

Naghti l-kunsens tieghi.

(L.S.)

EDWARD FENECH ADAMI
President

20 ta' Lulju, 2007

ATT Nru. XI ta' l-2007

ATT biex jemenda l-Att dwar il-Medicini, Kap. 458

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

1. (1) It-titolu fil-qosor ta' dan l-Att hu Att ta' l-2007 li jemenda l-Att dwar il-Medicini. Titolu fil-qosor.

(2) Dan l-Att għandu jinqara u jiftiehem haġa waħda ma' l-Att dwar il-Medicini, hawn iżjed 'il quddiem imsejjah "l-Att prinċipali".

2. L-artikolu 2 ta' l-Att prinċipali għandu jiġi emendat kif ġej: Emenda ta' l-artikolu 2 ta' l-Att prinċipali.

(a) fit-tifsira "apparat ta' radjonuklidi" minflok il-kliem "apparat ta' radjonuklidi" għandha tidhol il-kelma "apparat";

(b) minnufih wara t-tifsira:

"Awtorità dwar il-Medicini" għandha tizzied din it-tifsira ġdida li ġejja:-

"bilanċ bejn riskju u benefiċċju" tfisser valutazzjoni ta' l-effetti positivi terapewtiċi tal-prodott mediċinali għar-rigward tar-riskji kif imfissra fil-paragrafu (a) tat-tifsira "riskji li għandhom x'jaqsmu ma' l-użu tal-prodott mediċinali;"

(ç) minflok it-tifsira “distribuzzjoni bl-ingrossa” ghandha tidhol din li ġejja:-

“distribuzzjoni bl-ingrossa”, dwar prodott mediċinali, tinkludi l-attivitajiet kollha li jikkonsistu fl-akkwist, it-tiżmim, il-forniment jew l-esportazzjoni ta’ prodotti mediċinali, minbarra l-forniment ta’ prodotti mediċinali lill-pubbliku. Dawk l-attivitajiet isiru flimkien ma’ manufatturi jew id-depożituri tagħhom, importaturi, distributuri bl-ingrossa ohrajn jew ma’ spizjara u persuni awtorizzati jew intitolati għal forniment ta’ prodotti mediċinali lill-pubbliku f’Malta;”;

(d) fit-tifsira “esperiment kliniku”, minflok il-kliem “esperiment kliniku” ghandhom jidhlu l-kliem “prova klinika”;

(e) fit-tifsira “formola maġistrali” minflok il-kliem “skond ricetta li” ghandhom jidhlu l-kliem “skond ricetta medika li”;

(f) it-tifsira “formola uffijali” ghandha tithassar;

(g) minnufih wara t-tifsira “formola maġistrali” ghandha tidhol din it-tifsira ġdida li ġejja:-

“formola offiċinali” tfisser prodott mediċinali li jkun imhejji fi spizerija skond ir-ricetti ta’ farmakopoeia rikonoxxuta u li jkun intiż li jiġi fornut direttament lill-pazjenti li jinqed minn dik l-ispizerija;”;

(h) it-tifsira “ippakkettjar minn qabel” ghandha tithassar u minnufih wara t-tifsira “ippakkettjar immedjat”, ghandha tiżdied din it-tifsira ġdida li ġejja:-

“isem komuni” tfisser l-isem mhux proprjetarju internazzjonali rakkomandat mill-Organizzazzjoni Dinjija tas-Saħha (WHO), jew, jekk ma jkunx hemm wiehed, l-isem komuni tas-soltu;”;

(i) minnufih wara t-tifsira ġdida “isem komuni” ghandha tiżdied din it-tifsira ġdida li ġejja:-

“isem tal-prodott mediċinali” tfisser l-isem, li jista’ jkun sew isem inventat li mhux suppost jithawwad ma’ l-isem komuni, sew isem komuni jew xjentifiku li jkollu miegħu *trade mark* jew l-isem tad-detentur ta’ l-awtorizzazzjoni għat-tqeghid fis-suq;”;

(j) minflok it-tifsira “preparati erbali” ghandha tidhol din li ġejja:-

“ “preparati erbali” tfisser preparati li jinkisbu meta sustanzi erbali jiġu assoġġettati għal trattamenti bħall-estrazzjoni, distillazzjoni, espressjoni, frazzazzjoni, purifikazzjoni, koncentrazzjoni jew fermentazzjoni. Dawn jinkludu sustanzi erbali mithuna jew pulverizzati, tinturi, estratti, żjut essenzjali, meraq magħsur u likwidu mnixxi proċessat;”;

(k) fit-tifsira “prekursur ta’ radjonuklidi”, minflok il-kliem “apparat ta’ radjonuklidi” ghandha tidhol il-kelma “apparat”;

(l) minflok it-tifsira “prodott mediċinali” ghandha tidhol din li ġejja:-

“prodott mediċinali” tfisser kull sustanza jew kombinazzjoni ta’ sustanzi -

(a) li jiġu preżentati bħala li ghandhom proprjetajiet għall-kura jew il-prevenzjoni ta’ mard fil-bnedmin; jew

(b) li jistgħu jintużaw fil-bnedmin jew jiġu lilhom amministrati sew bil-għan li ssir ristawrazzjoni, korrezzjoni jew modifika ta’ funzjoni fiżjoloġika bl-għemil ta’ azzjoni farmakoloġika, immunoloġika jew metabolika, sew billi ssir djanjosi medika;”;

(m) minflok it-tifsira “prodott mediċinali erbali ” ghandha tidhol din li ġejja:-

“ “prodott mediċinali erbali ” tfisser kull prodott mediċinali, li esklusivament jkollu fih bħala ingredjenti attivi xi sustanza erbali wahda jew aktar jew xi preparat erbali wiehed jew aktar, xi sustanza erbali wahda jew aktar flimkien ma’ xi preparat erbali wiehed jew aktar;”;

(n) minflok it-tifsira “prodott mediċinali immunoloġiku” ghandha tidhol din li ġejja:-

“prodott mediċinali immunoloġiku” tfisser xi prodott mediċinali li jikkonsisti f’vaini, tossini, seri jew prodotti ta’ allergen, hekk li:

(a) vaċċin, tossin u serum ghandhom jinkludu:

(i) aġenti użati biex jipproduċu immunità attiva, bhalma huma l-vaċċin tal-kolera, BCG, vaċċini tal-poljo, vaċċini tal-ġidri;

(ii) aġenti użati għad-djanjosi ta' l-immunità, inklużi partikolarment it-tuberkulina u PPD tat-tuberkulina, tossini għat-Testijiet Schick u Dick, il-bruċċellina;

(iii) aġenti użati biex jipproduċu immunità passiva, bhal ma huma l-antitossin tad-difterija, il-globulina kontra l-ġidri, il-globulina kontra l-limfoitiċi; u

(b) 'prodott ta' allergen' tfisser kull prodott mediċinali intiż biex jidentifika jew iġib alterazzjoni miksuba speċifika fir-rispons immunoloġiku għal aġent allergizzanti;”;

(o) fit-tifsira “prodott mediċinali investigattiv”, minflok il-kliem “f’esperiment kliniku” ghandhom jidhlu l-kliem “fi prova klinika”;

(p) minnufih wara t-tifsira “prodott mediċinali investigattiv”, ghandha tizzied din it-tifsira ġdida li ġejja:-

“prodott mediċinali miksub mid-demmm jew plasma tal-bniedem” tfisser prodott mediċinali bażat fuq kostitwenti tad-demmm li jiġu preparati industrjalment minn stabbilimenti pubbliċi jew privati, prodotti mediċinali bhal dawkk inklużi, partikolarment, l-albumina, fatturi koagulanti u immunoglobulini li joriġinaw mill-bniedem;”;

(q) fit-tifsira “prodott mediċinali omeopatu”, minflok il-kliem “f’Malta” ghandhom jidhlu l-kliem “fl-Istati Membri”;

(r) minnufih wara t-tifsira “prodott mediċinali omeopatu” ghandha tizzied din it-tifsira ġdida li ġejja:-

“qawwa tal-prodott mediċinali” tfisser il-kontenut tas-sustanzi attivi espressi b’mod kwantitattiv għal kull unità ta’ dożaġġ, għal kull unità ta’ volum jew piż skond il-forma ta’ dożaġġ;”;

(s) minflok it-tifsira “radjofarmaċewtiku” ghandha tidhol din li ġejja:-

“radjofarmaċewtiku” tfisser kull prodott mediċinali li, meta jkun lest biex jintuża, ikun fih inkluzi xi radjonuklidu (isotopu radjoattiv) wiehed jew aktar għal skop mediċinali;”;

(t) fit-tifsira “radjonuklidi ġeneratur” minflok il-kliem “li ghandha titnehha” ghandhom jidhlu l-kliem “li ghandha tinkiseb”;

(u) minnufih wara t-tifsira “radjonuklidi ġeneratur” ghandha tidhol din it-tifsira ġdida li ġejja :-

“reazzjoni kuntrarja” tfisser rispons għal prodott mediċinali li hu noċiv u mhux intiż u li jokkorri f’dożi normalment użati fil-bniedem għall-profilassi, djanjosi jew terapija ta’ mard jew għar-ristawrazzjoni, korrezzjoni jew modifika ta’ funzjoni fiżjoloġika;”;

(v) minnufih wara t-tifsira ġdida “reazzjoni kuntrarja” ghandha tidhol din it-tifsira ġdida li ġejja:-

“reazzjoni kuntrarja gravi” tfisser reazzjoni kuntrarja li tirriżulta f’mewt, tkun thedded il-hajja, tehtieg li persuna tiddaħhal fi sptar bħala *inpatient* jew li jittawwal iż-żmien li hija jkollha tibqa’ fl-isptar, tirriżulta f’ diżabilità jew inkapacità persistenti jew sinifikanti, jew tkun anomalija kongenitali jew difett mit-twelid”;

(w) minnufih wara t-tifsira “reazzjoni kuntrarja gravi” ghandha tidhol din it-tifsira ġdida li ġejja:-

“reazzjoni kuntrarja mhux mistennija” tfisser reazzjoni kuntrarja, li ma ghandhiex natura, severità jew eżitu li huma konsistenti mal-ġabra tal-karatteristiċi tal-prodott;”

(x) fit-tifsira “riċetta mediċinali” minflok il-kliem “riċetta mahruġa” ghandhom jidhlu l-kliem “riċetta mediċinali mahruġa”;

(y) minnufih wara t-tifsira “riċetta mediċinali” ghandha tidhol din it-tifsira ġdida li ġejja:-

“riskji li ghandhom x’jaqsmu ma’ l-użu tal-prodott mediċinali” tfisser:-

(a) kull riskju li jkollu x'jaqsam mal-kwalità, sigurezza jew effikaja tal-prodott mediċinali dwar is-saħha tal-pazjenti jew is-saħha pubblika;

(b) kull riskju ta' effetti mhux mixtieqa fuq l-ambjent;”;

(z) minflok it-tifsira “sustanza” għandha tidhol din li ġejja:-

“sustanza” tfisser xi haġa irrispettivament mill-orġini li jista' jkun mill-bniedem (inkluż demm tal-bniedem u prodotti ġejjin mid- demm tal-bniedem), mill-annimali (inklużi mikro-organiżmi, annimali shah, partijiet ta' organi, tnixxija minn annimali, tossini, estratti, prodotti tad-demm), mill-haxix (inklużi mikro-organiżmi, pjanti, partijiet minn pjanti, tnixxija minn hxejjex, estratti), jew mill-kimika (inklużi elementi, materjal kimiku li jinsab b' mod naturali u prodotti kimiċi miksubin b'tidil kimiku jew sintesi kimika);”;

(aa) minflok it-tifsira “sustanzi erbali” għandha tidhol din li ġejja:-

“ “sustanzi erbali” tfisser tfisser kull pjanta prinċipalment shiha, mfarrka jew mqatta' biċċiet, partijiet minn pjanti, algi, fungi, *lichens* f' għamla mhux proċessata, soltu mnixxfa, imma xi kultant friska. Likwidu mnixxi li ma jkunux ġew assoġġettati għal xi trattament partikolari jitqiesu wkoll bhala sustanzi erbali. Is-sustanza erbali huma sewsew definiti bil-parti mill-pjanta u mill-isem botaniku skond is-sistema binomja (ġeneru, speċje, varjetà u awtur);”;

(bb) fit-test Malti biss ta' l-Att:

(i) it-tifsira ta' “*leaflets* ġo pakkett” għandha tithassar;

(ii) minnufih wara t-tifsira “farmakopeia rikonoxxuta” għandha tidhol din it-tifsira ġdida li ġejja:-

“ “fuljett ta' tagħrif” tfisser il-fuljett li jkun fih l-informazzjoni kollha għal min ikun se jużah u li jkun jinsab flimkien mal-prodott mediċinali;”

(iii) fit-tifsira “reklamar”, u fl-artikolu 28(3), minflok il-kliem “*leaflets* ġo pakkett” kull fejn dawn jinsabu għandhom jidhlu l-kliem “fuljetti ta' tagħrif” u “fuljett ta' tagħrif” rispettivament; u

(iv) fl-artikolu 102(1)(b), minflok il-kelma “*leaflet*” ghandha tidhol il-kelma “fuljett”.

3. L-artikolu 3 ta’ l-Att prinċipali ghandu jiġi emendat kif ġej:— Emenda ta’ l-artikolu 3 ta’ l-Att prinċipali.

(a) fit-test Malti tal-paragrafu (f) tas-subartikolu (2), minflok il-kliem “esperimenti kliniċi” ghandhom jidhlu l-kliem “provi kliniċi”; u

(b) minflok is-subartikolu (3) ghandu jidhol dan li ġej:

“(3) L-Awtorità dwar il-Liċenzjar tista’ taghmel regoli li jkunu jiddelegaw xi jew kull funzjoni taghha msemmija fil-paragrafi (l), (m), (n) u (o) tas-subartikolu (2) ta’ dan l-artikolu lill-Awtorità dwar il-Mediċini.”.

4. Fis-subartikolu (2) ta’ l-artikolu 10 ta’ l-Att prinċipali, minflok il-kliem “l-aġenzija”, kull fejn dawn jinsabu, ghandhom jidhlu l-kliem “l-Awtorità”. Emenda ta’ l-artikolu 10 ta’ l-Att prinċipali.

5. Minflok il-paragrafu (a) tas-subartikolu (2) ta’ l-artikolu 16 ta’ l-Att prinċipali, ghandu jidhol dan li ġej:— Emenda ta’ l-artikolu 16 ta’ l-Att prinċipali.

“(a) li jisma’ appell maghmul minn applikant ghal awtorizzazzjoni ghat- tqeghid fis-suq fuq xi rakkomandazzjoni ta’ l-Awtorità dwar il-Mediċini dwar is-sigurezza, il-kwalità u l-effikaċja ta’ xi prodott mediċinali.”.

6. Minflok l-artikolu 19 ta’ l-Att prinċipali, ghandu jidhol dan li ġej: Sostituzzjoni ta’ l-artikolu 19 ta’ l-Att prinċipali.

“19. (1) Id-disposizzjonijiet tat-Titoli I, II u III ghandhom japplikaw:

(a) ghal prodotti mediċinali li jintużaw mill-bniedem u li jkunu intiżi biex jinbieghu fi Stati Membri u li jew jiġu preparati industrjalment jew jiġu manufatturati b’metodu li jinvolvi proċess industrjali;

(b) f’każijiet dubbjużi, meta, wara li jitqiesu l-karatteristiċi kollha tiegħu, prodott jista’ jinkwadra fit-tifsira ta’ prodott mediċinali u fit-tifsira ta’ prodott kopert minn leġislazzjoni ohra Komunitarja.

(2) It-Titoli I, II u III ta’ dan Att ma ghandhomx japplikaw ghal –

(a) prodott mediċinali li jkun ippreparat skond formola maġistrali;

(b) prodott mediċinali li jkun ippreparat skond formola offiċinali;

(ċ) prodotti mediċinali li jkun intiż għar-riċerka u provi dwar l-izvilupp relattiv, iżda minghajr preġudizzju għad-disposizzjonijiet tar-Regolamenti ta' l-2004 dwar Provi Kliniċi;

(d) radjonuklidi f'għamla ta' sorsi sigillati;

(e) demm shiħ, plasma jew ċelloli tad-demm li joriġinaw mill-bniedem, hlief għal plasma preparata b'metodu li jinvolvi proċess industrjali;

(f) prodotti intermedji intiżi għal aktar ipproċessar minn manufattur awtorizzat.

(3) (a) L-Awtorità tista, skond liġijiet li jkunu fis-seħh u sabiex jiġu suffiċjentement mwettqa b'zonnijiet speċjali, teskludi mid-disposizzjonijiet ta' dan l-Att prodotti mediċinali furniti b'rispons għal xi ordni li ssir bonafidi u li ma tkunx mitluba, formulata skond l-ispeċifikazzjonijiet ta' professjonist awtorizzat tas-saħħa u sabiex tintuża minn pazjent individwali li jkun taht ir-responsabbiltà personali diretta tiegħu.

(b) L-Awtorità tista temporanjament tawtorizza d-distribuzzjoni ta' prodott mediċinali mhux awtorizzati b'rispons għall-firxa ta' aġenti patoġeniċi, tossini, aġenti kimiċi jew radjazzjoni nukleari, ilkoll suspettati jew konfermati, li kull waħda minnhom tista' tkun kaġun ta' 'hsara:

Iżda d-detenturi ta' l-awtorizzazzjoni għat-tqeghid fis-suq, manufatturi u professjonisti tas-saħħa m'huma soġġetti għal ebda responsabbiltà ċivili jew amministrattiva għal konsegwenzi li jirrizultaw mill-użu ta' prodott mediċinali xort'ohra minn dak ta' l-indikazzjonijiet awtorizzati jew mill-użu ta' prodotti mediċinali mhux awtorizzati, meta dak l-użu jkun rakkomandat jew mehtieg mill-Awtorità b'rispons għall-firxa ta' aġenti patoġeniċi, tossini, aġenti kimiċi jew radjazzjoni nukleari, ilkoll suspettati jew konfermati, li kull waħda minnhom tista' tkun kaġun ta' 'hsara. Dan japplika irrispettivament minn jekk tkunx nġhatat jew le awtorizzazzjoni nazzjonali jew Komunitarja:

Iżda wkoll ir-responsabbiltà ghal prodotti difettużi, skond m'hemm provdut dwarha bid-Direttiva tal-Kunsill 85/374/KEE tal-25 ta' Lulju, 1985 fuq it-tqarrib tal-liġijiet, regolamenti u disposizzjonijiet amministrattivi ta' l-Istati Membri, dwar ir-responsabbiltà ghal prodotti difettużi m'għandhiex tkun affettwata bil-proviso precedenti.”.

7. It-Titolu I fit-Taqsima III ta' l-Att prinċipali għandu jithassar milli jibqa' jidher qabel l-artikolu 19 u għandu jiddaħhal biex jidher minnufih qabel l-artikolu 20.

Emenda tat-Titolu I fit-Taqsima III ta' l-Att prinċipali.

8. L-artikolu 28 ta' l-Att prinċipali għandu jiġi emendat kif ġej:-

Emenda ta' l-artikolu 28 ta' l-Att prinċipali.

(a) minflok is-subartikoli (1) u (2), għandhom jidhlu dawn li ġejjin:

“(1) L-Awtorità dwar il-Liċenzjar għandha tissospendi, tirrevoka, tirtira jew tvarja l-awtorizzazzjoni għat-tqeghid fis-suq għal prodott mediċinali, tiżgura li l-forniment tal-prodott mediċinali jkun projbit u tordna li dan jiġi rtirat mis-suq jekk:

(a) il-prodott mediċinali jkun kaġun ta' hsara taht kondizzjonijiet ta' użu normali; jew

(b) ma jkollux effikaċja terapewtika, meta dan inuqqas ta' effikaċja terapewtika jitqies li jkun qieghed isehh meta jiġi konkluz li ma jistgħux jinkisbu riżultati terapewtiċi mill-prodott mediċinali; jew

(c) il-bilanc bejn riskju u benefiċċju ma jkunx wiehed favorevoli taht il-kondizzjonijiet ta' użu awtorizzati; jew

(d) il-kompożizzjoni kwalitattiva u kwantitattiva tal-prodott ma tkunx wahda skond ma jkun hemm dikjarat; jew

(e) ma jkunux saru l-kontrolli fuq il-prodott mediċinali u, jew fuq l-ingredjenti u l-kontrolli fi stadju intermedju tal-proċess ta' manifattura, jew inkella jekk xi hteġa jew obligazzjoni li jkollha x'taqsam ma' l-għoti ta' l-awtorizzazzjoni ta' manifattura ma tkunx ġiet mwettqa suffiċjentement:

Iżda l-Awtorità dwar il-Liċenzjar tista' tillimita l-projbizzjoni għall-forniment tal-prodott mediċinali, jew l-irtirar tiegħu mis-suq, għal daww il-lottijiet li jkunu fil-qalba tat-tilwima.

(2) Awtorizzazzjoni ghandha wkoll tkun sospiza, revokata, irtirata jew varjata meta d-dettalji li jkunu jsostnu l-applikazzjoni skond ma hemm provdut dwarhom f'dan l-Att jirriżultaw li ma jkunux korretti jew ikunu ġew emendati mingħajr ebda awtorizzazzjoni jew meta ma jkunux saru l-kontrolli mehtieġa skond dan l-Att jew tahtu"; u

(b) minnufih wara s-subartikolu (5) ghandhom jiżdiedu dawn l-artikoli ġodda li ġejjin:

“(6) L-Awtorità dwar il-Liċenzjar ghandha tissospendi jew tirrevoka l-awtorizzazzjoni għat-tqeghid fis-suq għal xi kategorija ta' preparati jew għall-preparati kollha meta ma jitharsux id-disposizzjonijiet tat-Titolu II.

(7) Id-disposizzjonijiet ta' dan l-artikolu u ta' l-artikoli 99 sa 104, ghandhom japplikaw għal prodotti mediċinali omeopatiċi.”.

Emenda ta' l-artikolu 32 ta' l-Att prinċipali.

9. Fis-subartikolu (1) ta' l-artikolu 32 ta' l-Att prinċipali, minflok il-kliem “Prodotti mediċinali omeopatiċi” ghandhom jidhlu l-kliem “Mingħajr preġudizzju għall-artikolu 28 ta' dan l-Att, prodotti mediċinali omeopatiċi”, u fit-test Malti tas-subartikolu (5), minflok il-kliem “esperimenti kliniċi” ghandhom jidhlu l-kliem “provi kliniċi”.

Emenda ta' l-artikolu 41 ta' l-Att prinċipali.

10. Fis-subartikolu (1) ta' l-artikolu 41 ta' l-Att prinċipali, il-kliem “taht dan l-Att” ghandhom jithassru.

Sostituzzjoni ta' l-artikolu 49 ta' l-Att prinċipali.

11. Minflok l-artikolu 49 ta' l-Att prinċipali, ghandu jidhol dan li ġejj:-

“49. Id-disposizzjonijiet ta' l-artikoli 37 sa 48 ghandhom japplikaw għall-manufattura u l-assemblaġġ ta' prodotti mediċinali omeopatiċi.”.

Emenda ta' l-artikoli 50, 51, 52 u 53 ta' l-Att prinċipali.

12. Fl-artikoli 50, 51, 52 u 53 ta' l-Att prinċipali, il-kliem “, minbarra l-prodotti elenkati fl-artikolu 32(a) (b) u (c)”, kull fejn dawn jinsabu, ghandhom jiġu mhassra.

Sostituzzjoni ta' l-artikolu 77 ta' l-Att prinċipali.

13. Minflok l-artikolu 77 ta' l-Att prinċipali, ghandu jidhol dan li ġejj:

“77. Il-kondizzjonijiet u l-kriterji li jistabbilixxu meta persuna ghandha jew m'għandhiex interess dirett jew indirett fi spiżerija ghandhom jiġu stabbiliti taht dan l-Att.”.

- 14.** Fis-subartikolu (2) ta' l-artikolu 80 ta' l-Att prinċipali, il-kliem “, formulazzjoni” għandhom jithassru. Emenda ta' l-artikolu 80 ta' l-Att prinċipali.
- 15.** Fl-artikolu 83 ta' l-Att prinċipali, minnufih wara l-kliem “jew formola maġistrali” għandhom jidhlu l-kliem “jew formola officinali”.
- 16.** Fl-artikolu 87 ta' l-Att prinċipali, minflok il-kliem “formoli maġistrali u ufficjali” għandhom jidhlu l-kliem “formoli maġistrali u formoli officinali” u minflok il-kliem “l-ippakkettjar minn qabel” għandhom jidhlu l-kliem “qsim ta' pakketti awtorizzati f'unitajiet izghar”. Emenda ta' l-artikolu 83 ta' l-Att prinċipali.
- 17.** Fil-paragrafu (e) tas-subartikolu (1) ta' l-artikolu 99 ta' l-Att prinċipali, il-kliem “66(2),” għandhom jithassru. Emenda ta' l-artikolu 99 ta' l-Att prinċipali.
- 18.** Fl-artikolu 101 ta' l-Att prinċipali, fis-subartikolu (1), minflok il-kliem “tidhol f'xi fond:” għandhom jidhlu l-kliem “tidhol u tagħmel spezzjonijiet ripetuti u mhux mgħarrfin f'xi fond:”. Emenda ta' l-artikolu 101 ta' l-Att prinċipali.
- 19.** L-artikolu 102 ta' l-Att prinċipali għandu jiġi emendat kif ġej: Emenda ta' l-artikolu 102 ta' l-Att prinċipali.
- (a) fil-paragrafu (c) tas-subartikolu (1), minflok il-kliem “minn dawk il-proċessi.” għandhom jidhlu l-kliem “minn dawk il-proċessi:” u, minnufih wara, għandu jiżdied dan il-proviso li ġej mas-subartikolu shih:-
- “Izda ufficjal awtorizzat jista' wkoll jagħmel spezzjonijiet ta' manufatturi ta' materjal tal-bidu wara li ssir talba speċifika għal dawk il-finijiet minn dak il-manufattur innifsu:
- Izda wkoll il-kampjuni li jista' jittiehed jista' jiġi analizzat f'laboratorju msemmi identifikat mill-Awtorità.”;
- (b) minnufih wara l-paragrafu (b) tas-subartikolu (3), għandu jiżdied dan il-paragrafu ġdid li ġej:
- “(c) li tiġbed fotografiji ta' kull tagħmir, fond, *record* u dokument.”; u
- (c) minnufih wara s-subartikolu (7), għandhom jidhlu dawn is-subartikoli godda li ġejjin:
- “(8) Wara kull ispezzjoni l-ufficjal awtorizzat għandu jirrapporta dwar jekk il-manufattur ikunx qiegħed jikkonforma

ruhu mal-prinċipji u linji direttivi ta' Prattika ta' manufattura kif imiss jew, fejn ikun adatt, mal-htigiet li jkollhom x'jaqsmu mal-farmakoviġilanza. Il-kontenut ta' dawk ir-rapporti għandhom jitwasslu lill-manufattur jew lid-detentur ta' l-awtorizzazzjoni għat-tqeghid fis-suq li tkun saritlu l-ispezzjoni.

(9) Fi żmien 90 jum minn ispezzjoni, għandu jinhareġ lil manufattur ċertifikat ta' Prattika ta' manufattura kif imiss jekk l-eżitu ta' l-ispezzjoni juri li l-manufattur jkun qiegħed jikkonforma ruhu mal-prinċipji u mal-linji direttivi ta' Prattika ta' manufattura kif imiss kif provdut dwar dan bil-legislazzjoni li tkun qiegħda ssehh f'dak il-waqt.”.

Emenda ta' l-artikolu 103 ta' l-Att prinċipali.

20. Minnufih wara s-subartikolu (4) ta' l-artikolu 103 ta' l-Att prinċipali, għandu jiżdied dan is-subartikolu ġdid li ġej:-

“(5) Meta jkun ġie elevat xi prodott mediċinali taht id-disposizzjonijiet ta' dan l-Att u sid-il prodott jagħti l-kunsens tiegħu bil-miktub għall-qirda ta' dak il-prodott mediċinali, l-Awtorità dwar il-Liċenzjar tista' wara li tiehu dawk il-kampjuni li tista tkun tehtieg biex jingiebu bhala preġudizzju għal kull proċediment li jista' jsir kontra l-persuna responsabbli għar-reat u l-Awtorità dwar il-Liċenzjar imsemmija għandha tirmborsa l-ispejjeż kollha li jkunu saru fil-qirda tal-prodott mediċinali.”.

Żjieda ta' l-artikolu 104A ġdid ma' l-Att prinċipali.

21. Minnufih wara l-artikolu 104 ta' l-Att prinċipali, għandu jiżdied dan l-artikolu ġdid li ġej:

“Prova tal-kontrolli li jsiru.

104A. (1) Id-detentur ta' l-awtorizzazzjoni għat-tqeghid fis-suq ta' prodott mediċinali u, fejn ikun adatt, id-detentur ta' l-awtorizzazzjoni għall-manufattura, għandhom jagħtu prova tal-kontrolli li jsiru fuq il-prodott mediċinali u, jew l-ingredjenti u tal-kontrolli li jsiru fi stadju intermedju tal-proċess ta' manufattura, skond il-metodi stipulati fl-artikolu 8(3)(h) tad-Direttiva 2001/83 KE u kull emenda fiha.

(2) Il-manufatturi ta' prodotti immunoloġiċi għandhom jipprezentaw lill-Awtorità kopji tar-rapporti kollha dwar il-kontroll iffirmati mill-persuna kwalifikata.

(3) Meta l-Awtorità tqis li jkun hekk mehtieg fl-interess tas-saħha pubblika, hija tista' tehtieg lid-detentur ta' awtorizzazzjoni għat-tqeghid fis-suq:

(a) ta' vaċċini hajjin,

(b) ta' prodotti mediċinali immunoloġiċi fl-immunizzazzjoni primarja ta' trabi jew ta' gruppi oħrajn f'riskju;

(ċ) ta' prodotti mediċinali immunoloġiċi li jintużaw fi programmi ta' immunizzazzjoni tas-saħha pubblika,

(d) prodotti mediċinali immunoloġiċi ġodda jew prodotti mediċinali immunoloġiċi manufatturati bl-użu ta' modi ta' teknoloġiji ġodda jew mibdulin jew ġodda għal xi manufattur partikulari, matul perjodu transitorju normalment speċifikat fl-awtorizzazzjoni għat-tqeghid fis-suq,

jippreżenta kampjuni minn kull lott ta' l-ingrossa u, jew il-prodott mediċinali għall-eżami minn laboratorju msemmi għal dak l-għan qabel ir-rilaxx fis-suq kemm-il darba, fil-każ ta' lott manufatturat fi Stat Membru ieħor, l-awtorità kompetent ta' dak l-Istat Membru ma tkunx qabel eżaminat il-lott involut u iddikjaratu bħala wiehed konformi ma' l-ispeċifikazzjonijiet approvati. L-Awtorità għandha tiżgura li bhal dak eżami jitlesta fi żmien 60 ġurnata minn meta jaslu l-kampjuni.

(4) Fl-interess tas-saħha pubblika, l-Awtorità tista' tehtieg lid-detentur ta' awtorizzazzjoni għat-tqeghid fis-suq għal prodotti mediċinali miksubin mid-demmi jew mill-plasma tal-bniedem jippreżenta kampjuni minn kull lott ta' l-ingrossa u, jew il-prodott mediċinali għall-ittestjar minn laboratorju msemmi għal dak l-għan qabel ma dawn jiġu rilaxxati f'ċirkolazzjoni libera, kemm-il darba l-awtoritajiet kompetenti ta' xi Stat Membru ieħor ma jkunux qabel eżaminaw il-lott involut u ddikjaraw li dan kien konformi ma' l-ispeċifikazzjonijiet approvati. L-Awtorità għandha tiżgura li kull tali eżami jsir fi żmien 60 ġurnata minn meta jiġu riċevuti l-kampjuni.”.

22. L-artikolu 106 ta l-Att prinċipali għandu jiġi emendat kif ġej:–

Emenda ta' l-artikolu 106 ta' l-Att prinċipali

(a) fit-test Malti tal-paragrafu (h), minflok il-kliem “esperimenti kliniċi” għandhom jidhlu l-kliem “provi kliniċi”; u

(b) minflok il-paragrafu (q), għandu jidhol dan li ġej:–

“(q) il-hlasijiet li jistgħu jingabru u l-fondi fejn daww il-hlasijiet jistgħu jiġu depożitati mill-Awtorità dwar il-Liċenzjar, l-Awtorità dwar il-Mediċini u kull kumitat iehor imwaqqaf minn jew taht dan l-Att jew regolamenti magħmulin tahtu;”.

Żjieda ta’
l-artikolu 110
għdid ma’ l-Att
prinċipali.

23. Minnufih wara l-artikolu 109 ta’ l-Att prinċipali, għandu jiżdied dan l-artikolu għdid li ġej:

“Disposizzjo-
nijiet
transitorji.

110. (1) Ebda haġa f’dan l-Att m’għandha b’ebda mod tidderoga minn xi Att jew regolamenti dwar il-protezzjoni minn radjazzjoni ta’ persuni li jkunu qegħdin jagħmlu xi eżami mediku jew li jkunu qegħdin jiehdu kura medika, jew minn regoli Komunitarji li jstipulaw il-livelli bażiċi ta’ sigurtà għall-harsien tas-saħħa tal-pubbliku b’mod ġenerali u tal-haddiema kontra l-perikli tar-radjazzjoni jonizzanti.

(2) Dan l-Att hu mingħajr preġudizzju għad-Deċiżjoni tal-Kunsill 86/346/KEE tal-25 ta’ Ġunju 1986 li taċċetta f’isem il-Komunità, il-Ftehim Ewropew fuq l-Iskambju ta’ Sustanzi Terapewtiċi li Joriginaw mill-Bniedem.

(3) Id-disposizzjonijiet ta’ dan Att m’għandjomx jaffettwaw is-setgħat ta’ l-Awtorità la dwar kif jiġu stabbiliti l-prezzijiet għal prodotti mediċinali u lanqas dwar l-inklużjoni tagħhom fl-iskop ta’ skemi ta’ l-assigurazzjoni tas-saħħa nazzjonali, abbażi ta’ kundizzjonijiet tas-saħħa u daww ekonomiċi u soċjali.

(4) Dan l-Att m’għandux jaffettwa l-applikazzjoni ta’ xi liġi li tipprojbixxi jew tirrestringi l-bejgħ, il-provvista jew l-użu ta’ prodotti mediċinali bħala kontraċettivi jew li jwasslu għall-abort.”.

Thassir tat-Tielet
Skeda li tinsab ma’
l-Att prinċipali.

24. It-Tielet Skeda li tinsab ma’ l-Att prinċipali għandha tiġi mħassra.

Mghoddi mill-Kamra tad-Deputati fis-Seduta Nru. 551 tas-16 ta’ Lulju, 2007.

ANTON TABONE
Speaker

RICHARD J. CAUCHI
Skrivan tal-Kamra tad-Deputati

I assent.

(L.S.)

EDWARD FENECH ADAMI
President

20th July, 2007

ACT No. XI of 2007

AN ACT to amend the Medicines Act, Cap. 458

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:-

1. (1) The short title of this Act is the Medicines (Amendment) Act, 2007. Short title.

(2) This Act shall be read and construed as one with the Medicines Act, hereinafter referred to as “the principal Act”.

2. Article 2 of the principal Act shall be amended as follows: Amendment of article 2 of the principal Act.

(a) immediately before the definition “advertising” there shall be inserted the following new definition:-

“ “adverse reaction” means a response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function;”;

(b) immediately after the definition “clinical trial”, there shall be added the following new definition:-

“ “common name” means the international non-proprietary name recommended by the World Health Organization, or, if one does not exist, the usual common name;”;

(c) in the Maltese text of the definition “esperiment kliniku”, for the words “esperiment kliniku” there shall be substituted the words “prova klinika”;

(d) for the definition “herbal medicinal product” there shall be substituted the following:-

““herbal medicinal product” means any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations;”;

(e) for the definition “herbal preparations” there shall be substituted the following:-

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

(f) for the definition “herbal substances” there shall be substituted the following:-

“ “herbal substances” means all mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author);”;

(g) in the definition “homeopathic medicinal product”, for the words “in Malta” there shall be substituted the words “in the Member States”;

(h) for the definition “immunological medicinal product” there shall be substituted the following:-

“immunological medicinal product” means any medicinal product consisting of vaccines, toxins, serums or allergen products, where –

(a) vaccines, toxins and serums shall cover in particular:

(i) agents used to produce active immunity, such as cholera vaccine, BCG, polio vaccines, smallpox vaccine;

(ii) agents used to diagnose the state of immunity, including in particular tuberculin and tuberculin PPD, toxins for the Schick and Dick Tests, brucellin;

(iii) agents used to produce passive immunity, such as diphtheria antitoxin, anti-smallpox globulin, antilymphocytic globulin;

(b) ‘allergen product’ shall mean any medicinal product which is intended to identify or induce a specific acquired alteration in the immunological response to an allergizing agent;”;

(i) in the definition “magistral formula” for the words “with a prescription” there shall be substituted the words “with a medical prescription”;

(j) in the definition “medicinal prescription” for the words “any prescription” there shall be substituted the words “any medicinal prescription”;

(k) for the definition “medicinal product” there shall be substituted the following:-

“ “medicinal product” means any substance or combination of substances -

(a) presented as having properties for treating or preventing disease in human beings; or

(b) which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;”;

(l) immediately after the definition “medicinal product”, there shall be added the following new definition:-

“ “medicinal products derived from human blood or human plasma” means medicinal products based on blood constituents which are prepared industrially by public or private establishments, such medicinal products including, in particular, albumin, coagulating factors and immunoglobulins of human origin;”;

(m) immediately after the definition “Minister” there shall be added the following new definition:-

“ “name of the medicinal product” means the name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorisation holder;”;

(n) the definitions “official formula” and “pre-packaging” shall be deleted;

(o) immediately after the new definition “name of the medicinal product” there shall be inserted the following new definition:-

““official formula” means any medicinal product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by such pharmacy;”;

(p) in the Maltese text of the definition “prodott medicinali investigattiv”, for the words “l-esperiment kliniku” there shall be substituted the words “fi prova klinika”;

(q) in the definition “radionuclide generator” for the word “removed” there shall be substituted the word “obtained”;

(r) in the definition “radionuclide kit” for the words “radionuclide kit” there shall be substituted the word “kit”, and the said definition “kit” shall now be inserted immediately after the definition “investigational medicinal product”;

(s) in the definition “radionuclide precursor”, for the words “radionuclide kit” there shall be substituted the words “kit”;

(t) for the definition “radiopharmaceutical” there shall be substituted the following:-

“ “radiopharmaceutical” means any medicinal product which, when ready for use, contains one or more radionuclides (radioactive isotopes) included for a medicinal purpose;”;

(u) immediately after the definition “responsible person” there shall be added the following new definition:-

“ “risk-benefit balance” means an evaluation of the positive therapeutic effects of the medicinal product in relation to the risks as defined in paragraph (a) of the definition”“risks related to use of the medicinal product;”;

(v) immediately after the definition “risk-benefit balance” there shall be added the following new definition:-

“ “risks related to use of the medicinal product” means:-

(a) any risk relating to the quality, safety or efficacy of the medicinal product as regards patients’ health or public health;

(b) any risk of undesirable effects on the environment; ”;

(w) immediately after the definition “rules” there shall be added the following new definition:-

“ “serious adverse reaction” means an adverse reaction which results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect”;

(x) immediately after the definition “serious adverse reaction” there shall be added the following new definition:-

“ “strength of the medicinal product” means the content of the active substances expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form;”;

(y) for the definition “substance” there shall be substituted the following:-

“ “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, toxins, extracts, blood products), vegetable (including micro-organisms, plants, parts of plants, vegetable secretions, extracts), or chemical (including elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis);”;

(z) immediately after the definition “Superintendent of Public Health” there shall be inserted the following new definition:-

“ “unexpected adverse reaction” means an adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics;”

(aa) for the definition “wholesale distribution” there shall be substituted the following:-

“ “wholesale distribution”, in relation to a medicinal product, includes all activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public. Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorised or entitled to supply medicinal products to the public in Malta.”;

(bb) in the Maltese text only thereof:

(i) the definition “*leaflets* ġo pakkett” shall be deleted;

(ii) immediately after the definition “farmakopeia rikonoxxuta” there shall be added the following new definition:-

“ “fuljett ta’ taghrif” tfisser il-fuljett li jkun fih l-informazzjoni kollha għal min ikun se juzah u li jkun jinsab flimkien mal-prodott mediċinali;”

(iii) in the definition “reklamar”, and in article 28(3), for the words “*leaflets*” and “*leaflets* ġo pakkett” wherever they occur there shall be substituted the words “fuljetti ta’ taghrif” and “fuljett ta’ taghrif” respectively; and

(iv) in article 102 (1)(b), for the word “leaflet” there shall be substituted the word “fuljett”.

3. Article 3 of the principal Act shall be amended as follows:–

Amendment of article 3 of the principal Act.

(a) in the Maltese text of paragraph (f) of subarticle (2), for the words “esperimneti kliniċi” there shall be substituted the words “provi kliniċi”; and

(b) for sub-article (3), there shall be substituted the following:

“(3) The Licensing Authority may by rules delegate any of its functions referred to in paragraphs (l), (m), (n) and (o) of sub-article (2) hereof to the Medicines Authority.”.

4. In sub-article (2) of article 10 of the principal Act, for the word “agency”, wherever it occurs, there shall be substituted the word “Authority”.

Amendment of article 10 principal Act.

5 For paragraph (a) of sub-article (2) of article 16 of the principal Act, there shall be substituted the following:–

Amendment of article 16 of the principal Act.

“(a) to hear an appeal submitted by the applicant of a marketing authorisation on any recommendation of the Medicines Authority in relation to the safety, quality and efficacy of a medicinal product”.

6. For article 19 of the principal Act, there shall be substituted the following:

Substitution of article 19 of the principal Act.

“19. (1) The provisions of Titles I, II and III shall apply:

(a) to medicinal products for human use intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process;

(b) in cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a medicinal product and within the definition of a product covered by other Community legislation.

(2) Titles I, II and III of this Act shall not apply to –

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

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

(c) medicinal products intended for research and development trials, but without prejudice to the provisions of the Clinical Trials Regulations, 2004;

(d) radionuclides in the form of sealed sources;

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

(f) intermediate products intended for further processing by an authorised manufacturer.

(3) (a) The Authority may, in accordance with legislation in force and to fulfill special needs, exclude from the provisions of this Act medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised health-care professional and for use by an individual patient under his direct personal responsibility.

(b) The Authority may temporarily authorise the distribution of an unauthorised medicinal product in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm:

Provided that marketing authorisation holders, manufacturers and health professionals are not subject to civil or administrative liability for any consequences resulting from the use of a medicinal product otherwise than for the authorised indications or from the use of an unauthorised medicinal product, when such use is recommended or required by the Authority in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm. This shall apply irrespective of whether or not national or Community authorisation has been granted:

Provided further that liability for defective products, as provided for by Council Directive 85/374/EEC of 25 July, 1985 on the approximation of the laws, regulations and administrative provisions of the Member States, concerning liability for defective products shall not be affected by the preceding proviso.”.

7. Title I of part III of the principal Act shall be deleted from appearing before article 19 and shall be inserted to appear immediately before article 20.

Amendment to Title I of Part III of the principal Act.

8. Article 28 of the principal Act shall be amended as follows:-

Amendment of article 28 of the principal Act.

(a) for sub-articles (1) and (2) thereof, there shall be substituted the following:

“(1) The Licensing Authority shall suspend, revoke, withdraw or vary the marketing authorization for a medicinal product, ensure that the supply of the medicinal product is prohibited and order its withdrawal from the market if:

(a) the medicinal product is harmful under normal conditions of use; or

(b) it lacks therapeutic efficacy, where such lack of therapeutic efficacy shall be deemed as occurring when it is concluded that therapeutic results cannot be obtained from the medicinal product; or

(c) the risk benefit balance is not favourable under the authorised conditions of use; or

(d) its qualitative and quantitative composition is not as declared; or

(e) the controls on the medicinal product and, or on the ingredients and the controls at an intermediate stage of the manufacturing process have not been carried out, or if the requirement or obligation relating to the grant of the manufacturing authorisation has not been fulfilled:

Provided that the Licensing Authority may limit the prohibition to supply the medicinal product, or its withdrawal from the market, to those batches which are the subject of dispute.

(2) An authorisation shall also be suspended, revoked, withdrawn or varied 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.”; and

(b) immediately after sub-article (5) thereof shall be added the following new articles:

“(6) The Licensing Authority shall suspend or revoke the marketing authorization for a category of preparations or all preparations where the provisions of Title II are not complied with.

(7) The provisions of this article and of articles 99 to 104, shall apply to homeopathic medicinal products.”.

Amendment of article 32 of the principal Act.

9. Article 32 of the principal Act shall be amended as follows:–

(a) in sub-article (1) for the words “Homeopathic medicinal products” there shall be substituted the words “Without prejudice to article 28 of this Act, homeopathic medicinal products”; and

(b) in the Maltese text of subarticle (5), for the words “esperimenti kliniċi” there shall be substituted the words “provi kliniċi”.

Amendment of article 41 of the principal Act.

10. In sub-article (1) of article 41 of the principal Act, the words “under this Act” shall be deleted.

Substitution of article 49 of the principal Act.

11. For article 49 of the principal Act, there shall be substituted the following:-

“49. The provisions of articles 37 to 48 shall apply to the manufacture and assembly of homeopathic medicinal products.”.

Amendment of articles 50,51, 52 and 53 of the principal Act.

12. In articles 50, 51, 52 and 53 of the principal Act, the words “other than the products listed in article 32(a) (b) and (c)”, wherever they occur shall be deleted.

substitution of article 77 of the principal Act.

13. For article 77 of the principal Act, there shall be substituted the following:–

“77. The conditions and criteria where any person can have or not have a direct or indirect interest in a pharmacy shall be prescribed under this Act.”.

Amendment of article 80 of the principal Act.

14. In sub-article (2) of article 80 of the principal Act, the words “, formulation” shall be deleted.

Amendment of article 83 of the principal Act.

15. In article 83 of the principal Act, for the words “or official formula” there shall be substituted the words “or officinal formula”.

16. In article 87 of the principal Act, for the words “official formulas” there shall be substituted the words “officinal formulas” and for the word “pre-packing” there shall be substituted the words “division of authorised packs into smaller units”.

Amendment of article 87 of the principal Act.

17. In paragraph (e) of subarticle (1) of article 99 of the principal Act, the words “66(2)” shall be deleted.

Amendment of article 102 of the principal Act.

18. In article 101 of the principal Act, in sub-article (1) thereof, for the words “to enter any premises:” there shall be substituted the words “to enter and carry out repeated and unannounced inspections at any premises:”.

Amendment of article 99 of the principal Act.

19. Article 102 of the principal Act shall be amended as follows:

Amendment of article 101 of the principal Act.

(a) in paragraph (c) of sub-article (1) thereof, for the words “to those processes.” there shall be substituted the words “to those processes:” and, immediately thereafter, there shall be added the following provisos to the whole sub-article:-

“Provided that an authorized officer may also carry out inspections of starting material manufacturers after a specific request for the purpose is made by such manufacturer himself:

Provided further that the samples that may be collected may be analysed at a designated laboratory identified by the Authority.”;

(b) immediately after paragraph (b) of sub-article (3) thereof, there shall be added the following new paragraph:

“(c) to take photographs of any equipment, premises, records and documents.”; and

(c) immediately after sub-article (7) thereof, there shall be inserted the following new sub-articles:

“(8) After every inspection the authorized officer shall report on whether the manufacturer complies with the principles and guidelines of good manufacturing practice or, where appropriate, with the requirements relating to pharmacovigilance. The content of such reports shall be communicated to the manufacturer or marketing authorisation holder who has undergone the inspection.

(9) Within 90 days of an inspection a certificate of good manufacturing practice shall be issued to a manufacturer if the outcome of the inspection shows that the manufacturer complies with the principles and guidelines of good manufacturing practice as provided for by legislation in force at the time.”.

Amendment of article 103 of the principal Act.

20. Immediately after sub-article (4) of article 103 of the principal Act, there shall be added the following new sub-article:-

“(5) Where any medicinal product has been seized under the provisions of this Act, and the owner thereof consents in writing to the destruction of such medicinal product the Licensing Authority may after taking such samples as may be required to prove the offence, direct that the said medicinal product be destroyed, without prejudice to the taking of any proceedings against the person responsible for the offence, and the said Licensing Authority shall recoup all the expenses involved in the destruction of the medicinal product.”.

Addition of new article 104A to the principal Act.

21. Immediately after article 104 of the principal Act, there shall be added the following new articles:

“Proof of controls carried out.

104A. (1) The holder of the marketing authorization for a medicinal product and, where appropriate, the holder of the manufacturing authorization, shall furnish proof of the controls carried out on the medicinal product and, or the ingredients and of the controls carried out at an intermediate stage of the manufacturing process, in accordance with the methods laid down in Article 8(3)(h) of Directive 2001/83 EC and any amendments thereto.

(2) Manufacturers of immunological products shall submit to the Authority copies of all the control reports signed by the qualified person.

(3) Where the Authority considers it necessary in the interests of public health, it may require the holder of an authorization for marketing:

(a) live vaccines,

(b) immunological medicinal products used in the primary immunization of infants or of other groups at risk;

(c) immunological medicinal products used in public health immunization programmes,

(d) new immunological medicinal products or immunological medicinal products manufactured using new or altered kinds of technology or new for a particular manufacturer, during a transitional period normally specified in the marketing authorization,

to submit samples from each batch of the bulk and, or the medicinal product for examination by a laboratory designated for that purpose before release on to the market unless, in the case of a batch manufactured in another Member State, the competent authority of that Member State has previously examined the batch in question and declared it to be in conformity with the approved specifications. The Authority shall ensure that any such examination is completed within 60 days of the receipt of the samples.

(4) In the interests of public health, the Authority may require the marketing authorization holder for medicinal products derived from human blood or human plasma to submit samples from each batch of the bulk and, or the medicinal product for testing by a laboratory designated for that purpose before being released into free circulation, unless the competent authorities of another Member State have previously examined the batch in question and declared it to be in conformity with the approved specifications. The Authority shall ensure that any such examination is completed within 60 days of the receipt of the samples.”.

22. Article 106 of the principal Act shall be amended as follows:— Amendment of article 106 of the principal Act.

(a) in the Maltese text of paragraph (h), for the words “esperimenti kliniċi” there shall be substituted the words “provi kliniċi”; and

(b) for paragraph (q), there shall be substituted the following:-

“(q) the fees that may be levied and the funds wherein such fees may be deposited by the Licensing Authority, the Medicines Authority and any other Committee established by or under this Act or regulations made thereunder;”.

Addition of new article 110 in the principal Act.

23. Immediately after article 109 of the principal Act, there shall be added the following new article:

“Saving provisions.

110. (1) Nothing in this Act shall in any way derogate from any Acts or regulations for the radiation protection of persons undergoing medical examination or treatment, or from the Community rules laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation.

(2) This Act shall be without prejudice to Council Decision 86/346/EEC of 25 June 1986 accepting on behalf of the Community the European Agreement on the Exchange of Therapeutic Substances of Human Origin.

(3) The provisions of this Act shall not affect the powers of the Authority either as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes, on the basis of health, economic and social conditions.

(4) This Act shall not affect the application of any law prohibiting or restricting the sale, supply or use of medicinal products as contraceptives or abortifacients.”.

Repeal of the Third Schedule to the principal Act.

24. The Third Schedule to the principal Act shall be repealed.

Passed by the House of Representatives at Sitting No. 551 of the 16th July, 2007.

ANTON TABONE
Speaker

RICHARD J. CAUCHI
Clerk to the House of Representatives

