

A.L. 393 ta' l-2005

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

**Regolamenti ta' l-2005 dwar it-Tqeghid ta' Tikketti u
Ppakkettjar ta' Prodotti Mediċinali**

BIS-SAHHA tas-setghat moghtija bl-artiklu 106 ta' l-Att ta' l-2003 dwar il-Mediċini, il-Ministru tas-Sahha, Anzjani u Kura fil-Komunità ghamel dawn ir-regolamenti:

1. (1) It-titolu ta' dawn ir-regolamenti hu **Regolamenti ta' l-2005 dwar it-Tqeghid ta' Tikketti u Ppakkettjar ta' Prodotti Mediċinali.** Titolu, bidu fis-sehh u skop.

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

(3) L-iskop ta' dawn ir-regolamenti hu li jittrassponu d-Direttiva 2001/83/KE.

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

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

“il-Kummissjoni” tfisser il-Kummissjoni skond id-Deciżjoni tal-Kunsill 1999/468/KE tat-28 ta' Ġunju, 1999;

“ippakkettjar fuq barra” tfisser it-tgeżwir li fih jitqiegħed l-ippakkettjar immedjat;

“ippakkettjar immedjat” tfisser il-kontenitur jew xi għamla ohra ta' tgeżwir li jkun imiss eżatt mal-prodott mediċinali,

“il-qawwa tal-prodott mediċinali” tfisser il-kontenut tas-sustanzi attivi espress b'mod kwantitattiv f'kull doża, f'kull unità tal-volum jew tal-piż skond l-għamla tad-doża;

“ir-rappreżentant tad-detentur ta’ l-awtorizzazzjoni ghat-tqeghid fis-suq “ tfisser il-persuna, soltu maghrufa bħala rappreżentant lokali, mahtura mid-detentur ta’ l-awtorizzazzjoni ghat-tqeghid fis-suq biex jirrapreżentah fi Stat Membru konċernat;

“isem komuni” tfisser l-isem mhux proprjetarju internazzjonali rakkomandat mill-Organizzazzjoni tas-Sahha Dinjija (WHO), jew, jekk dak l-isem ma jeżistix, l-isem komuni tas-soltu;

“isem tal-prodott mediċinali” tfisser l-isem, li jista’ jkun jew ivvintat u allura mhux soġġett għal xi konfużjoni ma’ l-isem komuni, jew isem komuni jew xjentifiku li jkollu miegħu *trademark* jew l-isem tad-detentur ta’ l-awtorizzazzjoni ghat-tqeghid fis-suq;

“tikketta” tfisser l-informazzjoni lit kun qeghda fuq l-ippakkettjar immedjat jew fuq barra.

Partikolaritajiet fuq l-ippakkettjar ta’ barra.

3. Dawn il-partikolaritajiet li ġejjin għandhom jidhru fuq l-ippakkettjar fuq barra tal-prodotti mediċinali jew, meta ma jkunx hemm ipakkettjar bħal dak, fuq l-ippakkettjar immedjat:-

(a) l-isem tal-prodott mediċinali segwit bil-qawwa u l-għamla tiegħu farmaċewtika, u, fejn jehtieg, jekk hux intenzjonat ghat-trabi, tfal jew adulti; meta l-prodott ikun fih sa tliet sustanzi attivi, l-isem internazzjonali mhux proprjetarju (INN) għandu jkun inkluż, jew, jekk ma jkollux wiehed, l-isem komuni;

(b) dikjarazzjoni tas-sustanzi attivi espressi skond il-kwantità u l-kwalità ta’ kull unità ta’ doża, jew skond kif jiġi amministrat volum jew piż individwali, billi jintuża l-isem komuni tagħhom;

(ċ) l-għamla farmaċewtika u l-kontenut bil-piż, bil-volum jew bl-għadd ta’ doži tal-prodott;

(d) lista ta’ dawk is-sustanzi mhux attivi (eċċipjenti) maghrufin li għandhom azzjoni jew effett rikonoxxuti u li huma inklużi fil-gwida dettaljata pubblikata mill-Kummissjoni konformement ma’ l-Artikolu 65 tad-Direttiva 2001/83/KE kif emendata bid-Direttiva 2004/27/KE. Madanakollu, jekk il-prodott jista’ jiġi injettat, jew użat fuq il-ġilda jew magħmul għall-ghajnejn, is-sustanzi eċċipjenti kollha għandhom jiġu dikjarati;

(e) il-metodu ta’ l-użu, u, jekk ikun hemm bżonn, ir-rotta mnejn jintuża. Għandu jkun hemm spazju fejn tista’ tiġi indikata d-doża preskritta;

(f) twissija speċjali li l-prodott mediċinali ghandu jiġi maħzun fejn ma jilhquhx u ma jarawhx it-tfal;

(g) kull twissija importanti li jista' jkun hemm bżonnha ghal xi prodott mediċinali partikolari;

(h) id-data meta jiskadi miktuba ċar (xahar/sena);

(i) prekawzjonijiet speċjali dwar il-ħażna, jekk ikun hemm;

(j) prekawzjonijiet speċifiċi, li ghandhom x'jaqsmu mar-rimi ta' prodotti mediċinali li ma jkunux intużaw jew skart ġej minn prodotti mediċinali, fejn ikun adatt, kif ukoll bhala referenza ghal kull sistema adatta ta' ġbir;

(k) l-isem u l-indirizz tad-detentur ta' l-awtorizzazzjoni ghat-tqeghid fis-suq u, meta jkun jghodd, l-isem tar-rappreżentant mahtur mid-detentur biex jirrappreżentah;

(l) in-numru ta' l-awtorizzazzjoni ghat-tqeghid fis-suq;

(m) in-numru tal-lott tal-manifattur;

(n) fil-każ ta' prodotti mediċinali li ma jehtigux riċetta, taghrif dwar kif dawn jintużaw.

4. (a) Il-partikolaritajiet stabbiliti taht bir-regolament 3 ghandhom *Blisters Packs*. jidhru fuq l-ippakkettjar immedjat li ma jkunx dak imsemmi fil-paragrafi (b) u (c) ta' dan ir-regolament.

(b) Dawn il-partikolarijiet li ġejjin ghandhom mill-inqas jidhru fuq l-ippakkettjar immedjat, meta dan jiehu l-ghamla ta' *blisters pack* li mbaghad jitqieghed f'ippakkettjar fuq barra li jkun konformi mal-provvedimenti stabbiliti fir-regolamenti 3 u 9:

(i) l-isem tal-prodott mediċinali kif stabbilit taht ir-regolament 3(a);

(ii) l-isem tad-detentur ta' l-awtorizzazzjoni ghat-tqeghid fis-suq;

(iii) id-data ta' l-gheluq;

(iv) in-numru tal-lott.

(ċ) Fil-każ ta' ippakkettjar immedjat żgħir li fuqu il-partikolaritajiet stabbiliti taht ir-regolamenti 3 u 9 ma jistghux jiġu murija, għandhom ta' l-anqas jiġu murija dawn il-partikolaritajiet li ġejjin:

(i) l-isem tal-prodott mediċinali kif ġie stabbilit taht ir-regolament 3(a), u, jekk ikun hemm bżonn, ir-rotta mnejn jista' jinghata;

(ii) il-metodu ta' kif jinghata;

(iii) id-data tal-ġheluq;

(iv) in-numru tal-lott;

(v) il-kontenut bil-piż, volum jew kull unità.

Dettalji ċari.

5. (1) Il-partikolaritajiet imsemmija fir-regolamenti 3, 4 u 9 għandhom ikunu jistgħu jinqraw, jiftiehm u ma jithassrux.

(2) L-isem tal-prodott mediċinali, kif imsemmi fir-regolament 3 (a), għandu wkoll jiġi muri fil-format Braille fuq l-ippakkettjar. Id-detentur ta' l-awtorizzazzjoni għat-tqeghid fis-suq għandu jiżgura li l-fuljett tal-pakkett bl-informazzjoni ikun disponibbli meta jiġi hekk mitlub minn organizzazzjonijiet tal-pazjenti f' suriet adattati għal min hu aghma jew aghma parzjalment.

Kif il-fuljett ta' tagħrif jiġi inkluz.

6. Għandu jiġi inkluz fuljett ta' tagħrif ma l-ippakkettjar tal-prodotti mediċinali kollha kemm-il darba l-informazzjoni kollha mehtieġa bir-regolamenti 7 u 9 ma tkunx murija direttament fuq l-ippakkettjar fuq barra jew fuq l-ippakkettjar immedjat.

Il-fuljett tal-pakkett.

7. (1) Il-fuljett tal-pakkett għandu jkun miktub skond il-karatteristiċi tal-prodott fil-qosor u għandu jkun jinkludi, fl-ordni li ġejja:

(a) sabiex jiġi dentifikat il-prodott mediċinali:

(i) l-isem tal-prodott mediċinali segwit bil-qawwa u l-ghamla farmaċewtika tiegħu, u meta jkun adatt, huwiex intenzjonat għat-trabi, tfal jew adulti. L-isem komuni għandu jiġi inkluz fejn il-prodott ikun fih biss sustanza wahda attiva u jekk l-isem tiegħu jkun isem ivvintat;

(ii) il-grupp farmako-terapewtiku jew it-tip ta' attività fi kliem li faċilment jiftiehm mill-pazjent;

(b) l-indikazzjonijiet terapewtiċi;

(ċ) lista ta' informazzjoni li tkun mehtieġa qabel ma jittiehed il-prodott:

(i) kontra-indikazzjonijiet;

(ii) prekawzjonijiet adatti dwar l-użu;

(iii) forom ta' interazzjoni ma' prodotti mediċinali ohra u forom ohra ta' interazzjoni (bhal alkohol, tabakk, oġġetti ta' ike) li jistgħu jolqtu l-effetti tal-prodott mediċinali;

(iv) twissijiet speċjali;

(d) l-istruzzjonijiet mehtieġa tas-soltu għal użu kif imiss u partikolarment:

(i) id-doża;

(ii) il-metodu u, jekk ikun hemm bżonn, ir-rota mnejn jista' jinghata;

(iii) kemm spiss għandu l-prodott jiġi mehud billi jiġi speċifikat, jekk ikun hemm bżonn, il-hin sew meta dan il-prodott mediċinali jista' jew għandu jittiehed, u, kif imiss, skond in-natura tal-prodott;

(iv) kemm għandha ddum il-kura, u meta din għandha tkun limitata fiż-żmien;

(v) x'għandu jsir fil-każ ta' doża żejda (bhal x'inhuma sintomi, proċeduri ta' emergenza);

(vi) x'għandu jsir meta doża waħda jew aktar ma jkunux ittiehdu;

(vii) indikazzjoni, jekk ikun mehtieġ, tar-riskju ta' l-effetti li jġib miegħu it-twaqqif li jittiehed il-prodott;

(viii) rakkomandazzjoni speċifika biex jiġi konsultat tabib jew spiżjar, skond il-bżonn, għal kull kjarifika mehtieġa dwar l-użu tal-prodott;

(e) deskrizzjoni ta' reazzjonijiet kuntrarji li jistgħu jinqalghu bl-użu normali tal-prodott mediċinali u, jekk ikun hemm bżonn, l-

azzjoni li ghandha tittiehed f'każ bhal dak; il-pazjent ghandu jiġi mwissi biex jikkomunika kull effett hażin li mhux imniżżel fuq il-fuljett ta' taghrif lit-tabib jew l-ispizjar tiegħu;

(f) referenza ghad-data ta' l-gheluq indikata fuq it-tiketeta u magħha:

(i) twissija ċara kontra l-użu tal-prodott wara dik id-data;

(ii) fejn ikun il-każ, prekawzjonijiet speċjali dwar il-ħażna tal-prodott;

(iii) jekk ikun hemm bżonn, twissija dwar ċerti sinjali ta' taħsir li jidhru;

(iv) il-kompożizzjoni kollha kwalitattivà (kemm f'sustanzi attivi kemm f'sustanzi eċċipjenti) u l-kompożizzjoni kwantitattivà f'sustanzi attivi, fejn jintużaw ismijiet komuni, għal kull preżentazzjoni tal-prodott mediċinali;

(v) għal kull preżentazzjoni tal-prodott, l-ghamla farmaċewtika u l-kontenut f'piż, volum jew unitajiet ta' doża;

(vi) l-isem u l-indirizz tad-detentur ta' l-awtorizzazzjoni għat-tqeghid fis-suq u, fejn dan ikun japplika, l-isem tar-rappreżentanti mahturin minnu f'Malta;

(vii) l-isem u l-indirizz tal-manifattur;

(g) Meta l-prodott mediċinali jkun huwa awtorizzat skond ir-rikonoxximent reċiproku u proċedura deċentralizzata taħt ismijiet differenti fl-Istati Membri konċernati, lista ta' l-ismijiet awtorizzati f'kull Stat Membru;

(h) id-data meta l-fuljett ta' taghrif kien l-aħhar rivedut.

(2) Il-lista mnizzla fil-paragrafu (ċ) tas-subregolament (1) għandha:

(a) tqis il-kundizzjonijiet partikolari ta' ċerti kategoriji ta' konsumaturi (tfal, nisa tqal jew qed li jkunu qeghdin iredgħu, l-anzjani, persuni b'kundizzjonijiet patoloġiċi partikolari);

(b) issemmi, skond il-htieġa, effetti possibli fuq il-kapacità li persuna ssuq vetturi jew thaddem xi makkinarju;

(c) tnizzel dawk is-sustanzi mhux effettivi (eċċipjenti) li wiehed ghandu jkun jaf bihom ghal użu tajjeb u effettiv tal-prodott mediċinali u li huma inklużi fil-gwida dettaljata pubblikata mill-Kummissjoni konformement ma' l-Artikolu 65 tad-Direttiva 2001/83/KE kif emendata bid-Direttiva 2004/27/KE.

(3) Il-fuljett tal-pakkett ghandu jirrifletti r-rizultati ta' konsultazzjonijiet ma' gruppi ta' pazjenti magħżulin sabiex jiġi żgurat li dan jista' jinqara faċilment, ikun ċar u jintuza bla ebda diffikultà.

8. (1) Kopja wahda jew aktar ta' l-ippakkettjar fuq barra jew ta' l-ippakkettjar immedjat ta' prodott mediċinali, flimkien ma' abozz tal-fuljett ta' tagħrif, ghandhon jiġu preżentati lill-Awtorità dwar il-Liċenzjar, hawn iżjed 'l quddiem imsejha l-Awtorità, meta tintalab l-awtorizzazzjoni ghat-tqeghid fis-suq. Ir-rizultati tal-valutazzjonijiet magħmulin b'koperazzjoni mal-gruppi ta' pazjenti magħżulin, ghandhom ukoll jiġu provduti lill-Awtorità. Kopji.

(2) l-Awtorità ghandha tiċhad l-awtorizzazzjoni ghat-tqeghid fis-suq jekk it-tikkettjar jew il-fuljett ta' tagħrif ma jkunux jikkonformaw ma' xi wiehed mill-provvedimenti ta' dawn ir-regolamenti jew jekk ma jkunux skond il-partikolaritajiet elenkati fil-karatteristiċi tal-prodott fil-qosor:

Iżda l-Awtorità ma ghandhiex tipprojbixxi jew iżzomm il-prodotti mediċinali milli jitqeghdu fis-suq minhabba fit-tikkettjar jew il-fuljett ta' tagħrif meta dawn ikunu konformi mal-htigijiet ta' dawn ir-regolamenti.

(3) Kull tibdil propost dwar xi aspett tat-tikkettjar jew dwar il-fuljett ta' tagħrif li jaqa' taht dawn ir-regolamenti li m'ghandhomx x'jaqsmu mal-karatteristiċi tal-prodott fil-qosor ghandhom jiġu preżentati lill-Awtorità.

Iżda jekk l-Awtorità ma topponix xi bidla proposta fi żmien disghin jum minn meta tircievi it-talba, l-applikant ikun jista' jagħmel dik il-bidla:

Iżda wkoll ir-responsabbiltà legali tal-manifattur u d-detentur ta' l-awtorizzazzjoni ghat-tqeghid fis-suq ghandha tibqa' bla mittiefsa jekk l-Awtorità, kuntrarju għall-provvedimenti ta' dan ir-regolament, tapprova awtorizzazzjoni ghat-tqeghid fis-suq jew xi bidla fit-tikkettjar jew fil-fuljett ta' tagħrif.

Materjal
promozzjonali
m' ghandux jiġi
inkluż.

9. L-ippakkettjar fuq barra u l-fuljett ta' taghrif ma ghandhomx jinkludu elementi ta' xorta promozzjonali imma jistgħu jinkludu simboli jew piktogrammi disinjati biex jiċċaraw ċerta informazzjoni msemmija fir-regolamenti 3 u 7(1) u informazzjoni oħra kompatibbli mal-karatteristiċi tal-prodott fil-qosor li jkunu utli għall-pazjent.

Partikolaritajiet
dwar it-tikkettjar.

10. (1) Il-partikolaritajiet dwar it-tikkettjar elenkati fir-regolamenti 3, 7 u 9 ghandhom jidhru fil-lingwi uffiċjali ta' Malta:

Iżda ikun possibli li dawn il-partikolaritajiet jiġu indikati f'diversi lingwi, sakemm daww l-istess partikolaritajiet ikunu jidhru fil-lingwi kollha wżati:

Iżda ukoll fil-każ ta' ċerti prodotti mediċinali orfni, il-partikolaritajiet elenkati taħt ir-regolament 3 jistgħu, fuq talba motivata, jidhru f'wahda mil-lingwi uffiċjali tal-Komunità.

(2) Il-fuljett ta' taghrif għandu jkun miktub u disinjat b'tali mod li jkun ċar u jiftiehem, biex jgħin lill-konsumaturi jaġixxu kif imiss, meta jkun hemm il-bżonn ukoll bl-għajnuna ta' professjonisti tas-saħħa. Il-fuljett tal-pakkett għandu jkun jinqara sew fil-lingwi uffiċjali ta' Malta:

Iżda dan ma għandux itellef milli l-fuljett jiġi stampat f'diversi lingwi, sakemm ukoll dik l-istess informazzjoni tkun mogħtija fil-lingwi kollha użati.

(3) Meta l-prodott ma jkunx intenzjonat li jiġi kunsinnat direttament lill-pazjent, l-Awtorità tista' tagħti eżenzjoni mill-obligazzjoni li ċerti partikolaritajiet għandhom jidhru fuq it-tikkettjar u fil-fuljett ta' taghrif u li l-fuljett għandu jkun fil-lingwi uffiċjali ta' Malta.

Sospensjoni ta' l-
awtorizzazzjoni
għat-tqeghid fis-
suq.

11. L-Awtorità għandha tissospendi l-awtorizzazzjoni għat-tqeghid fis-suq jekk, wara li tinnotifika avviż lid-detentur ta' l-awtorizzazzjoni għat-tqeghid fis-suq, it-tikkettjar u l-fuljett ta' taghrif tal-prodott mediċinali in kwistjoni ma jkunux konformi ma' xi wahda mill-provvedimenti ta' dawn ir-regolamenti. Sospensjoni bħal dik tispicċa milli tkun effettiva malli t-tikkettjar u l-fuljett ta' taghrif ta' dak il-prodott ikunu ntgħamlu konformi mal-htigiet ta' dawn ir-regolamenti.

Radjonuklidi.

12. (1) Fl-każ tar-radjonuklidi, il-kartuna ta' barra u l-kontenitur tal-prodott mediċinali għandhom jiġu ittikkettjati skond ir-regolamenti għat-trasport sigur ta' materjal radjoattiv stabbiliti mill-Aġenzija Internazzjonali għall-Enerġija Atomika. Iktar minn hekk, it-tikkettjar għandu jkun konformi mal-provvedimenti stabbiliti fis-subregolamenti (2) u (3) ta' dan ir-regolament.

(2) It-tikketta fuq il-pakk protettiv ghandha tinkludi il-partikolaritajiet imsemmija fir-regolament 3 u ghandha tkun:

(i) tispjega bid-dettalji kollha, is-simboli wżati fuq il-fjala, u

(ii) tindika, fejn ikun mehtieg, u ghal żmien u sa data speċifikati, l-ammont ta' radjuattività ghal kull doża u ghal kull fjala u l-ghadd ta' kapsuli, jew, ghal-likwidi, il-kontenut f' millilitri li jkun hemm fil-kontenitur.

(3) Il-fjala ghandu jkollha fuqha tikketta bl-informazzjoni li ġejja:

(a) l-isem jew kodiċi tal-prodott mediċinali, inkluż l-isem jew is-simbolu kimiku tar-radjunuklidi,

(b) l-identifikazzjoni tal-lott u d-data meta jiskadi,

(ċ) is-simbolu internazzjonali ghar-radjuattività;

(d) l-isem u l-indirizz tal-manifattur;

(e) l-ammont ta' radjuattività kif speċifikat fis-subregolament (2).

13. L-Awtorità ghandha d-dmir tizgura li jkun hemm inkluż fuljett ta' struzzjonijiet dettaljati skond il-provvediment tar-regolament 7 ma' l-ippakkettjar tar-radjofarmaċewtiċi, ġeneraturi radjunuklidi, *kits* ta' radjonuklidi u prekursori radjunuklidi. Il-fuljett ghandu jkun fih ukoll dawk il-prekawzjonijiet li ghandhon jittiehdu mill-utent u mill-pazjent matul il-preparazzjoni u t-tehid tal-prodott mediċinali kif ukoll prekawzjonijiet speċjali ghar-rimi ta' l-ippakkettjar u l-kontenut tiegħu li ma jkunx ġie użat. Dmir ta' l-Awtorità.

14. (1) Mingħajr preġudizzju għas-subregolament (2) ta' dan ir-regolament, prodotti mediċinali omeopatiċi ghandu jkollhom tikketta skond il-provvedimenti ta' dawn ir-regolament u ghandhom ikunu identifikati b'referenza fuq it-tikketti tagħhom, li tkun ċara u tista' tinqara faċilment, għan-natura omeopatika tagħhom. Prodotti mediċinali omeopatiċi.

(2) B'żieda mal-kliem ċar "prodott mediċinali omeopatiku", it-tikkettjar u, fejn ikun hemm il-htieġa, il-fuljett ta' tagħrif mall-prodotti mediċinali omeopatiċi li kkwalifikaw għal proċedura simplifikata speċjali kif imsemmija fir-regolament 10 tar-Regolamenti ta' l-2005 dwar il-Mediċini (Awtorizzazzjoni għat-Tqeghid fis-Suq), ghandu jkollu fuqu dan it-tagħrif li ġej u ebda tagħrif iehor:

(a) l-isem xjentifiku ta' l-istokk jew hażniet segwit minn grad ta' dilwizzjoni, jintużaw is-simboli tal-farmakopeja msemmija fid-definizzjoni ta' l-prodott mediċinali omeopatu; jekk il-prodott mediċinali omeopatu jkun kompost minn żewġ hażniet jew aktar, flimkien ma' l-ismijiet xjentifiċi tal-hażniet fuq it-tikkettjar jista' jiżdied ukoll isem ivvintat;

(b) l-isem u l-indirizz tad-detentur tar-registrazzjoni u, fejn ikun il-każ, tal-manifattur;

(ċ) metodu ta' teħid u, jekk ikun meħtieġ, b'liema rotta;;

(d) id-data meta jiskadi fi kliem ċar (xahar, sena);

(e) l-ghamla farmaċewtika;

(f) x'ikun fiha l-preżentazzjoni kummerċjali;

(g) il-prekawzjonijiet speċjali tal-hażna, jekk ikun hemm;

(h) twissija speċjali, jekk ikun hemm bżonn, fuq il-prodott mediċinali;

(i) in-numru tal-lott tal-manifattur;

(j) in-numru ta' registrazzjoni;

(k) il-prodott mediċinali omeopatu mingħajr indikazzjonijiet terapewtiċi approvati;

(l) twissija lill-utent biex jikkonsulta tabib jekk is-sintomi jippersistu.

L.N. 393 of 2005**MEDICINES ACT, 2003
(ACT NO. III OF 2003)****Medicinal Products (Labelling and Packaging) Regulations, 2005**

IN exercise of the powers conferred by article 106 of the Medicines Act, 2003, the Minister of Health, the Elderly and Community Care has made the following regulations:-

1. (1) The title of these regulations is the Medicinal Products (Labelling and Packaging) Regulations, 2005. Title, commencement and scope.

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

(3) The scope of these regulations is transpose Directive 2001/83/EC.

2. For the purposes of these regulations: Interpretation.

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

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

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

“labelling” means information on the immediate or outer packaging;

“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;

“outer packaging” means the packaging into which the immediate packaging is placed;

“package leaflet” means a leaflet containing information for the user which accompanies the medicinal product.

“representative of the marketing authorisation holder” means the person, commonly known as local representative, designated by the marketing authorisation holder to represent him in the Member State concerned;

“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.

Particulars on outer packaging.

3. The following particulars shall appear on the outer packaging of medicinal products or, where there is no such outer packaging, on the immediate packaging:-

(a) the name of the medicinal product followed by its strength and pharmaceutical form, and, if appropriate, whether it is intended for babies, children or adults; where the product contains up to three active substances, the international non-proprietary name (INN) shall be included, or, if one does not exist, the common name;

(b) a statement of the active substances expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using their common names;

(c) the pharmaceutical form and the contents by weight, by volume or by number of doses of the product;

(d) a list of those excipients known to have a recognised action or effect and which are included in the detailed guidance published by the Commission pursuant to Article 65 of Directive 2001/83/EC as amended by Directive 2004/27/EC. However, if the product is an injectable, or a topical or eye preparation, all excipients must be stated;

(e) the method of administration and, if necessary, the route of administration. Space shall be provided for the prescribed dose to be indicated;

(f) a special warning that the medicinal product must be stored out of the reach and sight of children;

(g) any special warning that may be necessary for the particular medicinal product;

(h) the expiry date in clear terms (month/year);

(i) special storage precautions, if any;

(j) specific precautions, relating to the disposal of unused medicinal products or waste derived from medicinal products, where appropriate, as well as reference to any appropriate collection system in place;

(k) the name and address of the marketing authorisation holder and, where applicable, the name of the representative appointed by the holder to represent him;

(l) the number of the marketing authorisation;

(m) the manufacturer's batch number;

(n) in the case of non-prescription medicinal products, instructions for use.

4. (a) The particulars laid down under regulation 3 shall appear on immediate packagings other than those referred to in paragraphs (b) and (c) hereof. Blister packs.

(b) At least the following particulars shall appear on the immediate packaging when this takes the form of a blister pack which is then placed in an outer packaging which complies with the provisions laid down in regulations 3 and 9:

(i) the name of the medicinal product as laid down under regulation 3(a);

(ii) the name of the holder of the marketing authorisation;

(iii) the expiry date;

(iv) the batch number.

(c) In the case of small immediate packaging units on which the particulars laid down under regulations 3 and 9 cannot be displayed, the following particulars at least shall appear:

(i) the name of the medicinal product as laid down in regulation 3(a), and, if necessary, the route of administration,

(ii) the method of administration ;

- (iii) the expiry date;
- (iv) the batch number;
- (v) the contents by weight, by volume or by unit.

Clarity of particulars.

5. (1) The particulars referred to in regulations 3, 4 and 9 shall be easily legible, clearly comprehensible and indelible.

(2) The name of the medicinal product, as referred to in regulation 3 (a), must also be expressed in Braille format on the packaging. The marketing authorisation holder shall ensure that the package information leaflet is made available on request from patients' organisations in formats appropriate for the blind and partially-sighted.

Inclusion of package leaflet.

6. A package leaflet shall be included in the packaging of all medicinal products unless all the information required by regulations 7 and 9 is directly conveyed on the outer or immediate packaging.

Package leaflet.

7. (1) The package leaflet shall be drawn up in accordance with the summary of the product characteristics and shall include, in the following order:

(a) for the identification of the medicinal product:

(i) the name of the medicinal product followed by its strength and pharmaceutical form, and, if appropriate, whether it is intended for babies, children or adults. The common name shall be included where the product contains only one active substance and if its name is an invented name;

(ii) the pharmaco-therapeutic group or type of activity in terms easily comprehensible for the patient;

(b) the therapeutic indications;

(c) a list of information which is necessary before the medicinal product is taken:

(i) contra-indications;

(ii) appropriate precautions for use;

(iii) forms of interaction with other medicinal products and other forms of interaction (e.g. alcohol, tobacco,

foodstuffs) which may affect the action of the medicinal product;

(iv) special warnings;

(d) the necessary and usual instructions for proper use, and in particular:

(i) the dosage;

(ii) the method and, if necessary, route of administration;

(iii) the frequency of administration specifying, if necessary, the appropriate time at which the medicinal product may or must be administered, and, as appropriate, depending on the nature of the product;

(iv) the duration of treatment, where it should be limited;

(v) the action to be taken in case of an overdose (such as symptoms, emergency procedures);

(vi) what to do when one or more doses have not been taken;

(vii) indication, if necessary, of the risk of withdrawal effects;

(viii) a specific recommendation to consult the doctor or the pharmacist, as appropriate, for any clarification on the use of the product;

(e) a description of the adverse reactions which may occur under normal use of the medicinal product and, if necessary, the action to be taken in such a case; the patient should be expressly asked to communicate any adverse reaction which is not mentioned in the package leaflet to his doctor or pharmacist;

(f) a reference to the expiry date indicated on the label, with:

(i) a warning against using the product after that date;

(ii) where appropriate, special storage precautions;

(iii) if necessary, a warning concerning certain visible signs of deterioration;

(iv) the full qualitative composition (in active substances and excipients) and the quantitative composition in active substances, using common names, for each presentation of the medicinal product;

(v) for each presentation of the product, the pharmaceutical form and content in weight, volume or units of dosage;

(vi) the name and address of the marketing authorisation holder and, where applicable, the name of his appointed representatives in Malta;

(vii) the name and address of the manufacturer;

(g) where the medicinal product is authorised in accordance with the mutual recognition and decentralised procedure under different names in the Member States concerned, a list of the names authorised in each Member State;

(h) the date on which the package leaflet was last revised.

(2) The list set out in paragraph (c) of sub-regulation(1) hereof shall:

(a) take into account the particular condition of certain categories of users (children, pregnant or breastfeeding women, the elderly, persons with specific pathological conditions);

(b) mention, if appropriate, possible effects on the ability to drive vehicles or to operate machinery;

(c) list those excipients knowledge of which is important for the safe and effective use of the medicinal product and which are included in the detailed guidance published by the Commission pursuant to Article 65 of Directive 2001/83/EC as amended by Directive 2004/27/EC.

(3) The package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use.

8. (1) One or more mock-ups of the outer packaging and the immediate packaging of a medicinal product, together with the draft package leaflet, shall be submitted to the Licensing Authority, hereinafter called the Authority, when the marketing authorisation is requested. The results of assessments carried out in cooperation with target patient groups shall also be provided to the Authority.

Mockups.

(2) The Authority shall refuse the marketing authorisation if the labelling or the package leaflet do not comply with any of the provisions of these regulations or if they are not in accordance with the particulars listed in the summary of product characteristics:

Provided that the Authority shall not prohibit or impede the placing on the market of medicinal products on grounds connected with labelling or the package leaflet where these comply with the requirements of these regulations.

(3) All proposed changes to an aspect of the labelling or the package leaflet covered by these regulations which are not connected with the summary of product characteristics shall be submitted to the Authority:

Provided that if the Authority does not oppose a proposed change within ninety days of receipt of the request, the applicant may put the change into effect:

Provided further that the legal liability of the manufacturer and the marketing authorisation holder shall remain unaltered if the Authority, contrary to the provisions of this regulation, approves a marketing authorisation or a change to the labelling or the package leaflet.

9. The outer packaging and the package leaflet shall not include elements of a promotional nature but may include symbols or pictograms designed to clarify certain information mentioned in regulations 3 and 7(1) and other information compatible with the summary of the product characteristics which is useful for the patient.

Promotion not to be included.

10. (1) The particulars for labelling listed in regulations 3, 7 and 9 shall appear in the official languages of Malta:

Labelling particulars.

Provided that it will be possible for these particulars to be indicated in several languages, as long as the same particulars appear in all the languages used:

Provided further that in the case of certain orphan medicinal products, the particulars listed under regulation 3 may on reasoned request, appear in one of the official languages of the Community.

(2) The package leaflet must be written and designed to be clear and understandable, enabling the users to act appropriately, when necessary with the help of health professionals. The package leaflet must be clearly legible in the official languages of Malta:

Provided that this shall not prevent the package leaflet from being printed in several languages, provided that the same information is given in all the languages used.

(3) When the product is not intended to be delivered directly to the patient, the Authority may grant an exemption to the obligation that certain particulars should appear on the labelling and in the package leaflet and that the leaflet must be in the official languages of Malta.

Suspension of
marketing
authorisation.

11. The Authority shall suspend the marketing authorisation if, after the serving of a notice on the marketing authorisation holder, the labelling and the package leaflet of the medicinal product in question do not comply with any of the provisions of these regulations. Such suspension shall cease to be effective as soon as the labelling and package leaflet of the product in question have been made to comply with the requirements of these regulations.

Radionuclides.

12. (1) In the case of radionuclides, the outer carton and container of the medicinal product shall be labelled in accordance with the regulations for the safe transport of radioactive materials laid down by the International Atomic Energy Agency. Moreover, the labelling shall comply with the provisions set out in sub-regulations (2) and (3) hereof.

(2) The label on the shielding shall include the particulars mentioned in regulation 3 and shall:

(i) explain in full, the codings used on the vial, and

(ii) indicate, where necessary, for a given time and date, the amount of radioactivity per dose or per vial and the number of capsules, or, for liquids, the number of millilitres in the container.

(3) The vial shall be labelled with the following information:

(a) the name or code of the medicinal product, including the name or chemical symbol of the radionuclide,

- (b) the batch identification and expiry date,
- (c) the international symbol for radioactivity,
- (d) the name and address of the manufacturer,
- (e) the amount of radioactivity as specified in subregulation (2).

13. It shall be the duty of the Authority to ensure that a detailed instruction leaflet in accordance with the provisions of regulation 7 is enclosed with the packaging of radiopharmaceuticals, radionuclide generators, radionuclide kits and radionuclide precursors. The leaflet shall also include any precautions to be taken by the user and the patient during the preparation and administration of the medicinal product and special precautions for the disposal of the packaging and its unused contents.

Duty of the Authority.

14. (1) Without prejudice to sub-regulation (2) of this regulation, homeopathic medicinal products shall be labeled in accordance with the provisions of these regulations and shall be identified by a reference on their labels, in clear and legible form, to their homeopathic nature.

Homeopathic medicinal products.

(2) In addition to the clear mention of the words “homeopathic medicinal product”, the labelling and, where appropriate, the package insert for the homeopathic medicinal products which have qualified for a special simplified registration procedure referred to in regulation 10 of the Medicines (Marketing Authorisation) Regulations, 2005, shall bear the following, and no other, information:

- (a) the scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia referred to in the definition of a homeopathic medicinal product ; if the homeopathic medicinal product is composed of two or more stocks, the scientific names of the stocks on the labelling may be supplemented by an invented name;
- (b) name and address of the registration holder and, where appropriate, of the manufacturer;
- (c) method of administration and, if necessary, route;
- (d) expiry date, in clear terms (month, year);

- (e) pharmaceutical form;
- (f) contents of the sales presentation;
- (g) special storage precautions, if any;
- (h) a special warning if necessary for the medicinal product;
- (i) manufacturer's batch number;
- (j) registration number;
- (k) homeopathic medicinal product without approved therapeutic indications;
- (l) a warning advising the user to consult a doctor if the symptoms persist.

Repeals L.N. 401 of 2003.

14. The Medicinal Products (Labelling and Packaging) Regulations, 2003 are hereby repealed.