali għandhom jinżammu skond il-ħtiġiet u *standards* stabbiliti b dan l-Att jew taħtu.

L-ispiżjar għandu jimxi skond *standards* stabbiliti.

**87.** Il-preparazzjoni ta formoli maġistrali u uffiċjali, u l-ippakkettjar minn qabel, rikostituzzjoni, bejgħ u amministrazzjoni ta prodotti mediċinali u kull attività oħra li għandha x taqsam ma prodotti mediċinali u l-użu tagħhom, għandhom ikunu skond tali *standards* li jistgħu jiġu stabbiliti taħt dan l-Att.

Spezzjoni ta spiżeriji.

**88.** (1) L-Awtorità dwar il-Liċenzjar għandu jkollha l-jedd tispezzjona kull spiżerija u fond li jkollhom liċenza biex jintużaw bħala mħażen taħt l-artikolu 68(2) kull meta tqis li jkun hekk meħtieġ.

(2) Kull spezzjoni bħal dik hawn qabel imsemmija għandha ssir fil-preżenza ta l-ispiżjar responsabbli jew ta l-ispiżjar li għal dak iż-żmien ikun qed jieħu ħsieb l-ispiżerija.

(3) Fil-waqt ta l-ispezzjoni, l-uffiċjal li jispezzjona għandu jagħmel lista ta defiċjenzi li jistgħu ikunu ġew identifikati fil-waqt ta l-ispezzjoni u għandu jiffirma dik il-lista, u dik il-lista għandha tiġi kontrosenjata mill-ispiżjar responsabbli jew mill-ispiżjar li f dak iż-żmien ikun qed jieħu ħsieb l-ispiżerija:

Iżda l-uffiċjal li jispezzjona għandu jagħmel rapport ta l-ispezzjoni fi żmien sebat ijiem tax-xogħol minn dik l-ispezzjoni u għandu jibgħat kopja ta dak ir-rapport lill-Awtorità dwar il-Liċenzjar, lid-detentur ta liċenza u lill-ispiżjar responsabbli:

Iżda wkoll l-ispiżjar responsabbli jew l-ispiżjar li f dak iż-żmien ikun qed jieħu ħsieb l-ispiżerija, jista jagħmel il-kummenti

tiegħu jew xort oħra jagħmel riservi dwar il-kontenut tal-lista msemmija.

(4) (a) Jekk filwaqt li tkun qed issir l-ispezzjoni, tinstab xi ħaġa bi ksur tad-disposizzjonijiet ta dan l-Att jew ta regolamenti magħmulin taħtu, l-uffiċjal li jispezzjona għandu minnufih jeleva dak l-oġġett.

(b) Il-folja tat-tisrir jew il-kontenitur li jkun fih l-oġġett elevat għandhom jiġu ssiġillat u l-uffiċjal li jispezzjona u l-ispiżjar responsabbli għandom jiffirmaw fuq is-siġill:

Iżda jekk l-ispiżjar responsabbli hekk jitlob, l-oġġett inkwistjoni għandu jiġi maqsum, mill-uffiċjal li jispezzjona, f żewġ partijiet indaqs, li jiġu ssiġillati u ffirmati bil-mod kif hawn qabel imsemmi, u parti waħda minnhom tingħata lill-ispiżjar rsponsabbli:

Iżda wkoll l-uffiċjal li jispezzjona għandu jibgħat l-oġġett elevat, iffirmat u ssiġġillat bil-mod imsemmi qabel, lill-Awtorità dwar il-Liċenzjar flimkien mar-rapport dwar l-ispezzjoni deskritt fis-subartikolu (3).

(5) Jekk l-ispiżjar responsabbli jew l-ispiżjar li f dak iż-żmien ikun qed jieħu ħsieb l-ispiżerija jirrifjuta milli jikkontrosenja l-lista imsemmija fis-subartikolu (3), l-uffiċjal li jispezzjona għandu jirreġistra dak il-fatt fuq il-lista msemmija flimkien mar-raġunijiet mogħtija, jekk ikun hemm, għal dak ir-rifjut.

Ftuħ ta spiżeriji.

**89.** L-Awtorità dwar il-Liċenzjar tista b avviż fil-Gazzetta tistabbilixxi l-ħinijiet tan-negozju ta spiżeriji u tista wkoll teħtieġ li spiżeriji f lokalitajiet jew distretti speċifikati jinfetħu għall-qadi ta parruċċani f dawk il-ġranet u f dawk il-ħinijiet li jistgħu jiġu speċifikati f dak l- avviż.

## TAQSIMA IV

## SUSTANZI VELENUŻI

Tifsira ta veleni.

**90.** Għall-finijiet tad-disposizzjonijiet li jinsabu f din it-Taqsima, "velenu" tfisser -

(a) dawk is-sustanzi kollha li, wkoll jekk jittieħdu f doża żgħira ħafna, jistgħu jikkaġunaw il-mewt jew feriment gravi fis-saħħa ta' bniedem,

(b) dawk is-sustanzi kollha li l-Ministru jista', bil-parir ta' l-Awtorità dwar il-Liċenzjar, minn żmien għal żmien jippreskrivi,

iżda ma tinkludi ebda sustanza simili li tintuża, jew li tkun intiża li tintuża, għal finijiet domestiċi ta kuljum, liema msemmija sustanza, madankollu, għandha titqies bħala velenu għall-fini ta l-artikolu 94.

Tiżmim eċċ., ta veleni.

**91.** Hadd ma jista jżomm għall-bejgħ, jimmanifattura, jbiegħ jew xort oħra jiddistribwixxi jew imexxi veleni mingħajr ma jkollu liċenza maħruġa mill-Awtorità dwar il-Liċenzjar.

Liċenza għall-bejgħ ta veleni.

**92.** (1) Il-liċenza msemmija fl-artikolu 91 għandha tingħata biss lil persuni li jimmanifatturaw u jmexxu prodotti kimiċi, koloristi u dawk il-persuni l-oħra li jkunu jeħtieġu jagħmlu użu mill-veleni fi-eżerċizzju tal-kummerċ jew il-professjoni tagħhom.

(2) Dik il-liċenza għandha tkun turi l-isem u l-kunjom tad-detentur ta liċenza, s-sengħa jew il-professjoni tiegħu, u l-post fejn ikun bi ħsiebu jiġġestixxi in-negozju jew il-professjoni tiegħu u kull informazzjoni oħra li tista tiġi minn żmien għal żmien stabbilita b regoli magħmula mill-Awtorità dwar il-Liċenzjar.

Tiżmim ta sustanzi velenużi f post sigur.

**93.** Kull persuna mogħtija liċenza taħt l-artikolu 91 għandha żżomm is-sustanzi velenużi kollha f post imwarrab u sigur, li ċ-ċavetta tiegħu għandha dejjem tinżamm mid-detentur tal-liċenza.

Bejgħ ta sustanzi velenużi.

**94.** (1) Ebda persuna mogħtija liċenza taħt l-artikolu 91 ma għandha tbiegħ jew tikkunsinna xi sustanza velenuża, kemm bl-ingrossa kemm bl-imnut, lil persuna li ma tkunx spiżjar, kemm-il darba ma tinġiebx riċetta jew għal għanijiet ta disinfettar jew ta industrja jew għal kull skop ieħor li jista jiġi awtorizzat mill-Awtorità dwar il-Liċenzjar.

(2) Kull persuna mogħtija liċenza taħt l-artikolu 91 għandu jkollha, żżomm, taġġorna, taħżen u tagħmel disponibbli lill-Awtorità dwar il-Liċenzjar jew lil kull persuna awtorizzata dik l-informazzjoni li tista minn żmien għal żmien tkun meħtieġa mill-Awtorità dwar il-Liċenzjar u b dak il-mod li jista minn żmien għal żmien jenħtieġ mill-Awtorità dwar il-Liċenzjar.

(3) Is-sustanzi velenużi għandu jkollhom dawk it-tikketti li l-Awtorità dwar il-Liċenzjar tista minn żmien għal żmien tistabbilixxi b'regoli.

Setgħa ta spezzjon.

**95.** L-Awtorità dwar il-Liċenzjar jew kull uffiċjal awtorizzat tista , fl-interess tas-saħħa pubblika, tagħmel viżti mhux avżati ġo xi fond kummerċjali ta persuni li jimmanifatturaw u jmexxu prodotti kimiċi u ta persuni oħra msemmija fl-artikolu 91.

Qmuħ, żrieragħ eċċ., ivvelenati. Kap. 430.

**96.** Mingħajr preġudizzju għad-disposizzjonijiet ta l-Att ta l-2002 dwar il-Kontroll tal-Pestiċidi, hu projbit ż-żrigħ, it-tfigħ, it-

tqegħid jew it-tħawwil, jew li ġġiegħel li jsir iż-żrigħ, it-tfigħ, it-tqegħid jew it-tħawwil fi jew fuq xi art jew xi post ieħor fil-beraħ ta' xi ħabba, żerriegħa, tmigħ jew sustanza li tkun ġiet hekk miblula jew mxarrba fil-velenu, jew li tkun hekk tħalltet ma xi velenu jew ingredjent jew preparazzjoni oħra b mod li ssir velenuża u jkollha l-iskop li teqred il-ħajja.

## TAQSIMA V

## MOD IEHOR KIF JIĠU TTRATTATI PRODOTTI MEDICINALI

Restrizzjonijiet speċjali fuq persuni li jiġu fornuti bi prodotti mediċinali.

**97.** L-Awtorità dwar il-Liċenzjar tista b regoli tipprovdi, kemm dwar prodotti mediċinali b mod ġenerali kemm dwar prodotti mediċinali ta xi deskrizzjoni jew li jaqgħu f xi klassi speċifikata fir-regoli li, bla ħsara għal dawk l-eċċezzjonijiet li jistgħu jiġu hekk speċifikati, ħadd -

(a) għax ikun id-detentur ta xi awtorizzazzjoni ta tqegħid fis-suq, jew

(b) fi-kors ta kummerċ ġestit minnu u li jikkonsisti, għalkollox jew f parti, fil-manifattura ta prodotti mediċinali jew fil-bejgħ ta prodotti mediċinali b negozju bl-ingrossa,

ma għandu jbiegħ jew iforni xi prodott mediċinali li dwaru japplikaw ir-regoli lil xi persuna li ma tinkwadrax fi klassi speċifikata f'dawk ir-regoli.

Adulterazzjoni ta prodotti mediċinali.

**98.** Ħadd ma għandu-

(a) jżid xi sustanza ma', jew jagħmel astrazzjoni ta xi sustanza minn, prodott mediċinali b mod li jolqot b mod dannuż il-kompożizzjoni tal-prodott, bil-ħsieb li l-prodott jinbiegħ jew jiġi fornut f dak l-istat; jew

(b) ibiegħ jew iforni, jew joffri jew jesponi għall-bejgħ jew forniment, jew ikollu fil-pussess tiegħu għall-fini ta bejgħ jew forniment, xi prodott mediċinali li l-kompożizzjoni tiegħu tkun ġiet milquta b mod dannuż biż-żjieda jew l-astrazzjoni ta xi sustanza.

## TAQSIMA VI

## REATI U PIENI

Reati u pieni.

**99.** (1) Mingħajr preġudizzju għal kull responsabbiltà oħra taħt xi liġi oħra, kull persuna li tonqos milli tosserva xi disposizzjoni ta dan l-Att jew xi regolamenti jew regoli magħmulin taħtu tkun

ħatja ta  reat u tista , meta tinsab ħatja, teħel, fil-każ ta  reat kontra:

(a) id-disposizzjonijiet ta  l-artikoli 20, 24, 28, 37, 39, 41 u 43, multa ta  mhux anqas minn għaxart elef lira u mhux iżjed minn ħamsin elf lira jew priġunerija għal żmien mhux iżjed minn sentejn, jew dik il-multa u priġunerija flimkien;

(b) id-disposizzjonijiet ta  l-artikoli 54, 56, 58 u 61, multa ta  mhux inqas minn ħamest elef lira u mhux iżjed minn tletin elf lira jew priġunerija għal żmien mhux iżjed minn sitt xhur, jew dik il-multa u priġunerija flimkien;

(ċ) id-disposizzjonijiet ta  l-artikoli 44, 45, 66(1), 71, 75(3), 75(4), 76(1), 81(1), 91 u 98, multa ta  mhux inqas minn elfejn lira u mhux iżjed minn għoxrin elf lira, jew priġunerija għal żmien mhux iżjed minn tliet xhur, jew dik il-multa u priġunerija flimkien;

(d) id-disposizzjonijiet ta  l-artikoli 59, 60, 65, 74(b), 75(1), 75(2), 84, 93, 94(1) u 96, multa ta  mhux inqas minn ħames mitt lira u mhux iżjed minn għaxart elef lira;

(e) d-disposizzjonijiet ta  l-artikoli 31, 66(2), 78, 85(1), 85(2) u 94(2), multa ta  mhux inqas minn mitejn lira u mhux iżjed minn ħamest elef lira;

(f) id-disposizzjonijiet ta  l-artikoli 29, 73(1) u 94(3), multa ta  mhux inqas minn mitt lira u mhux iżjed minn elf lira.

(2) Mingħajr preġudizzju għas-setgħat ta' l-Awtorità dwar il-Liċenzjar taħt dan l-Att, meta persuna li tkun għamlet reat tkun id-detentur ta  liċenza jew ta  awtorizzazzjoni taħt dan l-Att, u dak is-sejbien ta  ħtija jkun it-tielet sejbien ta  ħtija jew wieħed sussegwenti, il-qorti għandha, fuq talba tal-prosekuzzjoni, tordna r-revoka jew is-sospensjoni tal-liċenza jew awtorizzazzjoni hawn qabel imsemmija.

Proċedura speċjali.

**100.** (1) Minkejja kull liġi oħra li tipprovdi għal provvedimenti dwar reati, meta l-Awtorità dwar il-Liċenzjar tkun tal-fehma li persuna tkun ikkommettiet reat kontra dan l-Att jew xi regolamenti jew regoli magħmulin taħtu, l-Awtorità għandha tagħti avviż bil-miktub lil dik il-persuna fejn tiddeskrivi r-reat li dwaru dik il-persuna tkun qed tiġi akkużata, fejn jiġu indikati l-passi li għandhom jittieħdu sabiex jirrimedjaw ir-reat u l-penali li għandha titħallas għal dak ir-reat.

(2) Il-Ministru għandu jippreskrivi l-penalitajiet li jistgħu jintalbu mill-Awtorità dwar il-Liċenzjar dwar xi reat speċifikat:

Iżda penali bħal dik ma għandhiex tkun teċċedi ammont ta għaxart elef lira.

(3) Meta jkun ingħata avviż taħt dan l-artikolu, il-persuna msemmija fl-avviż tista , fi żmien wieħed u għoxrin jum minn meta tiġi notifikata bl-avviż, taċċetta r-responsabbiltà għar-reat speċifikat fl-avviż u fi żmien l-istess perjodu tħallas il-penali indikata fl-avviż, u tikkonforma ruħha ma kull disposizzjoni relattiva ta dan l-Att, jew tar-regolamenti jew regoli magħmulin taħtu u ma jkunu jistgħu jittieħdu ebda proċedimenti ulterjuri taħt dan l-Att dwar dak ir-reat.

(4) Meta l-persuna li jingħatalha l-avviż taħt is-subartikolu (1) ma tħallasx il-penali fi żmien il-perjodu ta' wieħed u għoxrin ġurnata msemmi fis-subartikolu (3) u ma osservatx, fiż-żmien speċifikat, il-ħtiġiet ta' dan l-Att, jistgħu jittieħdu proċedimenti ordinarji kontriha skond id-disposizzjonijiet tal-Kodiċi Kriminali, ta dan l-Att u ta kull liġi oħra li tkun tapplika dwar ir-reat.

Kap. 9.

## TAQSIMA VII

INFURZAR

Dritt ta dħul.

**101.** (1) Bla ħsara għad-disposizzjonijiet ta dan l-artikolu, u mingħajr preġudizzju għad-disposizzjonijiet l-oħra ta dan l-Att, persuna li tkun awtorizzata bil-miktub kif imiss mill-Awtorità dwar il-Liċenzjar għandu jkollha dritt, meta turi l-awtorizzazzjoni jew il-kredenzjali tagħha, f kull ħin raġonevoli tidħol f xi fond:

(a) bil-għan li taċċerta ruħha jekk ikunx hemm jew kienx hemm, jew x aktarx li jkun hemm xi ksur ta xi disposizzjoni ta dan l-Att jew ta xi regolamenti jew regoli magħmulin taħtu;

(b) ġeneralment għall-finijiet ta l-eżerċizzju mill-Awtorità dwar il-Liċenzjar tal-funzjonijiet tagħha taħt dan l-Att jew taħt regolamenti jew regoli magħmulin taħtu.

Għall-fini ta din it-Taqsima, fond jiftiehem bħala li jinkludi bini, struttura, xi post ieħor li jkun jew kwalunkwe mezz ta trasport.

(2) Uffiċjal awtorizzat ikollu d-dritt, meta juri l-awtorizzazzjoni tiegħu, f kull ħin raġonevoli jitla abbord kull bastiment jew inġenju ta l-ajru għall-fini li jaċċerta ruħu jekk ikunx hemm f xi bastiment jew inġenju ta l-ajru xi sustanza jew oġġett importat bi ksur ta xi disposizzjoni ta dan l-Att jew ta xi regolamenti jew regoli magħmulin taħtu jew jekk l-imsemmi inġenju jkunx qed iwettaq xi attività bi ksur ta xi waħda mill-imsemmija

disposizzjonijiet.

Setgħa li tispezzjona, tieħu kampjuni u taqbad merkanzija u dokumenti.

**102.** (1) Bil-għan li jiġi aċċertat jekk ikunx hemm jew kienx hemm jew x aktarx ikun hemm ksur ta dan l-Att jew ta regolamenti jew regoli magħmulin taħtu, uffiċjal awtorizzat ikollu d-dritt jispezzjona:

(a) kull sustanza jew oġġetti li jidhrulu li jkunu prodott mediċinali;

(b) kull oġġett li jintuża jew ikun maħsub li jintuża biex jitqiegħed fih xi prodott mediċinali jew bħala tikketta jew *leaflet* li jintuża jew ikun maħsub li jintuża f dak li għandu x jaqsam ma xi prodott mediċinali; jew

(ċ) kull impjant jew tagħmir li jidhrulu li jintużaw jew ikunu maħsuba li jintużaw f dak li għandu x jaqsam mal-manifattura jew l-assemblaġġ ta prodotti mediċinali, u kull proċess ta manifattura jew assemblaġġ ta prodotti mediċinali u l-mezzi li jintużaw għaldaqshekk, f kull stadju tal-proċess ta manifattura jew assemblaġġ, għal ittestjar ta kull materjal wara li jkunu għaddew minn dawk il-proċessi.

(2) Uffiċjal awtorizzat jista , għal kull fini speċifikata fis-subartikolu preċedenti, jieħu kampjun:

(a) ta sustanzi jew prodotti mediċinali mibjugħin jew fornuti jew maħsuba biex jinbiegħu jew jiġu fornuti; jew

(b) ta sustanzi jew oġġetti użati jew maħsuba biex jintużaw fil-manifattura ta xi prodott mediċinali.

(3) Għall-finijiet tas-subartikolu (1) ta dan l-artikolu, persuna awtorizzata jkollha l-jedd:

(a) li tispezzjona kull għamla ta *record*, f liema stat ikun, li jkollhom x jaqsmu mal-manifattura, l-assemblaġġ, il-bejgħ jew il-forniment ta xi prodott mediċinali u, meta tali *records* ikunu miżmuma f għamla elettronika:

(i) jista jkollha aċċess għal, u tispezzjona u tivverifika l-operazzjoni ta xi *computer*, xi apparat assoċjat jew materjal li jkun jew li kien qed jintuża f dak li għandu x jaqsam mar-*records*; u

(ii) tista titlob lil kull persuna li tkun responsabbli minn, jew li xort oħra jkollha x taqsam mat-tħaddim tal-*computer*, apparat jew materjal, li tagħtih kull

tali assistenza li hija tista raġonevolment titlob;

(b) li tagħmel kopji ta kull dħul fi ktieb jew dokument miġjuba konformement mal-paragrafu preċedenti u meta r-*records* ikunu miżmuma elettronikament, permezz ta *computer* jew xort oħra, teħtieġ li r-*records* jinġiebu f għamla intelliġibbli li tista tiġi trasportata.

(4) Uffiċjal awtorizzat ikollu d-dritt jeleva, jwarrab u jżomm għandu kull sustanza jew oġġett li jkollu tassew għaliex jaħseb li jkunu sustanzi jew oġġetti li dwarhom, jew permezz tagħhom, ikun qed isir jew kien qed isir reat taħt dan l-Att, u kull dokument li dwaru jkollu tassew għaliex jaħseb li jkun dokument li jista jenħtieġ li jinġieb bi prova fi proċedimenti taħt dan l-Att.

(5) Bil-għan li jeżerċita l-jedd mogħti lilu taħt subartikolu (4), kull persuna awtorizzata tista , sakemm ikun raġonevolment meħtieġ biex ikun hemm konformità mad-disposizzjonijiet ta dan l-Att u ta regolamenti jew regoli magħmulin taħtu, teħtieġ lil xi persuna tiftaħ billi tikser xi kontenitur, pakkett jew makna, jew li tħalliha tagħmel dan:

Iżda meta persuna televa xi sustanza jew oġġett, inkluż xi dokument, għall-finijiet speċifikati fis-subartikolu (4), hija għandha tinforma lill-persuna mingħand min dawn ikunu ġew elevati u tagħtiha riċevuta dwarhom.

(6) Mingħajr preġudizzju għad-disposizzjonijiet preċedenti ta dan l-artikolu, persuna awtorizzata għandu jkollha l-istess drittijiet bħal dawk mogħtija b dawk id-disposizzjonijiet għar-rigward ta oġġetti li jappartjenu lil, jew xi kummerċ ġestit minn, applikant għal awtorizzazzjoni jew ċertifikat taħt it-Taqsima III ta dan l-Att, u tista teżerċita dawk id-drittijiet għall-fini li tivverifika kull dikjarazzjoni jew informazzjoni li jkun hemm fl-applikazzjoni għall-awtorizzazzjoni jew iċ-ċertifikat; u, meta bis-saħħa tad-disposizzjonijiet ta dan is-subartikolu persuna teżerċita xi dritt bħal dak speċifikat fis-subartikolu (4), dan għandu jkun bla ħsara għad-dmir impost bis-subartikolu (5).

(7) Minkejja kull ħaġa li tinsab fid-disposizzjonijiet preċedenti ta dan l-artikolu, meta persuna li tippretendi li tkun qed teżerċita xi dritt bis-saħħa tal-disposizzjonijiet ta dan l-artikolu tenħtieġ iġġib xi awtorizzazzjoni jew kredenzjali li jkollha, dak il-jedd jista biss jiġi eżerċitat minnha wara li turi dik l-awtorizzazzjoni jew dawk il-kredenzjali li jkollha.

Kif tapplika proċedura ta teħid ta kampjuni dwar sustanza jew oġġett elevat.

**103.** (1) Id-disposizzjonijiet ta dan l-artikolu għandhom jgħoddu meta uffiċjal awtorizzat jeleva xi sustanza jew oġġett, ħlief għal dokument, fl-eżerċizzju ta dritt bħal dak speċifikat fl-artikolu 102(4) u (6).

(2) Jekk persuna li, skond l-artikolu 102(5) jkollha jedd tiġi informata bil-qbid ta oġġett hekk titlob, kemm fil-waqt tal-qbid kemm f xi waqt ieħor li jiġi wara, u li ma jkunx jaħbat aktar tard minn wieħed u għoxrin ġurnata wara li tkun ġiet informata bil-qbid, għaldaqstant u bla ħsara għal dawn id-disposizzjonijiet li ġejjin ta dan l-artikolu, l-uffiċjal awtorizzat għandu jew:

(a) iwarrab kampjun tas-sustanza jew ta l-oġġett elevat; jew

(b) jittratta dik is-sustanza jew dak l-oġġett bħala kampjun,

skond liema iqis l-aktar adatt meta titqies ix-xorta ta dik is-sustanza jew ta' dak l-oġġett.

(3) Uffiċjal awtorizzat ma jkunx meħtieġ bis-saħħa tas-subartikolu (2) iwarrab kampjun, jew jittratta sustanza jew oġġett bħala kampjun, jekk ix-xorta tas-sustanza jew ta l-oġġett tkun tali li ma jkunx raġonevolment prattikkabbli li taġixxi b dak il-mod.

(4) Meta skond is-subartikolu (2) uffiċjal awtorizzat iwarrab kampjun, jew jittratta sustanza jew oġġett bħala kampjun, huwa għandu jaqsmu fi tliet partijiet, hekk li kull parti tiġi mmarkata u siġillata jew marbuta b dak il-mod li x-xorta tagħha tkun tippermetti, u għandu jagħti parti waħda minnhom lill-persuna li tkun għamlet it-talba taħt is-subartikolu (2).

Disposizzjonijiet supplimentari dwar id-dritt ta dħul.

**104.** (1) Persuna li tidħol f xi proprjetà jew f xi fond, bastiment, inġenju ta l-ajru, posta jew post ieħor skond id-disposizzjonijiet ta l-artikolu 101, tista tkun akkompanjata minn kull persuna oħra jew tieħu magħha dak it-tagħmir li jista jidhrilha li jkun meħtieġ; u meta titlaq minn hemmhekk għandha, jekk il-proprjetà ma tkunx okkupata jew jekk l-okkupant jew kull persuna oħra li tkun qegħda tieħu ħsieb il-bastiment, l-inġenju ta l-ajru, il-posta jew post ieħor tkun temporanjament assenti, tħalli hemmhekk magħluq fiż-żgur kif kien.

(2) L-uffiċjal awtorizzat għandu wkoll ikollu kull tali poter ieħor li jistgħu jiġu preskritti b regolamenti magħmulin mill-Ministru għall-eżekuzzjoni tal-funzjonijiet tiegħu kif imiss.

## TAQSIMA VIII

DISPOSIZZJONIJIET MIXXELLANJI

Għarfien ta *standards* ekwivalenti.

**105.** Għall-finijiet ta dan l-Att, il-Ministru jista , bil-parir ta l-Awtorità dwar il-Liċenzjar, b regolamenti jippreskrivi li xi disposizzjoni jew disposizzjonijiet dwar l-awtorizzazzjoni ta tqegħid fis-suq ta prodott mediċinali għandhom jitqiesu li jkunu ġew sodisfatti jekk *standards* ta manifattura, kwalità ta prodott mediċinali, sigurezza jew effikaċja, jew id-disposizzjonijiet dwar l-għoti ta xi awtorizzazzjoni ta tqegħid fis-suq ta xi pajjiż indikat f dawk ir-regolamenti, jkunu ġew sodisfatti.

Setgħa tal-Ministru li jagħmel regolamenti.

**106.** Il-Ministru jista , wara konsultazzjoni ma l-Awtorità dwar il-Liċenzjar, jemenda l-iskedi taħt dan l-Att, jippreskrivi b regolamenti kull ħaġa li tista tiġi preskritta taħt dan l-Att u jipprovdi dwar kull ħaġa li tirrigwarda prodott mediċinali, veleni u spiżeriji sabiex jagħti effett iktar komplet lid-disposizzjonijiet ta dan l-Att, u b mod partikolari, imma mingħajr preġudizzju għall-ġeneralità ta dak hawn qabel imsemmi, għandu b dawk ir-regolamenti jew xort oħra jipprovdi dwar:

(a) l-għoti ta awtorizzazzjoni għat-tqegħid fis-suq;

(b) il-manifattura ta prodotti mediċinali u l-materjal grezz li jintuża f dik il-manifattura;

(ċ) id-distribuzzjoni bl-ingrossa ta prodotti mediċinali;

(d) il-bejgħ u l-forniment ta prodotti mediċinali;

(e) il-liċenzjar ta spiżeriji;

(f) ir-rappurtar ta reazzjonijiet mediċinali avversi;

(g) ir-reklamar ta prodotti mediċinali, u l-preżentazzjoni u l-informazzjoni li jiddaħħlu fir-reklam:

Iżda r-reklamar ta ċerti prodotti mediċinali jew klassijiet ta prodotti mediċinali jista' b'dawk ir-regolamenti, jkun projbit;

(h) it-tmexxija ta esperimenti kliniċi;

(i) il-klassifikazzjoni ta prodotti mediċinali;

(j) l-ittestjar ta prodotti mediċinali;

(k) ir-regolament ta prodotti mediċinali omeopatiċi;

radjofarmaċewtiċi u prodotti mediċinali li jinkisbu mid-demm tal-bniedem u plasma tal-bniedem; prodotti immunoloġiċi, u prodotti erbali;

(l) il-kompiti u r-responsabbiltajiet li jkollu detentur ta liċenza jew ta' awtorizzazzjoni;

(m) il-kompiti u r-responsabbiltajiet ta spiżjar responsabbli, persuna responsabbli u persuna kwalifikata;

(n) *standards* ta prattika tajba fil-manifattura, bejgħ bl-ingrossa, distribuzzjoni u dispensa ta prodotti mediċinali:

Iżda fil-każ ta *standards* ta dispensa l-Ministru jista wkoll jieħu l-parir tal-Bord dwar l-Ispiżjara;

(o) l-għarfien ta standards ekwivalenti għall-kwalità u l-effikaċja ta prodotti mediċinali dwar dawk il-pajjiżi li jistgħu jiġu hekk preskritti;

(p) l-għarfien ta standards ekwivalenti għal prattika tajba fil-manifattura dwar dawk il-pajjiżi li jistgħu jiġu hekk preskritti;

(q) id-drittijiet li jistgħu jingħabru mill-Awtorità dwar il-Liċenzjar u mill-Awtorità dwar il-Mediċini;

(r) eċċezzjonijiet li jistgħu jsiru għal xi disposizzjoni fl-interess tas-saħħa pubblika.

Disposizzjoni transitorja.

**107.** Podotti mediċinali li jkunu fis-suq fid-data tad-dħul fis-seħħ ta l-artikolu 20 għandhom ikunu soġġetti għad-disposizzjonijiet ta dak l-artikolu biss f dak il-waqt u kif soġġetti għal dawk il-kondizzjonijiet li jistgħu b regoli jiġu stabbiliti mill-Awtorità dwar il-Liċenzjar.

Emendi għall-Ordinanza dwar il-Professjoni Medika u l-Professjonijiet li għandhom x jaqsmu magħha. Kap. 31.

**108.** L-Ordinanza dwar il-Professjoni Medika u l-Professjonijiet li għandhom x jaqsmu magħha għandha tiġi emendata kif ġej:

(a) għal dak li jirrigwarda spiżeriji: l-artikoli 22, 23, 25, 26, 27, 28, 30, 31, 33, 34, 35, 36, 37, 38, 39, 41, 42 u 48 għandhom jiġu mħassra; u

(b) għal dak li jirrigwarda velenu: l-artikoli 88, 89, 92, 93 u 95 għandhom jiġu mħassra.

Riserva.

**109.** (1) Regolamenti magħmulin taħt id-disposizzjonijiet, ta' l-Ordinanza dwar il-Professjoni Medika u l-Professjonijiet li għandhom x jaqsmu magħha, li qed jiġu revokati bl-artikolu 108,

għandhom, sakemm ma jsirx provvediment taħt jew bis-saħħa ta dan l-Att, jibqgħu jseħħu u jkollhom effett bħallikieku magħmulin taħt dan l-Att.

(2) Kull liċenza, permess jew awtorizzazzjoni oħra mogħtija taħt kull disposizzjoni ta' l-artikoli mħassra hawn qabel imsemmija, għandhom jibqgħu fis-seħħ bħallikieku kienu liċenza, permess jew awtorizzazzjoni mogħtija taħt disposizzjoni jew awtorità korrispondenti mogħtija taħt dan l-Att u għandhom jiġu ttrattati u jsir minnhom skond hekk.

(3) Kull azzjoni meħuda jew proċedimenti mibdija kontra jew dwar xi persuna taħt xi disposizzjoni ta' l-artikoli mħassra hawn qabel imsemmija, għandhom ikomplu jkollhom effett bħallikieku kienu xi azzjoni jew proċedimenti meħuda jew mibdija taħt xi disposizzjoni korrispondenti ta dan l-Att.

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L-EWWEL SKEDA

Oqsma ta kompetenza

Anatomija

Anestesjoloġija

Apparat mediku

Biokimika

Bjoloġija molekulari

Dentistrija

Dermatoloġija

Djabete

Ematoloġija

Endokrinoloġija

Epidemjoloġija

Erbali

Farmakoloġija

Farmakognosija

Fiżjoloġija

Gastroenteroloġija

Ġenetika

Gerjatrija

Immunoloġija

Kardjoloġija

Kimika analitika

Kimika farmaċewtika

Kirurġija

Kosmiċewtiċi

Kura intensiva

Mediċina tal-Familja

Mediċina interna

Mediċina Respiratorja

Mediċina Trasfużjonali

Mediċina tal-Widnejn, Imnieħer u Griżejm

Microbjoloġija (bħal Viroloġija, Batterjoloġija)

Nefroloġija

Newroloġija

Nutraċewtiċi

Nutrizzjoni

Oftalmoloġija

Omeopatika

Onkoloġija

Ortopedija

Ostetrika u Ġinekoloġija

Patoloġija

Pedjatrija

Prodotti bioteknoloġiċi

Prodotti mid-demm

Psikjatrija

Radjofarmaċewtiċi

Radjoloġija

Rewmatoloġija

Statistika medika

Teknoloġija farmaċewtika

Tossikoloġija

Uroloġija

Vaċċinazzjoni

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IT-TIENI SKEDA

Proċedimenti tal-Bord ta Reviżjoni dwar il-Mediċini

1. Il-membri kollha tal-Bord ta Reviżjoni dwar il-Mediċini għandhom ikunu preżenti għas-smigħ ta xi appell jew il-formulazzjoni ta fehma ulterjuri.

2. Il-membri kollha tal-Bord ikollhom vot u l-fehma tal-Bord għandha tirrifletti l-fehma tal-maġġoranza tal-membri:

Iżda membru li ma jaqbilx jista wkoll jitlob li l-fehma tiegħu tintehmeż mar-rapport tal-fehma tal-Bord bħala rapport minoritarju.

3. L-appellant għandu jidher quddiem il-Bord jew personalment jew kif rappreżentat minn xi aġent fil-ġurnata u l-ħin

appuntati għas-smigħ, jagħmel is-sottomissjonijiet tiegħu u jġib dawk il-provi li l-Bord jista jħalli li jinġiebu:

Iżda l-Bord jista jippostponi s-smigħ ta l-appell jekk ikun sodisfatt li l-appellant ma setax jidher quddiemu minħabba f mard jew assenza minn Malta jew għal xi kawża raġonevoli oħra simili.

4. Il-Bord għandu jagħti lill-Awtorità dwar il-Mediċini l-opportunità li tagħmel is-sottomissjonijiet tagħha b ġustifikazzjoni tal-fehma jew fehmiet li jkollha, u li ġġib kull prova li l-Bord jista jqis li tkun meħtieġa.

5. Il-Bord ikollu s-setgħa jħarrek xhieda u jagħti l-ġurament lil kull min jidher quddiemu.

6. Il-Bord ikollu s-setgħa jikkonferma jew inkella joħroġ fehma differenti minn dik li jsir appell kontriha, skond ma jista jqis li jkun xieraq.

7. Il-fehma tal-Bord għandha tkun waħda finali għad li ma tkunx skond id-deċiżjoni ta l-Awtorità dwar il-Liċenzjar u ma jista jsir ebda appell minnha ħlief fuq xi punt ta liġi biss.

8. Bla ħsara għad-disposizzjonijiet ta qabel u għad-disposizzjonijiet ta dan l-Att, il-Bord jirregola l-proċedura tiegħu nnifsu.

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## IT-TIELET SKEDA

### Kondizzjonijiet u kriterji li jistabbilixxu jekk persuna għandha jew m għandhiex interess dirett jew indirett fi spiżerija

(1) Ħadd ma jkollu dritt għal liċenza ta spiżerija jekk ikun tabib, kirurgu dentali, dentist jew veterinarju jew jekk ikun il-mara jew ir-raġel ta tabib, kirurgu dentali, dentist jew veterinarju.

(2) Ebda liċenza ma tingħata jew tiġġedded jekk tabib, kirurgu dentali, dentist jew veterinarju għandu interess dirett jew indirett fl-ispiżerija.

(3) Ebda tabib, kirurgu dentali, dentist jew veterinarju jew ħaddieħor awtorizzat minnhom biex joħroġ preskrizzjonijiet taħt l-Att dwar il-Mediċini jew Att ieħor, ma jista jagħmel qbil ma spiżjar jew ħaddieħor sabiex ikollu sehem mill-profitti ta l-ispiżerija, jew li jkollu interess dirett jew indirett ta kwalunkwe xorta fi kwalunkwe spiżerija.

(4) Ebda spiżjar ma jista :

(a) imexxi speżerija għal, jew bi ftehim ma tabib, kirurgu dentali, dentist jew veterinarju jew ħaddieħor awtorizzat minnhom biex joħroġ preskrizzjonijiet taħt l-Att dwar il-Mediċini jew Att ieħor;

(b) li jagħmel ftehim ma tabib, kirurgu dentali, dentist jew veterinarju jew ħaddieħor awtorizzat minnhom biex joħroġ preskrizzjonijiet kif diġà msemmi biex ikollu sehem fil-profitti mill-ispiżerija;

(ċ) li jislef ismu sabiex l-ispiżerija tinżamm minn ħaddieħor.

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Mgħoddi mill-Kamra tad-Deputati fis-Seduta Nru. 875 tal-25 ta Frar, 2003.

ANTON TABONE
*Speaker*

RICHARD J. CAUCHI
*Skrivan tal-Kamra tad-Deputati*

# MEDICINES ACT, 2003

Arrangement of Articles

## PART III - GENERAL PROVISIONS

### *TITLE I - Marketing authorisation relating to Medical Products*



### *TITLE II - Manufacture of Medicinal Products for Human Use*

109. Saving

| | | |
|---|---|---|
| First Schedule | - | Panel of experts to sit on Medicines Review Board |
| Second Schedule | - | Proceedings of the Medicines Review Board |
| Third Schedule | - | Conditions and criteria where any person can have or not have a direct or indirect interest in a pharmacy |

I assent.

**(L.S.)** GUIDO DE MARCO
President

5th March, 2003

**ACT No. III of 2003**

*AN ACT to make provision for matters connected with the manufacture, preparation and assembly, wholesale distribution, storage, destruction, disposal, advertising and authorisation of medicinal products and any activity connected therewith and the regulation of the sale of medicinal products, pharmacies and related pharmaceutical activities and for any other matters ancillary thereto or connected therewith.*

BE IT ENACTED by the President, by and with the advice and consent of the House of Representatives, in this present Parliament assembled, and by the authority of the same, as follows:-

Short title and commencement.

**1.** (1) The short title of this Act is the Medicines Act, 2003.

(2) This Act shall come into force on such date as the Minister responsible for health may by notice in the Gazette appoint, and different dates may be so appointed for different provisions or different purposes of this Act.

## PART I

### PRELIMINARY

Interpretation.

**2.** In this Act, unless the context otherwise requires -

"advertising" in relation to medicinal products includes any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products and without prejudice to the generality of the

foregoing in particular includes:

(a) the advertising of medicinal products to the general public;

(b) the advertising of medicinal products to persons qualified to prescribe or supply them;

(c) visits by medical or sales representatives to persons qualified to prescribe medicinal products;

(d) the supply of samples;

(e) the provision of inducements to prescribe or supply medicinal products, by way of a gift, offer or promise of any benefit or bonus, whether in money or in kind, except when the intrinsic value of such an inducement is minimal;

(f) sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products;

(g) sponsorship of any scientific congress attended by persons qualified to prescribe or supply medicinal products and in particular where payment of their travelling and accommodation expenses is offered in connection therewith;

but shall exclude:

(i) the labelling and the accompanying package leaflets, as may be specified in accordance with the provisions of Part III, Title I of this Act;

(ii) correspondence, even if accompanied by material of a non-promotional nature, which is in reply to a specific question about a particular medicinal product;

(iii) factual, informative, announcement or reference material relating to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues, price lists and other material of a similar nature provided that such material does not include any product claim;

(iv) any statement relating to human health or disease, provided there is no reference, whether direct or indirect, to a medicinal product;

"analysis" includes testing of a medicinal product or any of its

constituents, both active or inactive, in respect of their chemical, physical, pharmaceutical, biological, toxicological or pharmacological properties;

"assemble", in relation to a medicinal product, means to enclose the product in a container which is labelled before the product is sold or supplied, or, where the product is already enclosed in the container in which it is to be sold or supplied, labelling the container before the product is sold or supplied in it, and shall also include the act of introducing approved information in or on the container and "assembly" shall be construed accordingly;

"authorised officer" in relation to the Medicines Authority means any officer or employee of the Authority or any other person authorised by the Authority to act on its behalf and in relation to the Licensing Authority means any officer or employee of the Department as referred to in article 5 of the Department of Health (Constitution) Ordinance authorised by the Licensing Authority to act on its behalf; Cap. 94.

"business" means any economic activity whether carried out by the individual or by a body of persons, whether corporate or unincorporate and includes the exercise of a profession;

"clinical trial" means any investigation in human subjects intended to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal product under investigation, or to identify any adverse reactions to one or more medicinal product under investigation or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product with the object of ascertaining its safety or efficacy; and includes clinical trials carried out in either one site or multiple sites, whether locally or in one or more states recognised by the Licensing Authority;

"composition" in relation to a medicinal product, means the ingredients constituting it and the proportions, and the degrees of strength, quality and purity, in which those ingredients are respectively contained in it and as may be established in a recognised pharmacopoeia;

"container" in relation to a medicinal product, means the immediate packaging or outer packaging;

"cosmetic product" shall have the same definition as found under the Product Safety Act;

Cap. 31.

"dental practitioner" means a person who is authorised to exercise such profession under the Medical and Kindred Professions Ordinance or any other law replacing the same;

"disease" includes any injury, ailment or adverse condition, whether of body or mind;

"dispensing" includes sale or supply of medicinal products;

"foodstuff" shall have the same meaning as that under the Food Safety Act;

"good practice" in relation to manufacturing practice, laboratory practice, distribution practice, clinical practice and dispensing practice means the standards for the proper execution of the relative activity as established by or under this Act;

"herbal medicinal product" means any medicinal product containing as active ingredients one or more herbal substances or one or more herbal preparations or one or more herbal substances in combination with one or more such herbal preparations;

"herbal preparations" means preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration and fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates;

"herbal substances" means all mainly whole, fragmented or cut plants, plant parts, algae, funghi, lichen in an unprocessed, usually in dried form but sometimes fresh. Certain exudates which have not been subjected to a specific treatment are also considered to be herbal substances;

"homeopathic medicinal product" means any medicinal product prepared from products, substances or compositions referred to as homeopathic stocks in terms of a homeopathic manufacturing procedure described by a recognised Pharmacopoeia;

"immediate packaging" means the container or other form of packaging immediately in contact with the medicinal product;

"immunological medicinal product" means any medicinal product consisting of vaccine, toxin, serum or allergen product where:

(a) vaccine, toxin and serum include -

(i) agents used to produce active immunity;

(ii) agents used to diagnose immunity;

(iii) agents used to produce passive immunity; and

(b) "allergen product" means any medicinal product which is intended to identify or induce a specific acquired alteration in the immunological response to an allergising agent;

"ingredient" in relation to the manufacture or the preparation of a substance, includes anything which is the sole active ingredient of the substance as manufactured or prepared;

"investigational medicinal product" means a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, and includes products already with a marketing authorisation but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form;

"labelling" means any information on the immediate or outer packaging;

"licence" means a licence issued under the provisions of this Act;

"licensee" means any person who is the holder of a licence for a particular activity granted under this Act;

"magistral formula" means any medicinal product prepared in a pharmacy in accordance with a prescription for an individual patient;

"manufacture", in relation to a medicinal product, includes any process carried out in the course of manufacturing the product, but does not include dissolving or dispersing the product in, or diluting or mixing it with, some other substance used as a vehicle for the purpose of administering it;

"medical device" means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including any software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of -

(a) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

(c) investigation, replacement or modification of the anatomy or of a physiological process; and

(d) control of conception and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

"medical practitioner" means a person who is authorised to exercise such profession under the Medical and Kindred Professions Ordinance or any other law replacing same;

"medicinal prescription" means any prescription issued by a professional person qualified to prescribe medicinal products by or under this Act;

"medicinal product" means any substance or combination of substances presented for treating or preventing disease in human beings, as well as any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings;

"medicinal purpose" includes any one or more of the following purposes:

(a) the treating or preventing disease;

(b) the diagnosing of disease or ascertaining the existence, degree or extent of a physiological condition;

(c) contraception;

(d) inducing anaesthesia;

(e) the prevention or interference with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing or increasing or accelerating the operation of that function or in any other way.

"Medicines Authority" means the Authority established under article 4;

"Medicines Review Board" means the Board established under

article 14;

"Minister" means the Minister responsible for public health;

"official formula" means any medicinal product that is prepared in a pharmacy in accordance with instructions found in a prescription of a recognised pharmacopoeia and which is intended to be supplied directly to a patient being served by the said pharmacy;

"outer packaging" means the packaging into which the immediate packaging is placed;

"package", in relation to any medicinal product, means any box, packet or other article in which one or more container of the product are, or are intended to be, enclosed, and, where any such box, packet or other article is, or is to be itself enclosed in one or more other boxes, packets or articles, includes any of the said boxes, packets or articles;

"package leaflet" means a leaflet containing information for the user which accompanies the medicinal product;

"pharmacist" means a person who is authorised to exercise such profession under the Medical and Kindred Professions Ordinance, or any other law replacing the same;

"pharmacy technician" means a person authorised to act as such under the Medical Kindred and Profession Ordinance or any other law replacing the same;

"pre-packaging" means the act by which a pharmacist divides a medicinal product into quantities more appropriate for individual patient use, thus changing the outer packaging of this product for the act of dispensing;

"prescribed" means prescribed by regulations made by the Minister under this Act;

"qualified person" means any person who is a qualified person in relation to a manufacturer’s licence as provided in article 38 (1)(e);

"radionuclide generator" means any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be removed by elution or by any other method and used in a radiopharmaceutical;

"radionuclide kit" means any preparation to be reconstituted or combined with radionuclides in the final radiopharmaceutical, usually

prior to its administration;

"radionuclide precursor" means any radionuclide not being a radiopharmaceutical, radionuclide generator or radionuclide kit which is produced for the radio-labelling of another substance prior to administration;

"radiopharmaceutical" means a medicinal product which, when ready for use, contains one or more radionuclides included for a medicinal purpose;

"recognised laboratory" means any laboratory recognised as such by the Licensing Authority for the purposes of this Act;

"recognised pharmacopeia" means a pharmacopeia recognised by rules for the purpose of this Act;

"responsible person" means any person who is a responsible person in relation to a wholesale dealer's licence as provided in article 55(1)(d);

"rules" means rules made by the Licensing Authority under the provisions of this Act;

"substance" means any matter irrespective of origin be it human (including human blood and human blood products), animal (including micro-organisms, whole animals, parts of organs, animal secretions, extracts), vegetable (including micro-organisms, plants, parts of plants, vegetable secretions, extracts), or chemical (including elements, naturally occurring chemical materials or chemical products obtained by chemical change or synthesis);

"Superintendent of Public Health" has the same meaning as is assigned to it by article 4 of the Department of Health (Constitution) Ordinance;

"veterinary surgeon" means a person who is authorised to exercise such profession under the Veterinary Services Act, 2002, or any other law replacing the same;

"wholesale distribution" in relation to a medicinal product, includes all activities consisting of procuring, holding, supplying, distributing, exporting or importing medicinal products, other than retail sale or for personal use.

## PART II

ADMINISTRATION

*Title I - The Licensing Authority*

Functions of the Licensing Authority.

**3.** (1) The Superintendent of Public Health shall be the Licensing Authority for the purposes of this Act.

(2) The Licensing Authority shall have the following functions:

(a) to establish standards to ensure the quality, safety and efficacy of medicinal products;

(b) to establish standards for the operation of pharmacies;

(c) to establish standards for the manufacture, preparation, assembly, packing, packaging or re-packing and labelling of medicinal products or any substance which is used or is intended to be used in such products;

(d) to establish standards for the operation of wholesale distribution;

(e) to establish standards for the testing or analysis of medicinal products or any substance which is used or is intended to be used therein;

(f) to establish standards for the carrying out of clinical trials;

(g) to establish standards for the reporting of adverse reactions, serious adverse reactions or suspected unexpected adverse reactions and make provision for the collection or submission of related information from any person or activity regulated by or under this Act;

(h) to establish standards in relation to the advertising of medicinal products;

(i) to advise the Minister in the making of regulations in respect of the classification of medicinal products;

(j) to issue, renew, amend, vary, suspend or revoke marketing authorisations for medicinal products;

(k) to withdraw or recall medicinal products from the market in the interest of public health ; and

(l) to ensure compliance with international obligations entered into by the Government of Malta in relation to any matter regulated by or under this Act;

(m) to issue, renew, amend, vary, suspend or revoke any authorisation or licence that may be required by or under this Act;

(n) to carry out inspections of any activity, service or procedures in relation to medicinal products and to do all such things as may be necessary for the purpose of ensuring compliance with any provisions of this Act, or made thereunder v;

(o) to authorise the advertising and promotion of medicinal products;

(p) to carry out any other activity as may be prescribed;

(q) to advise the Minister on any matter connected with its functions or any other provision of this Act.

(3) The Licensing Authority may by rules delegate any of its functions referred to in subarticle (2)(m) (n) and (o) to the Medicines Authority.

(4) The Licensing Authority shall levy such fees as may be prescribed for the purpose of this Act:

Provided that such regulations may provide for the waiving of such fees in such circumstances as may be prescribed.

(5) For the proper exercise of its functions, the Licensing Authority may establish advisory committees as it may deem necessary.

*Title II - The Medicines Authority*

Establishment of the Medicines Authority.

**4.** There shall be established a Medicines Authority, which shall be headed by a Chief Executive Officer.

Legal personality of the Medicines Authority.

**5.** (1) The Medicines Authority shall be a body corporate having a separate and distinct legal personality and shall be capable, subject only to the provisions of this Act, of entering into any contract, of acquiring, holding and disposing of any kind of property

both movable and immovable, of employing personnel for the purposes of its operations; and of suing and being sued, and to which any function or operation of government are or may be assigned under this or any other law.

(2) The legal and judicial representation of the Medicines Authority shall vest in the Chief Executive Officer:

Provided that the Medicines Authority may appoint one or more of its officers or employees to appear in its name and on its behalf in any judicial proceedings or in any act, contract, instrument or other document whatsoever.

Functions of the Medicines Authority.

**6.** (1) The Medicines Authority shall have the following functions:

(a) to carry out those such functions as may be delegated to it by the Licensing Authority in terms of article 3(3);

(b) to assist and advise the Licensing Authority on any matter relating to the regulation of medicinal products and related activities;

(c) to undertake such activities and projects as may be necessary or expedient for the proper exercise of its functions;

(d) to establish such procedures as may be necessary for obtaining and assessing information as regards the safety, quality and efficacy of medicinal products to be placed on the market in Malta;

(e) to establish such procedures as may be necessary to make such assessments of medicinal product safety, quality and efficacy as it may deem necessary for those products to be placed on the market in Malta;

(f) to establish such procedures as may be necessary for monitoring and obtaining reports on the quality, safety or efficacy of medicinal products;

(g) to make recommendations to the Licensing Authority in relation to standards and licensing;

(h) to advise the Licensing Authority on the precautions or restrictions to which medicinal products may be subjected for their marketing or continued use in Malta; and

(i) to furnish, whenever it so thinks fit or is so requested by the Licensing Authority, advice or make recommendations to the Licensing Authority in relation to any matter connected with its functions.

(2) For the proper exercise of its functions, the Medicines Authority may require the production of such information or documents as may be necessary for any of its functions and may seek expert advice from any person, who is not a member of the Medicines Review Board, possessing the necessary qualifications and experience in the fields listed in the First Schedule, and may also establish such advisory committees as it may deem necessary, either for general or specific purposes.

(3) The Medicines Authority shall levy such fees as may be prescribed for the purposes of this Act:

Provided that such regulations may provide for the waiving of such fees in such exceptional circumstances as may be prescribed .

Organisation of the Medicines Authority.

**7.** The Authority shall establish such Directorates as may be necessary, and shall assign to each such Directorate those functions which it may deem expedient for the proper exercise of its functions.

The Chief Executive Officer of the Medicines Authority.

**8.** (1) The Chief Executive Officer shall be appointed by the Minister from amongst persons who are suitably qualified and experienced in the medical, pharmaceutical or medical science sector.

(2) The Chief Executive Officer shall be responsible for the overall management and performance of the Authority including the management of the day-to-day operations of the Authority.

(3) A person shall not be eligible to be appointed or to hold office as Director or Chief Executive Officer of the Authority if he:

(i) is a member of the House of Representatives; or

(ii) is a Judge or a Magistrate; or

(iii) is legally incapacitated; or

(iv) has been declared bankrupt or has made a composition or arrangement with his creditors; or

(v) has been convicted of fraud or any other offence against public trust, or has otherwise been sentenced to a term of imprisonment for a term not less

than three months; or

(vi) has a financial or other interest whether direct or indirect, in any enterprise or activity which is likely to affect the discharge of his functions as a member of the Authority.

(4) (a) The Chief Executive Officer of the Authority shall hold office for a period not exceeding five years and shall be eligible for re-appointment for further periods each not exceeding five years.

(b) The Chief Executive Officer of the Authority may be relieved from office by the Minister prior to the expiry of his term of office where, in the opinion of the Minister, he has been guilty of misconduct or on the ground of inability to continue to perform the functions of his office, whether due to infirmity of mind or of body, or to any other cause, or of misbehaviour.

Employees of the Medicines Authority.

**9.** (1) Subject to the provisions of the Constitution and of any other enactment applicable thereto, and without prejudice to the other provisions of this Act, the appointment of officers or employees of the Authority shall be made by the Authority. The terms and conditions of employment shall be established by the Authority with the concurrence of the Minister, given after consultation with the Minister responsible for finance.

(2) The Prime Minister may, at the request of the Authority after it consults with the Minister, from time to time and by direction detail a public officer for duty with the Authority in such a capacity and for such term and under such conditions as may be established in relation to the officer so detailed.

(3) The Prime Minister may at any time revoke any such direction given under subarticle (2).

(4) Where an officer is detailed for duty with the Authority such officer shall, during the time in which such a direction is in force, be under the administrative direction and control of the Chief Executive Officer and shall otherwise remain and retain all rights and duties as a public officer and for the purposes of any law relating to government service pension, service with the Authority shall be deemed to be service with the Government:

Provided that no account shall be taken in assessing the pensionable emoluments of such officer for the purposes of any law relating to government service pensions of any allowances, bonuses or gratuities paid to such officer by the Authority in excess to what he is entitled as a public officer:

Provided further that during the time in respect of which he is so detailed to perform duties with the Authority the terms and conditions of his service shall not be less favourable than those which are attached to his appointment under the Government during the period aforesaid. Such terms and conditions shall not be deemed to be less favourable merely because they are not in all respects identical with or superior to those enjoyed by the officer concerned at the date of such offer, if such terms and conditions, taken as a whole, in the opinion of the Prime Minister offer substantially equivalent or greater benefits.

Accounts of the Medicines Authority.

**10.** (1) The Authority shall keep proper books of account in such manner as the Minister of Finance may from time to time direct. Such accounts shall be audited by an auditor appointed for the purpose by the Authority and shall moreover be subject to audit by the Auditor General.

(2) The Authority shall, not later than six weeks after the end of each financial year, present to the Minister and the permanent secretary the audited accounts together with a report on the workings of the agency which report shall state the manner in which the agency has operated to fulfil its functions and its plans in the future.

(3) The reports referred to in subarticle (2) shall be laid on the Table of the House of Representatives by the Minister not later than six weeks after its receipt, or where the House is during the period not in session not later than the second week after the House resumes its sittings.

Procurement by the Medicines Authority.

**11.** Except with the approval of the Minister, the Authority shall not enter into any contract for the supply of goods or materials or for the execution of work or for the rendering of services, to or for the benefit of the Authority, which is estimated by the Authority to involve an expenditure exceeding one hundred thousand liri or such other amount as the Minister may from time to time direct in writing, except after notice of the intention of the Authority to enter into such contract has been published and competitive tenders have been issued.

Applicability of the Code of Ethics.

**12.** The Chief Executive Officer and all other executive officers and employees of the Authority shall conform with and abide by any public service values and Code of Ethics that may be in force from time to time in relation to public officers.

Exemption from tax, etc.

**13.** The Authority shall be exempt from any liability for the payment of any tax on income or duty on documents for the time being in force in Malta.

*Title III - Medicines Review Board*

Establishment of Medicines Review Board.

**14.** (1) There shall be a Medicines Review Board which shall be composed of three members and three substitute members appointed by the Minister, as follows:

(a) a person who shall be a legal practitioner having at least seven years' legal experience who shall act as the chairperson; and

(b) two other persons who possess the technical and scientific qualifications and experience in the field of regulation of medicinals.

(2) The Minister shall designate a public officer to act as secretary for the Medicines Review Board.

(3) The members of the Medicines Review Board shall be appointed by the Minister for a term of three years under such terms and conditions as may be specified in their appointment. Members so appointed may be re-appointed on the expiration of their term of office.

(4) Where any member of the Medicines Review Board is unable to act, the substitute member having the same qualifications shall act in his stead.

(5) A person shall not be qualified to hold office as a member or substitute member of the Medicines Review Board if he:

(i) is a member of the House of Representatives, or

(ii) is a Judge or a Magistrate; or

(iii) is legally incapacitated; or

(iv) has been declared bankrupt or has made a composition or arrangement with his creditors; or

(v) has been convicted of fraud or any other offence against public trust, or has otherwise been sentenced to a term of imprisonment for a term not less than three months; or

(vi) has a financial or other interest, whether direct or indirect, in any enterprise or activity which is likely to affect the discharge of his functions as a member

of the Board.

Cap. 12.

(6) The provisions of Sub-title II of Title II of Book Third of the Code of Organization and Civil Procedure shall, *mutatis mutandis*, apply to members of the Medicines Review Board who may be challenged or may abstain from sitting on that Board during the hearing of an appeal.

(7) A person shall cease to be a member of the Medicines Review Board at the expiration of his term of office, or if any circumstances arise that, if he were not a member of the Medicines Review Board, he would cease to be qualified for such appointment.

(8) A member of the Medicines Review Board may be removed from office by the Minister if, in his opinion, such member is no longer fit to continue in office or has become incapable of properly performing his duties as a member.

Medicines Review Board may appoint advisors.

**15.** (1) In the execution of its functions, the Medicines Review Board may seek the advice of any knowledgeable person on any matter which is the subject of an appeal being heard.

(2) The Board may also require any government department and, or authority to provide it with such information or advice it may deem necessary for the proper exercise of its functions.

Functions of the Medicines Review Board.

**16.** (1) It shall be the function of the Medicines Review Board:

(a) to hear any appeal made by any person aggrieved by any recommendation of the Medicines Authority in relation to the safety, quality and efficacy of a medicinal product following an application for a marketing authorisation submitted by the appellant;

(b) to provide advice and make its recommendations to the Licensing Authority regarding any appeal or request made to it.

(2) Concurrently with the submission of its recommendations to the Licensing Authority, the Board shall also submit a copy of such recommendations to the appellant and to the Medicines Authority.

(3) Any administrative and financial support required by the Medicines Review Board for the performance of its functions shall be provided by the Licensing Authority.

(4) Subject to the foregoing provisions the business of the

Medicines Review Board shall be conducted in accordance with the rules contained in the Second Schedule and otherwise the Board may regulate its own procedure.

Procedure of appeal.

**17.** (1) Where an applicant for a marketing authorisation feels aggrieved by the findings and recommendations made by the Medicines Authority to the Licensing Authority, he may, within fourteen days of the receipt of a copy of such findings and recommendations, file an appeal with the Medicines Review Board.

(2) The Licensing Authority may, if it deems it necessary, within fourteen days of the receipt of the findings and recommendations of the Medicines Authority on the safety, quality and efficacy of a medicinal product, request the Medicines Review Board to provide it with a second opinion on the case.

(3) Any appeal or request for review shall be made in writing and shall be accompanied by the prescribed fee.

(4) The application for an appeal or request for review shall clearly and comprehensively state the grounds for the appeal or review and shall provide all evidence and documentation to sustain any claim made and which may be necessary to enable the Board to decide on the case:

Provided that the Medicines Review Board may require the submission of such further information or documentation as it may deem necessary:

Provided further that the Medicines Review Board shall after obtaining all the relevant information, process the application within a time limit specified in regulations made under this Act.

Public hearing.

**18.** (1) The Medicines Review Board shall appoint the matter for public hearing within thirty days of the day of filing of the appeal or request for review and shall decide the matter as expeditiously as possible.

(2) The Medicines Review Board will inform the appellant, the Licensing Authority and the Medicines Authority of its opinion in writing as soon as is practicable.

## PART III

GENERAL PROVISIONS

*Title I - Marketing Authorisation Relating to Medicinal Products*

Applicability of certain provisions.

**19.** (1) The provisions of articles 20 to 36 shall apply to industrially produced medicinal products for human use intended to be placed on the market in Malta.

(2) Articles 20 to 36 shall not apply to -

(a) any medicinal product prepared in accordance with a magistral formula;

(b) any medicinal product prepared in accordance with an official formula;

(c) medicinal products intended for research and development trials;

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

(e) radionuclides in the form of sealed sources.

Authorisation to place medicinal products on the market.

**20.** (1) No person shall place a medicinal product on the market in Malta unless he is in possession of a marketing authorisation from the Licensing Authority, in accordance with the provisions of this Act or any regulations or rules made thereunder:

Provided that the Licensing Authority may, in exceptional cases, allow the use of a medicinal product without a marketing authorisation subject to such conditions as it may attach to it:

Provided further that a medicinal product that is essentially identical to a medicinal product for which a marketing authorisation has already been granted shall only be subject to conditions as may be determined by the Licensing Authority.

(2) Any application for the grant of a marketing authorisation shall be made to the Licensing Authority and shall be accompanied by the prescribed fee.

(3) The application shall contain all the information and documents necessary for the assessment of the safety, quality and efficacy of the medicinal product and shall be submitted in such form and manner as the Licensing Authority may by rules require.

(4) The Licensing Authority shall forward the application submitted to it to the Medicines Authority as soon as possible.

(5) Where an application for the issue of a marketing authorisation is received by the Medicines Authority, the Authority may -

(a) refuse to process the application if such application is not submitted in accordance with the provisions of this Act;

(b) request the applicant to furnish it with such further information relating to the application as it may consider necessary; and where any such request has been made, the Medicines Authority shall not be required to determine the application until the information as requested has been submitted to it;

(c) assess the application in respect of medicinal product safety, quality and efficacy in such a manner and within such period as may be prescribed by or under this Act; and

(d) carry out any other activity as may be prescribed by the Minister from time to time.

(6) The Medicines Authority shall report its findings and make its recommendations to the Licensing Authority, and shall submit a copy thereof to the applicant, in such a manner and within such period as may be prescribed.

Review or appeal.

**21.** Where the Licensing Authority or the applicant disagree with the findings or recommendations of the Medicines Authority, either party may lodge an appeal to the Medicines Review Board in the manner established under this Act.

Granting of marketing authorisation.

**22.** (1) On receipt of the findings and recommendations of the Medicines Authority, or following an appeal or a request for a review by the Medicines Review Board, the Licensing Authority may refuse or otherwise issue a marketing authorisation either as recommended by the Medicines Authority or subject to any such condition or obligation as it may deem necessary.

(2) The decision of the Licensing Authority shall be final and together with the detailed reasons for such decision shall be communicated to the Medicines Review Board, the Medicines Authority and the applicant as necessary.

Notification of marketing authorisation.

**23.** (1) In granting or refusing a marketing authorisation, the Licensing Authority shall also inform the Medicines Authority of

such a decision.

(2) A marketing authorisation shall specify:

(a) the summary of product characteristics as approved;

(b) the approved labelling and packaging;

(c) any conditions that may be attached to the granting of the marketing authorisation;

(d) the classification of the medicinal product;

(e) the term of validity of the marketing authorisation;

(f) any other specification that the Licensing Authority may deem necessary.

Validity of market authorisation.

**24.** (1) Every marketing authorisation granted under this Act, shall unless previously revoked, expire at the end of its validity.

(2) Every marketing authorisation so granted under this Act shall unless previously revoked, be renewable upon an application by the holder made at least three months before the expiry of the period of validity.

Application of renewal.

**25.** (1) Where an application for the renewal of a marketing authorisation under this Act has been duly made, the validity of the marketing authorisation shall be deemed to continue to have effect until such time as the Licensing Authority has determined the application.

(2) Notwithstanding the provisions of any other law, no court may issue a warrant of prohibitory injunction restraining the Licensing Authority from determinining any such application.

Notification of refusal.

**26.** The Licensing Authority shall refer an application for renewal of a marketing authorisation to the Medicines Authority, and in such case the provisions of article 20(4), (5) and (6) and of article 21 shall, *mutatis mutandis* apply.

Refusal to renew marketing authorisation.

**27.** (1) The Licensing Authority may refuse to grant or renew the marketing authorisation on the basis of poor quality, safety and efficacy of the medicinal product or in the interest of public health or any other reason that would normally be a valid reason for the suspension, revocation or refusal of a marketing authorisation:

Provided that the Licensing Authority shall notify the Medicines Authority and the applicant of the decision giving detailed

reasons for such decision.

(2) A renewal of a marketing authorisation shall specify -

(a) the summary of product characteristics as approved;

(b) the approved labelling and packaging;

(c) any conditions that may be attached to the granting of the marketing authorisation;

(d) the classification of the medicinal product;

(e) the term of validity of the marketing authorisation;

(f) any other specification that the Licensing Authority may deem necessary.

Suspension or revocation of marketing authorisation.

**28.** (1) The Licensing Authority shall suspend or revoke a marketing authorisation for a medicinal product where that product proves to be harmful in the normal conditions of use, or where its therapeutic efficacy is lacking, or where its qualitative and quantitative composition is not as declared. For the purpose of this article therapeutic efficacy shall be deemed to be lacking when it is established that therapeutic results cannot normally be obtained with the medicinal product.

(2) An authorisation shall also be suspended or revoked where the particulars supporting the application as provided for in this Act are found to be incorrect or have been amended without authorisation or when the requisite controls required by or under this Act have not been carried out.

(3) When the packaging, labelling or the package leaflet of the medicinal product in question do not comply with the requirements as specified by or under this Act, the Licensing Authority may suspend the marketing authorisation by notice served on the holder of the marketing authorisation concerned and the suspension shall continue to have effect until the Licensing Authority is satisfied that the requirements have been fulfilled.

(4) If the Licensing Authority suspends or revokes a marketing authorisation, it shall notify the holder of the marketing authorisation and the Medicines Authority of such decision stating in detail the reasons on which such a decision is based.

(5) The holder of the marketing authorisation may, within fourteen days of such notification, request the Medicines Review

Board to examine the circumstances leading to the suspension or the revocation of the marketing authorisation, and the Medicines Review Board shall make its recommendations on the matter to the Licensing Authority:

Provided that the request shall not suspend the effects of the decision of the Licensing Authority and that the Licensing Authority shall not be bound by the recommendations made by the Medical Review Board.

Classification of medicinal products.

**29.** (1) When a marketing authorisation is granted or renewed, the Licensing Authority shall specify the classification of the medicinal product in accordance with the provisions of this Act, but in general into:

(a) a medicinal product subject to a medicinal prescription; or

(b) a medicinal product not subject to a medicinal prescription, where such medicinal product is considered that with reasonable safety it can be sold or supplied by or under the supervision of a pharmacist unless otherwise provided for by this Act that a medicinal product under paragraph (b) of subarticle (1) is classified under paragraph (a) of subarticle (1).

(2) The Licensing Authority may by rules determine the type, content and presentation or otherwise of a prescription and who is authorised to issue the said prescription that may be needed for a medicinal product or class of medicinal products.

List of medicinal products having a marketing authorisation.

**30.** (1) The Licensing Authority shall, at least annually, publish in the Gazette a list specifying -

(a) the medicinal products that have a valid marketing authorisation;

(b) the medicinal products which may only be sold by prescription; and

(c) where applicable, the type of prescription required and the person or persons authorised to issue the said prescription.

(2) Whenever a marketing authorisation has been issued in relation to a medicinal product the Licensing Authority shall publish in the Gazette the information specified in subarticle (1)(a), (b) and (c) and such publication shall be deemed to amend the list of medicinal products issued under subarticle (1).

(3) The Licensing Authority shall publish in the Gazette, as soon as is practical, the list of medicinal products for which the marketing authorisation has been suspended or revoked and such publication shall be deemed to amend the list of medicinal products issued under subarticle (1).

Advertising of medicinal products.

**31.** A medicinal product may only be advertised in accordance with such conditions as may be established by or under this Act.

Homeopathic medicinal products.

**32.** The provisions of this Part shall apply to homeopathic medicinal products for human use except for homeopathic medicinal products which:

(a) are administered orally and externally, subject to such regulations as may be made by the Minister in respect thereof;

(b) have no specific therapeutic indication appearing on the labelling of the medicinal product or in any information relating thereto; and

(c) have a sufficient degree of dilution to guarantee the safety of the medicinal product, in particular, the medicinal product may not contain either more than one part per 10,000 of the mother tincture or more than $1/100^{th}$ of the smallest dose used in allopathy with regard to active principles whose presence in an allopathic medicinal product results in the obligation to submit a medicinal prescription.

Products derived from human blood or human plasma.

**33.** The provisions of this Part shall apply to medicinal products based on blood constituents which are prepared industrially by a private or a public establishment but shall not apply to blood, plasma or blood cells of human origin.

Radiopharmaceutical medicinal product.

**34.** The marketing authorisation referred to in article 20 shall be required for generators, kits, precursor radiopharmaceuticals and industrially prepared radiopharmaceuticals other than radiopharmaceuticals prepared at the time of use by a person or by an establishment authorised, under this Act, to use such medicinal products in an approved health care establishment exclusively from authorised generators, kits or precursor radiopharmaceuticals in accordance with the manufacturer's instructions.

Immunological medicinal products.

**35.** (1) The provisions of this Part shall apply to immunological medicinal products.

(2) The Licensing Authority may prescribe rules regulating the issue or otherwise of a marketing authorisation for immunological

medicinal products.

Herbal medicinal products.

**36.** (1) The provisions of this Part shall apply to herbal medicinal products other than herbal medicinal products prepared in accordance with a magistral or an official formula:

(2) The Licensing Authority may prescribe rules regulating the issue or otherwise of a marketing authorisation for herbal medicinal products.

*Title II - Manufacture of Medicinal Products for Human Use*

Manufacturer's licence.

**37.** Without prejudice to any exemption that may be granted under this Act, no person shall manufacture, assemble or in any way modify any medicinal product except in accordance with a manufacturer's licence issued in accordance with the provisions of this Act or any regulations or rules made thereunder:

Provided that such a licence shall not be required for the preparation, division, changes in packaging or presentation where these processes are carried out for the purpose of dispensing or administering as provided under this Act.

Application for manufacturer's licence.

**38.** (1) Any application for the grant of a licence to manufacture, assemble or modify a medicinal product shall be made to the Licensing Authority and shall contain such information, documents, samples and other material as provided by or under this Act:

Provided that such application shall indicate the following:

(a) the name of the medicinal product and pharmaceutical form or forms, which is to be manufactured, assembled or in any way modified;

(b) the place where such activity is to take place, and such information and documentation as may be required in order to show that such place is suitable and sufficient for that purpose;

(c) the equipment and control facilities as may be required by or under this Act;

(d) the name and address of the applicant;

(e) the name of at least one qualified person who shall be professionally responsible for the activity, such person having such qualifications as may be prescribed:

Provided that when more than one qualified person is nominated, the application will clearly delineate the specific responsibilities of each person;

(f) any other information, documentation or evidence as may be requested by the Licensing Authority in accordance with or under this Act.

(2) The Licensing Authority shall determine the application in the period of time as may be established under this Act:

Provided that such time may be suspended until the relevant information is provided.

Granting of manufacturer's licence.

**39.** (1) The Licensing Authority shall, before determining an application, inspect the premises indicated in the application and shall not issue a licence until it is satisfied that such premises conform with the requirements established by or under this Act:

Provided that a licence may be made conditional to the carrying out of such obligations as may be imposed therein.

(2) The manufacturer's licence shall specify the premises and the medicinal products and pharmaceutical form or forms to which it applies.

(3) The licence holder shall ensure that the activity is carried out in accordance to the provisions of this Act and any regulations made thereunder.

Notice for further information.

**40.** Where the Licensing Authority considers that circumstances may exist which would render necessary the consideration of whether the licence should be varied, suspended or revoked, the Licensing Authority may serve on the holder of a manufacturer's licence a notice requiring him, within such time as may be specified in the notice, to furnish it with any information specified in the notice.

Suspension or revocation of manufacturer's licence.

**41.** (1) The Licensing Authority may suspend a manufacturer's licence under this Act for such period as it may determine, or may revoke, or vary the provisions of, any such licence.

(2) The powers vested in subarticle (1) shall only be exercisable in any of the following circumstances, where:

(a) the matters stated in the application on which the licence was granted were false or incomplete in a material particular;

(b) a material change of circumstances has occurred in relation to any of those matters;

(c) any of the conditions of the licence has been contravened;

(d) the requirements in relation to the licences as established by or under this Act have not been complied with;

(e) the processes of manufacture or assembly of a medicinal product are carried out in a manner that is not in compliance with the provisions of the marketing authorisation of that medicinal product;

(f) the conditions for good manufacturing practice are not being complied with; and

(g) in any other circumstance as is established by or under this Act.

Inspection in relation to manufacturers, etc.

**42.** (1) The Licensing Authority shall carry out regular inspections to ensure that the requirements established by or under this Act in relation to the manufacture, assembly or modification of a medicinal product are complied with.

(2) The Licensing Authority or any person carrying out an inspection shall:

(a) inspect the manufacturing establishment and any other location he may deem necessary;

(b) examine any relevant documents;

(c) take any samples he may deem necessary;

(d) draw up a report of the findings and communicate the contents of such report to the licensee or the applicant for a licence in relation to such inspection and to the qualified person;

(e) carry out any other activity he may deem appropriate for the proper execution of his duties and responsibilities as provided for by or under this Act.

(3) Except in urgent cases an inspection shall be carried out in the presence of a qualified person or his representative, if any, .

Duration and renewal of manufacturer's licence.

**43.** (1) Subject to the provisions of this Act, every licence granted under this Part shall, unless previously renewed or revoked, expire at the end of its validity.

(2) Any licence so granted shall, unless previously revoked, be renewable upon an application by the licensee made at least three months before the expiry of the validity period.

(3) The Licensing Authority may by rules establish the period of validity of any licence issued under this Part.

(4) On an application to the Licensing Authority for the renewal of a licence under this Part, the Licensing Authority:

(a) may renew the licence, with or without modifications, for such a further period as specified; or

(b) if, having regard to the provisions of this Act, it considers it necessary or expedient to do so, may refuse to renew the licence.

(5) The provisions of articles 25, 39 and 40 shall apply to such applications.

Responsibilities of manufacturer's licence holder.

**44.** It shall be the duty of the holder of a manufacturer's licence -

(a) to immediately inform the Licensing Authority of any change of the qualified person;

(b) to provide authorised officers access to his premises at any reasonable time;

(c) to enable the qualified person to carry out his duties established by or under this Act;

(d) to maintain such records for any transaction in medicinal products as may be established by or under this Act and have such records available for inspection by any authorised officer for such period of time as may be required by or under this Act;

(e) to have at his disposal the services of staff to satisfy the requirements specified by or under this Act in relation to the manufacture, assembly or modification of medicinal products;

(f) to apply in writing to the Licensing Authority of any change proposed or modification required in relation to the licence;

(g) to comply with the regulations or Orders relating to good practice in manufacture as may be established by or under

this Act or under any other Act;

(h) to dispose of medicinal products as established by or under this Act or under any other Act;

(i) other responsibilities as may be established from time to time by or under this Act.

Responsibilities of the qualified person.

**45.** (1) The responsibilities of a qualified person shall be:

(a) to ensure that standards of good practice in manufacturing are complied with at all times;

(b) to ensure that each batch of medicinal products has been manufactured, tested and complies in all respects with any requirement established by or under this Act; and

(c) to ensure that each batch of medicinal products has been manufactured in accordance with the requirements of the marketing authorisation.

(2) The qualified person shall at all times be present at the premises when the activity is being carried out:

Provided that the qualified persons may nominate another person similarly qualified to act as his representative.

(3) When the qualified person has nominated a representative as aforesaid he shall immediately inform the Licensing Authority of such nomination.

Suspension of activity of a qualified person.

**46.** The Licensing Authority, may if it has reasonable suspicion to believe that any qualified person is acting in contravention of any of the provisions of this Act, suspend the activity of such qualified person by notice in writing specifying the reasons for such suspension until such person has complied with any requirement of the Licensing Authority to remedy the non-compliance.

Change in conditions of manufacturer's licence.

**47.** The Licensing Authority may upon an application made by the holder of licence in request thereof, vary the conditions of the licence if it is satisfied that such variation will not adversely affect standards of good practice in manufacture as may be prescribed.

Obligations of Licensing Authority.

**48.** The Licensing Authority may vary, suspend, revoke or refuse to renew a manufacturer's licence, or it may refer the matter to the Medicines Authority, and in such case the provisions of article 20(4), (5) and (6) and of article 21 shall, *mutatis mutandis* apply.

**49.** Without prejudice to article 32, the provisions of articles 37 to 48 shall apply to the manufacture and assembly of homeopathic medicinal products other than the products listed in article 32(a) (b) and (c). Manufacture of homeopathic medicinal products.

**50.** Without prejudice to article 33, the provisions of articles 37 to 48 and any regulations made thereunder shall apply to the manufacture and assembly of medicinal products derived from human blood and human plasma other than the products listed in article 32(a) (b) and (c). Manufacture of medicinal products derived from human blood and human plasma, etc.

**51.** Without prejudice to article 34, the provisions of articles 37 to 48 and any regulations made thereunder shall apply to the manufacture and assembly of radiopharmaceutical medicinal products other than the products listed in article 32(a) (b) and (c). Manufacture of radiopharma-ceuticals.

**52.** Without prejudice to article 35, the provisions of articles 37 to 48 and any regulations made thereunder shall apply to the manufacture and assembly of immunological medicinal products other than the products listed in article 32(a) (b) and (c). Immunological medicinal product.

**53.** Without prejudice to article 36, the provisions of articles 37 to 48 and any regulations made thereunder shall apply to the manufacture and assembly of herbal medicinal products other than the products listed in article 32(a) (b) and (c). Herbal medicinal products.

*Title III - Wholesale Distribution of Medicinal Products for Human Use*

**54.** (1) Without prejudice to any exemptions that may be granted by or under this Act, no person shall engage in the wholesale distribution of any medicinal product unless he is the holder of a wholesale dealer's licence issued in accordance with the provisions of this Act. and unless the medicinal product has been granted a marketing authorisation by the Licensing Authority. Wholesale dealing.

(2) The wholesale distribution of a medicinal product by way of wholesale dealing shall only be carried out from the place specified in, and in accordance with the conditions of, the licence.

**55.** (1) Any application for the grant of a wholesaler's licence shall be made to the Licensing Authority and shall contain such information, documents, and other material as provided by or under this Act: Application for a wholesale dealer's licence.

Provided that such application shall indicate the following:

(a) the name and address of the applicant;

(b) the address of the premises that are to be used for the purpose of wholesale distribution;

(c) the equipment and control facilities as may be required by or under this Act;

(d) information, documentation or evidence to prove that the premises is suitable and adequate, and that there are suitable facilities, installations and equipment so as to ensure proper conservation and distribution of medicinal products;

(e) the name of at least one responsible or qualified person who shall be professionally responsible for the activity, such person having such qualifications as may be prescribed:

Provided that when more than one qualified or responsible person is nominated, the application will clearly delineate the specific responsibilities of each person;

(f) any other information, documentation or evidence as may be requested by the Licensing Authority in accordance with or under this Act.

(2) The Licensing Authority shall determine the application in the period of time as may be established under this Act:

Provided that such time may be suspended until the relevant information is provided.

Granting of a wholesale dealer's licence.

**56.** (1) The Licensing Authority shall, before determining an application, inspect the premises indicated in the application and shall not issue a licence until it is satisfied that such premises conform with the requirements established by or under this Act:

Provided that a licence may be made conditional to the carrying out of such obligations as may be imposed therein.

(2) The wholesale dealer's licence shall specify the premises and the activities to which it applies.

(3) The licence holder shall ensure that the activity is carried out in accordance to the provisions of this Act and any regulations made thereunder.

Notice for further information.

**57.** Where the Licensing Authority considers that circumstances may exist which would render necessary the consideration of whether the licence should be varied, suspended or revoked, the Licensing Authority may serve on the holder of a

wholesale dealer's licence a notice requiring him, within such time as may be specified in the notice, to furnish it with any information specified in the notice.

Duration and renewal of wholesale dealer's licence.

**58.** (1) Subject to the provisions of this Act, every licence granted under this Part shall, unless previously renewed or revoked, expire at the end of its validity.

(2) Any licence so granted shall, unless previously revoked, be renewable upon an application by the licensee made at least three months before the expiry of the validity period.

(3) The Licensing Authority may by rules establish the period of validity of any licence issued under this Part.

(4) On an application to the Licensing Authority for the renewal of a licence under this Part, the Licensing Authority:

(a) may renew the licence, with or without modifications, for such a further period as specified; or

(b) if, having regard to the provisions of this Act, it considers it necessary or expedient to do so, may refuse to renew the licence.

(5) The provisions of articles 25, 39 and 40 shall apply to such applications.

Obligations of holder of wholesale dealer's licence.

**59.** It shall be the duty of the holder of a wholesale dealer's licence -

(a) to immediately inform the Licensing Authority of any change of the qualified or responsible person;

(b) to provide authorised officers access to his premises at any reasonable time;

(c) to enable the Licensing Authority to carry out its duties established by or under this Act;

(d) to maintain such records for any transaction in medicinal products as may be established by or under this Act and have such records available for inspection by any authorised officer for such period of time as may be required by or under this Act.

Responsibilities of the responsible person.

**60.** (1) The responsible person shall ensure that standards of good practice in wholesale distribution as may be prescribed are complied with at all times.

(2) The qualified or responsible person shall at all times be present at the premises when the licenced activity is being carried out:

Provided that the qualified or responsible person may nominate another person to act as his representative.

(3) When the qualified or responsible person has nominated a representative as aforesaid he shall immediately inform the Licensing Authority of such nomination.

Suspension or revocation of wholesale dealer's licence.

**61.** The Licensing Authority may suspend a wholesale dealers' licence granted under this Act for such period as it may determine, or may revoke, or vary the provisions of, any such licence in any of the following cases:

(a) where the matters stated in the application on which the licence was issued were false or incomplete in a material particular;

(b) where a material change of circumstances has occurred in relation to any of those matters;

(c) where any of the conditions of the licence has been contravened;

(d) where the requirements in relation to the licence as established by or under this Act have not been complied with;

(e) where conditions of good practice in wholesale distribution are not being complied with; and

(f) in any other circumstance as may be established by or under this Act.

Change in conditions of a wholesale dealer's licence.

**62.** The Licensing Authority may, upon an application made by the holder of a licence in respect thereof, vary the conditions of the licence, if it is satisfied that such variation will not adversely affect the standards of good practice in wholesale distribution.

Obligations of Licensing Authority.

**63.** The Licensing Authority may vary, suspend, revoke or refuse to renew a wholesale dealer's licence, or it may refer the matter to the Medicines Authority, and in such case the provisions of article 20(4), (5) and (6) and of article 21 shall, *mutatis mutandis* apply.

Inspecting in relation to wholesale.

**64.** (1) The Licensing Authority shall ensure that the requirements established by or under this Act in relation to the wholesale dealing of a medicinal product are complied with.

(2) The Licensing Authority shall:

(a) inspect the wholesale dealing establishment and any other location it may deem necessary;

(b) examine any documents relating to the inspection;

(c) take any samples it may deem necessary;

(d) draw up a report of the findings, which shall be communicated to the licensee or the applicant for a licence in relation to such inspection and to the responsible person;

(e) carry out any other activity it may deem appropriate for the proper execution of its duties and responsibilities as provided for by or under this Act.

Special provisions.

**65.** Without prejudice to the provisions of this Part, the Licensing Authority may by rules establish additional requirements for the wholesale distribution of:

(a) narcotic or psychotropic substances;

(b) medicinal products derived from blood;

(c) immunological medicinal products;

(d) radiopharmaceuticals;

(e) such other medicinal products or class or classes of medicinal products as the Minister may prescribe.

*Title IV - Pharmacies and Related Pharmaceutical Activity*

Licence to open a pharmacy.

**66.** (1) It shall not be lawful for any person to open or keep a pharmacy unless he is in possession of a pharmacy licence issued in accordance with the provisions of this Act or any regulations made thereunder.

(2) Licences are to be issued in accordance with geo-demographic criteria as may be established by regulations made under this Act.

(3) Regulations under this article shall not be made unless the Minister shall have first published a draft thereof in the Government Gazette allowing any person a period of at least four weeks to make representations to the Minister.

(4) The Minister shall request the Licensing Authority to report on any representation made to him after hearing such person or taking such expert advice as it considers expedient, together with any

views it may have and the Minister may, upon receipt of the report by the Licensing Authority proceed to revise the draft regulations and to promulgate such regulations in accordance with such revision.

(5) Without prejudice to any exemption that may be granted by or under this Act, no person shall sell by retail any medicinal product expect in accordance with a pharmacy licence issued in accordance with the provisions of this Act or any regulations or rules made thereunder.

(6) The licensee shall be responsible for complying with the conditions of the licence as may be established by or under this Act.

Application for a pharmacy licence.

**67.** (1) Any application for the grant of a pharmacy licence shall be made to the Licensing Authority and shall contain such information, documents, samples and other material as provided by or under this Act:

Provided that such application shall indicate the following:

(a) the name and address of the applicant;

(b) the address of the premises that are to be used for the purpose of the retail sale of the medicinal products;

(c) the equipment and control facilities as may be required by or under this Act;

(d) information, documentation or evidence to prove that the premises is suitable and adequate, and that there are suitable facilities, installations, and equipment so as to ensure proper conservation and dispensing of medicinal products;

(e) the name of a managing pharmacist who shall be professionally responsible for all activities;

(f) any other information, documentation or evidence as may be requested by the Licensing Authority in accordance with or under this Act.

(2) The Licensing Authority shall determine the application in the period of time as may be established under this Act:

Provided that such time may be suspended until the relevant information is provided.

Grant of a pharmacy licence.

**68.** (1) The Licensing Authority shall, before determining an application, inspect the premises indicated in the application and

shall not issue a licence until it is satisfied that such premises conform with the requirements established by or under this Act:

Provided that a licence may be made conditional to the carrying out of such obligations as may be imposed therein.

(2) The pharmacy licence shall specify the premises and the activities to which it applies:

Provided that the Licensing Authority may, upon application, grant an additional licence for the use of identified premises to be used as a store for the purpose of the pharmacy after it is satisfied that such premises comply with any requirements established by or under this Act.

Notice for further information.

**69.** Where the Licensing Authority considers that circumstances may exist which would render necessary the consideration of whether the licence should be varied, suspended or revoked, the Licensing Authority may serve on the holder of a pharmacy licence a notice requiring him, within such time as may be specified in the notice, to furnish it with any information specified in the notice.

Duration and renewal of pharmacy licence.

**70.** (1) Subject to the provisions of this Act, every licence granted under this Part shall, unless previously renewed or revoked, expire at the end of its validity.

(2) Any licence so granted shall, unless previously revoked, be renewable upon an application by the licensee made at least three months before the expiry of the validity period.

(3) The Licensing Authority may by rules establish the period of validity of any licence issued under this Part.

(4) On an application to the Licensing Authority for the renewal of a licence under this Part, the Licensing Authority:

(a) shall renew the licence, with or without modifications, for such a further period as specified; or

(b) if, having regard to the provisions of this Act, it considers it necessary or expedient to do so, may refuse to renew the licence.

(5) The provisions of articles 25 and 39 shall apply to such applications.

Transfer of a pharmacy licence.

**71.** No person may transfer a licence unless authorised by the Licensing Authority which authorisation shall not be issued unless the Licensing Authority is satisfied that the new licensee complies with any requirement established by or under this Act, and on payment of the prescribed fee.

Suspension or revocation of pharmacy licence.

**72.** The Licensing Authority may suspend a pharmacy licence granted under this Act for such period as it may determine or may revoke, or vary the provisions of any such licence in any of the following circumstances:

(a) where any matter stated in the application on which the licence was issued is false or incomplete

(b) where a material change of circumstances has occurred in relation to any of those matters;

(c) where the provisions of the licence have been contravened by the licensee; or

(d) in any other circumstance as may be established by or under this Act:

Provided that the Licensing Authority shall notify the licensee of the decision giving detailed reasons for such decision.

Temporary closure of pharmacy.

**73.** (1) The licensee of a pharmacy shall not close a pharmacy, temporarily or otherwise, unless he has given at least twenty-four hours notice to, and such closure has been authorised by, the Licensing Authority:

Provided that the temporary closure shall not be construed to include the closure of a pharmacy resulting from the unforeseen or unexpected absence of a pharmacist, *force majeure* resulting in the inability to open the premises, or closure outside the business hours established for pharmacies by rules made the Licensing Authority.

(2) Subject to the provisions of subarticle (1), the licence in relation to a pharmacy which has remained closed for a period of five consecutive working days without the authorisation of the Licensing Authority shall be deemed to have been automatically revoked.

(3) The Licensing Authority may, on receipt of a notice as is referred to in subarticle (1), or where it has come to its knowledge that a pharmacy has been closed, seal all the medicinal products, wherever kept by the licensee in terms of the provisions of this Act, and take charge of any register required to be kept by the licensee under this or any other law.

**74.** It shall be the duty of the holder of a pharmacy licence - Obligations of the holder of a pharmacy licence.

(a) to inform the Licensing Authority of any change of the managing pharmacist, prior to such change;

(b) to provide authorised officers access to his premises at any reasonable time;

(c) to enable the Licensing Authority to carry out its duties established by or under this Act;

(d) to maintain such records for any transaction in medicinal products as may be established by or under this Act and have such records available for inspection by any authorised officer for such period of time as may be required by or under this Act;

(e) to comply with regulations or Orders relating to good practice in retail sale of medicinal products as may be established by or under this Act;

(f) to dispose of medicinal products as established by or under this Act or any other law;

(g) other responsibilities as may be established from time to time by or under this Act.

**75.** (1) Every pharmacy shall be managed by a pharmacist hereinafter referred to as the "managing pharmacist". Managing pharmacist.

(2) The managing pharmacist shall:

(a) act as the managing pharmacist of a licensed pharmacy including any other premises used as a store by the said pharmacy in terms of article 68(2);

(b) ensure that he or another pharmacist sells or supervises the sale of medicinal products present in the pharmacy and keep records of the pharmacist who was present at all times while the pharmacy was open;

(c) keep any documents, information or evidence in the manner as may be required to be kept by or under this Act;

(d) carry out such obligations pertaining to a managing pharmacist as may be established by or under this Act;

(e) nominate a substitute managing pharmacist when he cannot carry out his duties for a period of five or more

consecutive days and shall notify the Licensing Authority of this substitution:

Provided that in exceptional cases the licensee may nominate a replacement and notify the Licensing Authority;

(f) comply with regulations or rules relating to good practice in the dispensing of medicinal products as may be established by or under this Act;

(g) dispose of medicinal products as established by or under this Act or any other law.

(3) No pharmacist may, without the authority in writing of the Licensing Authority, act as a managing pharmacist of two or more pharmacies:

Provided that the Licensing Authority shall not give such authority unless it is satisfied that such pharmacist can reasonably carry out the duties of a managing pharmacist for more than one pharmacy.

(4) No pharmacist shall take up or abandon his duties as a managing pharmacist of any pharmacy without giving prior notice in writing to that effect to the Licensing Authority.

Duties of pharmacist.

**76.** (1) Unless otherwise provided by or under this Act, a medicinal product shall only be prepared or dispensed from a pharmacy and by a pharmasist:

Provided that a pharmacist may permit medicinal products to be prepared or dispensed by a pharmacy technician under his personal supervision as regulated by or under this Act.

(2) In carrying out his functions in the preparation and dispensing of medicinal products from a pharmacy, a pharmacist shall act in accordance with such standards as may be established by or under this Act or any other Act.

Interest in a pharmacy.

**77.** The conditions and criteria where any person can have or not have a direct or indirect interest in a pharmacy are to be defined in the Third Schedule to this Act.

Licensee may employ one or more pharmacists.

**78.** The licensee shall employ a pharmacist to carry out the responsibilities of a managing pharmacist and shall provide all the support and in no way interfere with the managing pharmacist's or a pharmacist's professional responsibilities in the performance of his duties as defined in by or under this Act or under any other law.

Medicinal products to be sold from a pharmacy.

**79.** (1) A pharmacy shall only dispense in medicinal products and trade in products or groups or classes of products that may from time to time be established by rules made by the Licensing Authority.

(2) Unless otherwise provided by or under this Act, a medicinal product shall only be sold from a pharmacy:

Provided that the Licensing Authority may, in special circumstances relating to the provision of services to the public, by rules prescribe that a medicinal product or class or classes of medicinal products therein specified may be sold from a premises other than a pharmacy such premises not being a general retail outlet:

Provided further that the Licensing Authority may with same circumstances by rules prescribe that a medicinal product of class or classes of medicinal products therein specified may be sold, prepared or provided to a patient by a person, other than a pharmacist, who is suitably qualified for such purpose:

Provided also that such rules shall provide for the circumstances under which such a sale, preparation or provision may occur and impose such restrictions as may be provided.

(3) The Licensing Authority may by rules establish a list of medicinal products that as a minimum must be available at a pharmacy at all times:

Provided that this requirement may be temporarily waived in relation to a particular medicinal product or class of medicinal product in exceptional circumstances, if the Licensing Authority is satisfied that the unavailability of such a medicinal product or class of medicinal product from a pharmacy is beyond the control of the managing pharmacist.

Dispensing of a medicinal product.

**80.** (1) A pharmacist shall prepare or dispense any medicinal product required by any person presenting a prescription unless he has a justified reason of concern that the prescription is false, that the person is misusing the prescribed medicinal product, or that the medicinal product is not available or if he has professional reasons for not preparing or dispensing the prescription.

(2) Upon presentation of a prescription for a medicinal product, unless the prescriber specifically requests a particular branded product by writing "branded" or "®" on the prescription, a pharmacist can dispense the medicinal product prescribed or an equivalent medicinal product having the same chemical entity, dose, dosage form, formulation and dosage frequency as the medicinal

product indicated on the prescription.

(3) When, in dispensing any medicinal product, a pharmacist discovers that there are reasons why the medicinal product should not be dispensed to the patient or that the dosage regimen indicated on the prescription goes beyond what can be considered a safe therapeutic dose, the pharmacist is bound to draw the attention thereto of the person prescribing the same and may require such person to write out in ink or in other indelible manner on the prescription a statement assuming responsibility for the prescription.

(4) The pharmacist shall assume full responsibility for the dispensing of medicinal products which do not need a prescription for dispensing to patients.

Dispensing against prescription.

**81.** (1) It shall not be lawful for any pharmacist to dispense any medicinal product except on the prescription of a medical or dental practitioner, veterinary surgeon or other person authorized to prescribe under this or any other Act, unless the medicinal product is deemed not to require a medicinal prescription by the Licensing Authority.

(2) The provisions of subarticle (1) shall also apply to products or substances not classified as medicinal products but which have been deemed to require a medicinal prescription for their use by the relevant competent authority.

Presentation of a prescription.

**82.** The Licensing Authority may by rules prescribe the format, content and presentation of a prescription required by or under this Act.

Labelling of dispensed products.

**83.** The pharmacist shall label each medicinal product or magistral formula or official formula dispensed in accordance with such regulations or rules made under this Act.

Disposal of expired, deteriorated or imperfect products.

**84.** It shall not be lawful for any managing pharmacist to sell, allow the sale, dispensing or supply in any other way of -

(a) any imperfect, deteriorated or harmful substance;

(b) any medicinal product bearing an expiry date which has expired;

(c) food not in accordance with the provisions of the Food Safety Act, 2002, or any regulations made thereunder:

Provided that such imperfect, deteriorated or expired substances or medicinal products shall only be kept in such place and

in such a manner as the Licensing Authority may from time to time by rules establish.

Storage of medicinal products in pharmacy.

**85.** (1) It shall not be lawful for any managing pharmacist to keep anywhere within the pharmacy any medicinal product in any container or under such conditions which are not suitable to the nature thereof and which are not such as to protect it from alteration, deterioration or contamination.

(2) It shall not be lawful for any managing pharmacist to permit any medicinal product under his charge to be kept or stored outside the pharmacy under his management, and it shall be his duty to ensure that the pharmacy has the facilities to ensure that medicinal products are stored in accordance with storage recommendations:

Provided that in the case where the Licensing Authority has granted a licence for the keeping or storage of medicinal products in any premises other than the pharmacy, the responsibilities of the managing pharmacist shall also apply to such premises.

Premises, etc., in accordance with requirements and standards.

**86.** Premises, facilities, records and equipment used for the storage, preparation and dispensing of medicinal products are to be kept in accordance with the requirements and standards established by or under this Act.

Pharmacist to be guided by set standards.

**87.** The preparation of magistral and official formulas, and the pre-packing, reconstitution, dispensing and administration of medicinal products and any other activity related to medicinal products and their use shall be in accordance with such standards as may be established under this Act.

Inspections of pharmacies.

**88.** (1) The Licensing Authority shall have the right to inspect pharmacies and any premises licensed for use as stores under article 68(2) whenever it deems necessary.

(2) Any inspection as aforesaid shall be carried out in the presence of the managing pharmacist or of the pharmacist for the time being in charge of the pharmacy.

(3) At the time of the inspection, the inspecting officer shall draw up a list of deficiencies that may have been identified at the time of the inspection and shall sign this list, and such list shall be countersigned by the managing pharmacist or by the pharmacist for the time being in charge of the pharmacy:

Provided that the inspecting officer shall draw up a report of the inspection within seven working days of the inspection and shall forward a copy of such report to the Licensing Authority, the

licensee and the managing pharmacist:

Provided also that the managing pharmacist or pharmacist for the time being in charge of the pharmacy may make comments or otherwise make reservations in respect of the contents of the said list.

(4) (a) If in the course of the inspection, any article is found to be in breach of the provisions of this Act or any regulation made thereunder, the inspecting officer shall forthwith seize the said article.

(b) The wrapper or receptacle containing the article so seized shall be sealed and the signature of the inspecting officer and the managing pharmacist shall be appended to the seal:

Provided that if the managing pharmacist so requests, the article in question shall be divided, by the inspecting officer, in two equal parts, sealed and signed in the manner as aforesaid, and one part be given to the managing pharmacist:

Provided further that the inspecting officer shall send the seized article, sealed and signed in the manner aforesaid to the Licensing Authority together with the inspection report as described in subarticle (3).

(5) If the managing pharmacist or the pharmacist for the time being in charge of the pharmacy refuses to countersign the list referred to in subarticle (3), the inspecting officer shall record such fact on the said list together with the reason given, if any, for such refusal.

Opening of pharmacies.

**89.** The Licensing Authority may by notice in the Gazette establish the business hours of pharmacies and may also require pharmacies in specified localities or districts to open for the serving of customers on such days and for such times as may be specified in such notice.

## PART IV

## POISONOUS SUBSTANCES

Definition of poisons.

**90.** For the purposes of the provisions contained in this Part, "poison" means -

(a) all those substances which, taken even in a very small dose, may cause the death or serious injury to any person,

(b) all those substances which the Minister may, on the advice of the Licensing Authority, prescribe,

but does not include any similar substance which is used, or is intended to be used, for day to day domestic purposes, which latter substance, however shall be deemed to be a poison for the purpose of article 94.

Keeping, etc., of poisons.

**91.** It shall not be lawful for any person to keep for sale, manufacture, sell or otherwise distribute or deal in any poison without a licence from the Licensing Authority .

Licence for sale of poisons.

**92.** (1) The licence mentioned in article 91 shall only be granted to manufacturers of, and dealers in chemical products, colorists and such other persons as require to make use of poisons in the exercise of their trade or profession.

(2) Such licence shall show the name and surname of the licensee, his trade or profession, and the place in which he intends to carry on such trade or profession and any other information as may be established from time to time by rules made by the Licensing Authority.

Keeping of poisonous substances in a safe place.

**93.** Every person granted a licence under article 91 shall keep all poisonous substances in a separate and safe place the key whereof shall be always kept by the licence holder.

Sale of poisonous substances.

**94.** (1) No person granted a licence under article 91 shall sell or deliver any poisonous substance, either by wholesale or retail, to any person not being a pharmacist, except on production of a prescription or for purposes of disinfection or industry or for any other purpose as may be authorised by the Licensing Authority.

(2) Every person granted a licence under article 91 shall keep, maintain, update, store and make available to the Licensing Authority or any authorised person any information as may from time to time be required by the Licensing Authority and in any such manner as may be form time to time be required by the Licensing Authority.

(3) Poisonous substances shall be labelled in such a manner the Licensing Authority may from time to time by rules establish.

Power of inspection.

**95.** The Licensing Authority or any authorised officer, may in the interest of public health, pay surprise visits to the business premises of manufacturers of and dealers in chemical products and of the other persons referred to in article 91.

Poisoned grain, seed etc., Cap. 430.

**96.** Without prejudice to the provisions of the Pesticides Control Act, it is prohibited to sow, cast, put or place, or cause to be sown, cast, put or placed in or upon any land or other exposed place any grain, seed, meal, or flesh which has been so dipped or steeped in

poison, or has been so mixed with poison or other ingredient or preparation as to be rendered poisonous and calculated to destroy life.

## PART V

## OTHER DEALINGS WITH MEDICINAL PRODUCTS

Special restrictions on persons to be supplied with medicinal products.

**97.** The Licensing Authority may by rules provide, either in respect of medicinal products generally or in respect of medicinal products of a description or falling within a class specified in the rules that, subject to such exceptions as may be so specified, no person -

(a) being the holder of a marketing authorisation, or

(b) in the course of business carried by him and consisting, in whole or in part, of manufacturing medicinal products or of selling medicinal products by way of wholesale dealing,

shall sell or supply any medicinal product to which the rules apply to any person who does not fall within a class specified in those rules.

Adulteration of medicinal products.

**98.** No person shall -

(a) add any substance to, or abstract any substance from, a medicinal product so as to affect injuriously the composition of the product, with the intent that the product shall be sold or supplied in that state; or

(b) sell or supply, or offer or expose for sale or supply, or have in his possession for the purpose of sale or supply, any medicinal product whose composition has been injuriously affected by the addition or abstraction of any substance.

## PART VI

## OFFENCES AND PENALTIES

Offences and penalties.

**99.** (1) Without prejudice to any other liability under any other law, any person who fails to comply with any of the provisions of this Act or any regulations or rules made thereunder shall be guilty of an offence and shall, on conviction, be liable, in the case of an offence against:

(a) the provisions of articles 20, 24, 28, 37, 39, 41 and 43, to a fine (*multa* ) of not less than ten thousand liri and not exceeding fifty thousand liri or to imprisonment for a term not exceeding two years, or both such fine and imprisonment;

(b) the provisions of articles 54, 56, 58 and 61, to a fine (*multa*) of not less than five thousand liri and not exceeding thirty thousand liri or to imprisonment for a term not exceeding six months, or both such fine and imprisonment;

(c) the provisions of articles 44, 45, 66(1), 71, 75(3), 75(4), 76(1), 81(1), 91 and 98, to a fine (*multa*) of not less than two thousand liri and not exceeding twenty thousand liri or to imprisonment for a term not exceeding three months, or to both such fine and imprisonment;

(d) the provisions of articles 59, 60, 65, 74(b), 75(1), 75(2), 84, 93, 94(1) and 96, to a fine (*multa*) of not less than five hundred liri and not exceeding ten thousand liri;

(e) the provisions of articles 31, 66(2), 78, 85(1), 85(2) and 94(2), to a fine (*multa*) of not less than two hundred liri and not exceeding five thousand liri;

(f) the provisions of articles 29, 73(1) and 94(3), to a fine (*multa*) of not less than one hundred liri and not exceeding one thousand liri.

(2) Without prejudice to the powers of the Licensing Authority under this Act, where any person who has committed an offence is the holder of a licence or an authorisation under this Act, and the conviction is the third or subsequent conviction, the Court shall, at the request of the prosecution, order the revocation or suspension of the aforesaid licence or authorisation.

Special procedure.

**100.** (1) Notwithstanding any other law providing for the trial of offences, where the Licensing Authority believes that a person has committed an offence against this Act or any regulations or rules made thereunder, the Authority shall give notice in writing to such person describing the offence of which the person is accused, indicating the steps to be taken to remedy the offence and the penalty which he is required to pay in respect of that offence.

(2) The Minister shall prescribe the penalties that may be demanded by the Licensing Authority in relation to any specified offence:

Provided that such penalty shall not exceed an amount of ten thousand liri.

(3) Where a notice under this article has been given, the person named in the notice may, within twenty-one days of the service of the notice, accept responsibility for the offence specified in

the notice and within the same period pay the penalty indicated in the notice, and comply with the relative provision of this Act, or of the regulations or rules made thereunder and no further proceedings may be taken under this Act in respect of such offence.

(4) Where the person to whom notice is given under subarticle (1) has not paid the penalty within the twenty-one day period referred to in subarticle (3) and has not, within the time specified, complied with the requirements of this Act, criminal proceedings may be taken against him in accordance with the provisions of the Criminal Code, of this Act and of any other law applicable of the offence.

Cap. 9.

## PART VII

ENFORCEMENT

Right of entry.

**101.** (1) Subject to the provisions of this article, and without prejudice to the other provisions of this Act, any person duly authorised in writing by the Licensing Authority shall, on production of his authorisation or credentials, have a right at any reasonable time to enter any premises:

(a) for the purpose of ascertaining whether there is or has been, or there is likely to be any contravention of any provisions of this Act or of any regulations or rules made thereunder;

(b) generally for the purposes of the exercise by the Licensing Authority of its function under this Act or under any regulations or rules made thereunder.

For the purposes of this Part, premises shall include any building, structure, any other place whatsoever or any means of transport.

(2) Any authorised officer shall, on the production of his authorisation, have a right at any reasonable time to board any ship or aircraft for the purpose of ascertaining whether there is in the ship or aircraft any substance or article imported in contravention of any provisions of this Act or of any regulations or rules made thereunder or whether the said craft is carrying out any activity in contravention to any of the said provisions.

Power to inspect, take samples and seize goods and documents.

**102.** (1) For the purpose of ascertaining whether there is or has been or there is likely to be a contravention of this Act or of any regulations or rules made thereunder, an authorised officer shall have a right to inspect:

(a) any substance or article appearing to him to be a medicinal product;

(b) any article used or intended to be used to contain any medicinal product or to be a label or leaflet used or intended to be used in connection with a medicinal product; or

(c) any plant or equipment appearing to him to be used or intended to be used in connection with the manufacture or assembly of medicinal products, and any process of manufacture or assembly of any medicinal products and the means employed, at any stage in the process of manufacture or assembly, for testing the materials after they have been subjected to those processes.

(2) An authorised officer may, for the purpose specified in the preceding subarticle, take a sample of any:

(a) substance or medicinal product sold or supplied or intended to be sold or supplied; or

(b) substance or article used or intended to be used in the manufacture of a medicinal product.

(3) For the purposes of subarticle (1), an authorised person shall have the right:

(a) to inspect any records, in whatever form they are held, related to the manufacture, assembly, sale or supply of a medicinal product and, where such records are kept in electronic form:

(i) may have access to, and inspect and check the operation of any computer, any associated apparatus or material which is or has been in use in connection with the records; and

(ii) may require any person having charge of, or otherwise connected with the operation of, the computer, apparatus or material to afford him such assistance as he may reasonably require;

(b) to take copies of any entry in any book or document produced in pursuance of the preceding paragraph and where the records are kept electronically, by means of a computer or otherwise, require the records to be produced in an intelligible form which may be taken away.

(4) Any authorised officer shall have a right to seize, remove and detain any substance or article which he has reasonable cause to believe to be a substance or article in relation to which, or by means of which, an offence under this Act is being or has been committed, and any document which he has reasonable cause to believe to be a document which may be required as evidence in proceedings under this Act.

(5) For the purpose of subarticle (4), any authorised person may, so far as is reasonably necessary in order to secure compliance with the provisions of this Act and any regulations or rules made thereunder, require any person to break open any container, package or machine, or to permit him to do so:

Provided that where a person seizes any substance or article, including any document, for the purposes specified in subarticle (4), he shall inform the person from whom it is seized and give him a receipt thereof.

(6) Without prejudice to the preceding provisions of this article, any authorised person shall have the same rights conferred by those provisions in relation to things belonging to, or any business carried on by, an applicant for an authorisation or certificate under Part III of this Act, and may exercise such rights for the purpose of verifying any statements or information contained in the application for the authorisation or certificate; and, where by virtue of the provisions of this subarticle a person exercises any such right as is specified in subarticle (4), he shall be subject to the duty imposed by subarticle (5).

(7) Notwithstanding anything in the preceding provisions of this article, where a person claiming to exercise a right by virtue of the provisions of this article is required to produce his authorisation or credentials, the right shall only be exercisable by him on the production of the authorisation or credentials.

Application of sampling procedure to substance or article seized.

**103.** (1) The provisions of this article shall apply where an authorised officer seizes a substance or article, other than a document, in the exercise of such a right as is specified in article 102(4) and (6).

(2) If any person who in accordance with article 102(5) is entitled to be informed of the seizure so requests, either at the time of the seizure or at any subsequent time, not being later than twenty-one days after he is informed of the seizure, then subject to the following provisions of this article, the authorised officer shall either:

(a) set aside a sample of the substance or article seized;

or

(b) treat that substance or article as a sample,

whichever he considers more appropriate having regard to the nature of that substance or article.

(3) An authorised officer shall not be required by virtue of subarticle (2) to set aside a sample, or to treat a substance or article as a sample, if the nature of the substance or article is such that it is not reasonably practicable to do either of those things.

(4) Where in accordance with subarticle (2) an authorised officer sets aside a sample, or treat a substance or article as a sample, he shall divide it into three parts, each part to be marked and sealed or fastened up in such manner as its nature will permit, and shall supply one excerpt of it to the person who made the request under subarticle (2).

Supplementary provisions as to right of entry.

**104.** (1) Any person entering any property or any other premises, ship, aircraft, stall or place in accordance with the provisions of article 101, may be accompanied by such other person or take such equipment as may appear to him to be necessary; and on leaving any such property shall, if the property is unoccupied or the occupier or any other person who is in charge of a ship, aircraft, vehicle, stall or place, is temporarily absent, leave it as effectively secured.

(2) The authorised officer shall also have such other powers as may be prescribed by regulations made by the Minister for the proper execution of his functions.

## PART VIII

## MISCELLANEOUS PROVISIONS

Recognition of equivalent standards.

**105.** (1) For the purposes of this Act, the Minister may, on the advice of the Licensing Authority, by regulations prescribe that a provision or provisions in relation to the marketing authorisation of a medicinal product shall be deemed to be satisfied, if the standards of manufacture, medicinal product quality, safety or efficacy, or the provisions in relation to the granting of a marketing authorisation of a country designated in such regulations, are satisfied.

Power of Minister to make regulations.

**106.** The Minister may, after consultation with the Licensing Authority, amend the schedules to this Act, prescribe by regulations anything that may be prescribed under this Act and make provision on any matter relating to medicinal products, poisons and pharmacies in

order to give fuller effect to the provisions of this Act, and, in particular, but without prejudice to the generality of the aforesaid, shall by such regulations regulate or otherwise provide for:

(a) the grant of marketing authorisations;

(b) the manufacture of medicinal products and raw materials used in such manufacture;

(c) the wholesale distribution of medicinal products;

(d) the sale and supply of medicinal products;

(e) the licensing of pharmacies;

(f) the reporting of adverse drug reactions;

(g) advertising in respect of medicinal products, and the presentation and information contained in the advert:

Provided that the advertising of certain medicinal products or classes of medicinal products may, by such regulations, be prohibited;

(h) the conduct of clinical trials;

(i) the classification of medicinal products;

(j) the testing of medicinal products;

(k) the regulation of homeopathic medicinal products; radiopharmaceuticals and medicinal products derived from human blood and human plasma; immunological products, and herbal products;

(l) the roles and responsibilities of a licence or authorisation holder;

(m) the roles and responsibilities of the managing pharmacist, responsible person and qualified person;

(n) standards of good practice in the manufacture, wholesale, distribution and dispensing of medicinal products:

Provided that in the case of dispensing the Minister may take the opinion of the Pharmacy Board;

(o) the recognition of equivalent standards for medicinal product quality and efficacy in relation to such

countries as may be prescribed;

(p) the recognition of equivalent standards for good practice in manufacture in relation to such countries as may be prescribed;

(q) the fees that may be levied by the Licensing Authority and the Medicines Authority;

(r) exceptions to any provision in the interest of public health.

Transitory provision.

**107.** Any medicinal products on the market on the date of the coming into force of article 20 shall only be subject to the provisions of that article at such time and subject to such conditions as may by rules be established by the Licensing Authority.

Amendment of Medical and Kindred Professions Ordinance, Cap. 31.

**108.** Articles 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 41, 42, 48, 88, 89, 92, 93 and 95 of the Medical and Kindred Professions Ordinance shall be deleted.

Saving.

**109.** (1) Any regulations made under the provisions of the articles, of the Medical and Kindred Professions Ordinance, which are being repealed by article 108, shall, until provision is made under or by virtue of this Act, continue in force and have effect as if made under this Act.

(2) Any licence, permission or other authorisation granted under any provision of the repealed articles as aforesaid, shall continue in force thereafter as if it were a licence, permission or authorisation granted under a corresponding provision or authority granted under this Act and shall be treated and dealt with accordingly.

(3) Any action taken or proceedings commenced against or in relation to any person under the repealed articles as aforesaid shall continue to have effect as if it were action or proceedings taken or commenced under a corresponding provision of this Act.

FIRST SCHEDULE

Areas of competency.

Anaesthesiology

Analytical Chemistry

Anatomy

Biochemistry

Biotechnology Products

Blood Products

Cardiology

Cosmiceuticals

Dentistry

Dermatology

Diabetes

Endocrinology

ENT Medicine

Epidemiology

Family Medicine

Gastroenterology

Genetics

Geriatrics

Haematology

Herbals

Homeopathics

Immunology

Intensive care

Internal Medicine

Medical Devices

Medical Statistics

Microbiology (such as Virology, Bacteriology)

Molecular Biology

Neurology

Nephrology

Nutraceuticals

Nutrition

Obstetrics & Gynaecology

Oncology

Ophthalmology

Orthopaedics

Paediatrics

Pathology

Pharmaceutical Chemistry

Pharmaceutical Technology

Pharmacognosy

Pharmacology

Physiology

Psychiatry

Radiology

Radiopharmaceuticals

Respiratory Medicine

Rheumatology

Surgery

Toxicology

Transfusion Medicine

Urology

Vaccines

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SECOND SCHEDULE

Proceedings of the Medicines Review Board

1. All members of the Medicines Review Board shall be present for a hearing of an appeal or the development of a second opinion.

2. All members of the Board shall have a vote and the opinion of the Board shall reflect the opinion of the majority of members:

Provided that a dissenting member may also request that his opinion be attached to the Board's opinion report as a minority report.

3. The appellant shall appear before the Board either in person or through an agent on the day and at the time fixed for the hearing, make his submissions and produce such evidence as the Board may allow:

Provided that the Board may postpone the hearing of the appeal if it is satisfied that the appellant was prevented from appearing before it owing to illness or absence from Malta or other similar reasonable cause.

4. The Board shall give the Medicines Authority an opportunity to make its submissions in justification of its opinion/s, and bring such evidence as the Board may consider necessary.

5. The Board shall have the power to summon witnesses and to administer the oath to any person appearing before it.

6. The Board shall have power to confirm or issue a different opinion to that appealed against, as it may deem appropriate.

7. The opinion of the Board shall be final albeit not binding to the decision of the Licensing Authority and no appeal shall lie therefrom except on a question of law only.

8. Subject to the foregoing provisions and to the provisions of this Act, the Board shall regulate its own procedure.

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## THIRD SCHEDULE

Conditions and criteria where any person can have or not have a direct or indirect interest in a pharmacy

(1) No person shall qualify for a licence if he is a medical practitioner, dental surgeon, dentist or veterinary surgeon or if he is the husband or wife of any such medical practitioner, dental surgeon, dentist or veterinary surgeon.

(2) No licence shall be granted or renewed if a medical practitioner, dental surgeon, dentist or veterinary surgeon has any direct or indirect interest in a pharmacy.

(3) It shall not be lawful for any medical practitioner, dental surgeon, dentist or veterinary surgeon or any other person authorised to issue prescriptions under the Medicines Act or any other Act, to enter into any agreement with any pharmacist or any other person for any share in the profits of a pharmacy, or to have any direct or indirect interest of whatever nature in any pharmacy.

(4) It shall not be lawful for any pharmacist:

(a) to carry on the business of a pharmacy on account of, or in partnership with any medical practitioner, dental surgeon, dentist or veterinary surgeon or any other person authorised to issue prescriptions under the Medicines Act or any other Act;

(b) to enter into any agreement with any medical practitioner, dental surgeon, dentist or veterinary surgeon or any other person authorised to issue prescriptions as aforesaid, for any share in the profits of a pharmacy;

(c) to lend his name in order that the business may be carried out by some other person.

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A 260

Passed by the House of Representatives at Sitting No. 875 of the 25th February, 2003.

ANTON TABONE
*Speaker*

RICHARD J. CAUCHI
*Clerk to the House of Representatives*

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