

**A.L. 60 ta' l-2008****ATT DWAR IL-MEDIĊINI  
(KAP. 458)****Regolamenti ta' l-2008 dwar Prodotti Mediċinali  
(Ingunzjoni dwar ir-Riklamar)**

BIS-SAHHA tas-setghat moghtija bl-artikoli 31 u 106 ta' l-Att dwar Mediċini, il-Ministru tas-Sahha l-Anzjani u Kura fil-Komunità ghamel ir-regolamenti li ġejjin:-

**1.** (1) It-titolu ta' dawn ir-regolamenti hu Regolamenti ta' l-2008 dwar Prodotti Mediċinali (Ingunzjoni dwar ir-Riklamar). Titolu u bidu fis-sehh.

(2) Dawn ir-regolamenti ghandhom jidhlu fis-sehh fl-ahhar ta' Frar, 2008.

**2.** (1) Sakemm f'dawn ir-regolamenti ma jkunx mehtieg mod iehor: - Tifsir.

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

“l-Awtorità” tfisser l-Awtorità dwar il-Mediċini mwaqqfa taht l-artikolu 4 ta' l-Att;

“id-Direttiva” tfisser id-disposizzjonijiet tad-Direttiva 98/27/KE tal-Parlament Ewropew u tal-Kunsill tad-19 ta' Mejju, 1998 dwar l-ingunzjonijiet għall-harsien ta' l-interessi tal-konsumaturi;

“entità kwalifikata” tfisser kull ghaqda jew organizzazzjoni li, għax imwaqqfa kif jixraq skond il-liġi ta' Stat Membru, għandha interess legittimu tara li jkun hemm qbil mad-disposizzjonijiet imsemija fl-artikolu 3 ta' dan l-Ordni, bla preġudizzju għall-generalità ta' dak hawn qabel imsemmi, u tinkludi:-

(a) ghaqda registrata ta' konsumaturi skond kif imfissra fit-Taqsima IV ta' l-Att dwar l-Affarijiet tal-Konsumatur; Kap. 378.

(b) ghaqda wahda jew aktar ta' ghaqdiet pubbliċi indipendenti li ghandhom interess legittimu li jiżguraw il-harsien ta' l-interessi kollettivi tal-konsumaturi fir-reklamar ta' prodotti mediċinali fi Stati Membri ohra jew fi Stati ŻEE fejn ikun hemm ghaqdiet bhal dawn;

(ċ) organizzazzjonijiet volontarji fi Stati Membri ohra jew fi Stati ŻEE li ghandhom l-ghan iharsu l-interessi msemmija f'paragrafu (a) ta' din it-tifsira skond il-kriterji stabbiliti bil-liġi nazzjonali tagħhom;

(d) organizzazzjonijiet rikonoxxuti mill-Awtorità kompetenti bhala li jkunu qeghdin kollettivament jirrapprezentaw lil min jimmanifattura, jipprokura u jiddistribwixxi prodotti mediċinali; jew

(e) kull entità kwalifikata minn Stat Membru jew Stat ŻEE li jkun qieghed fil-lista ta' entitajiet kwalifikati;

“il-Komunità Ewropea” tfisser l-organizzazzjoni mwaqqfa bit-Trattat ta' Ruma fl-1957 u emendat istituzzjonalment u mod iehor fl-1986 bl-Att Wahdieni Ewropew, fl-1993 bit-Trattat dwar l-Unjoni Ewropea, fl-1997 bit-Trattat ta' Amsterdam u fl-2001 bit-Trattat ta' Nizza u kif emendat bit-trattati ta' adeżjoni u kif jista' jkun aktar emendat minn żmien għall-żmien;

“il-Kummissjoni” tfisser il-Kummissjoni tal-Komunità Ewropea;

“lista ta' entitajiet kwalifikati” tfisser il-lista miġbura u aġġornata mill-Kummissjoni u publikata fil-ġurnal Uffiċjali tal-Komunitajiet Ewropej li jkun fiha mnizzla l-entitajiet kwalifikati fi Stati Membri u Stati ŻEE skond l-Artikolu 4 tad-Direttiva;

“il-Ministru” tfisser il-Ministru responsabbli għas-saħha.

“prodotti mediċinali” tfisser mediċinali għall-użu uman;

“Qorti ta' l-Appell” tfisser il-Qorti ta' l-Appell fil-ġurisdizzjoni inferjuri tagħha kif kostitwita skond ma hemm fis-subartikolu (6) ta' l-artikolu 41 tal-Kodiċi ta' Organizzazzjoni u Proċedura Ċivili;

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“ir-Regolamenti ta' l-2005” tfisser ir-Regolamenti ta' l-2005 dwar Prodotti Mediċinali (Riklamar);

“Stat Membru” tfisser membru tal-Komunità Ewropea;

“Stat ŻEE” tfisser kull Stat li hu parti kontraenti fil-ftehim dwar iż-żona Ekonomika Ewropea iffirmit f’Oporto fit-2 ta’ Mejju, 1992 u emendat bil-Protokoll iffirmit fi Brussell fis-17 ta’ Marzu, 1993 u emendat minn żmien għall-żmien.

(2) Kliem u frażijiet użati f’ dawn ir-regolamenti u li jinsabu wkoll fl-Att jew fir-Regolamenti ta’ l-2005 għandhom l-istess tifsir li għandhom fl-Att jew f’ dawk ir-regolamenti.

**3.** L-għan ta’ dan l-Ordni hu biex jiġu implimentati d-Għan. disposizzjonijiet tad-Direttiva, skond kif jghodd għar-rikliamar ta’ prodotti mediċinali msemmija fid-Direttiva 92/28/KEE kif inkorporati fir-Regolamenti ta’ l-2005, u dawn għandhom jiġu mfissra w applikati skond hekk.

**4.** Dawn ir-regolamenti japplikaw għal kull tip ta’ reklamar ta’Skop. prodotti mediċinali ġo u minn Malta kif regolat bid-Direttiva 92/28/KEE.

**5.** (1) Entità kwalifikata li tixtieq titlob il-hruġ ta’ ordni ta’Talba minn entitajiet kwalifikati għal ordnijiet ta’ konformità. konformità għandha tibghat applikazzjoni bil-miktub lill-Awtorità. F’ din l-applikazzjoni hija trid tissodisfa lill-Awtorità li għamlet hilitha biex dan il-ksur tal-liġi ma jibqax isir billi hija tkun diġà ikkonsultat ruhha kemm mal-konvenut wahdu kemm mal-konvenut u entità oħra kwalifikata ta’ l-Istat Membru jew ta’ l-Istat ŻEE fejn tkun qed tintalab l-ingunzjoni. L-awtorità kompetenti tikkonsidra biss applikazzjoni bil-miktub jekk l-entità kwalifikata tissodisfaha b’ dak li tkun għamlet billi turi li l-ksur tal-liġi ma jkunx waqaf sa ġimghatejn wara li tkun waslitilha t-talba għall-konsultazzjoni.

(2) Meta l-entità kwalifikata tkun minn Stat Membru jew Stat ŻEE iehor, l-Awtorità tqis il-lista ta’ entitajiet kwalifikati stampata mill-Kummissjoni bhala prova konklużiva tas-setgħa legali ta’ l-entità legali li tipprezenta dik l-applikazzjoni miktuba f’ Malta.

(3) L-Awtorità, fuq talba ta’ entità kwalifikata minn Malta, għandha twassal lill-Kummissjoni l-isem u l-għanijiet ta’ dawk l-entitajiet u li dik l-entità kwalifikata għandha tizdied mal-lista ta’ entitajiet kwalifikati biex tkun tista’ tisewwa l-hsara ta’ ksur ta’ liġi inter-komunitarja.

(4) Qabel ma tasal biex tohroġ l-ordni halli dak li jkun jimxi mal-liġi taht l-artikolu 6, l-Awtorità għandha, jekk thoss li dan ikun possibbli u raġonevoli, tipprova l-ewwel tikseb qbil volontarju minn persuna li tinharġilha liċenzja taht l-Att u oħrajn involuti, skond dawn

ir-regolamenti, l-Att jew xi liġi oħra li jkollha x'taqsam mal-harsien u l-jeddijiet tal-konsumatur.

(5) Għall-iskopijiet ta' dawn ir-regolamenti, il-ksur tal-liġi jsehh meta jsir xi att kontra d-Direttiva 92/28/KEE, kif traspost bir-Regolamenti ta' l-2005.

Hruġ ta' ordnijiet ta' konformità.

**6.** (1) Meta l-Awtorità tqis li hu raġonevolment adatt jew mehtieġ tipproteġi l-konsumatur, tista' wara li tircievi talba bil-miktub minn entità kwalifikata, tohroġ ordni ta' konformità kontra xi persuna li jkollha liċenzja taht l-Att għal xi wiehed jew aktar minn dawn l-ghanijiet li ġejjin:-

(a) tordna lil tali persuna sabiex twaqqaf kull reklam ta' prodotti mediċinali li l-Awtorità tqis bhala li jkun qed jikser il-provvedimenti tar-Regolamenti ta' l-2005;

(b) titlob lil tali persuna tiehu kull pass mehtieġ kif imfisser f' dik l-ordni ta' konformità, fiż-żmien speċifikat fl-istess ordni biex tiżgura li dik l-ordni tiġi osservata;

(ċ) tinhtieġ lil tali persuna tieqaf u ma tkomplix tikser dawn ir-regolamenti jew tad-disposizzjonijiet tar-Regolamenti ta' l-2005.

(2) Meta l-Awtorità tohroġ ordni ta' konformità skond dawn ir-regolamenti, hija ghandha:-

(a) twassal kopja ta' l-ordni ta' konformità kontra kull min tkun qed issir l-ordni;

(b) tinkludi ma' l-ordni ta' konformità, taghrif dwar il-jedd li tinfetaħ kawża quddiem il-Qorti ta' l-Appell, skond ir-regolament 9; u

(ċ) taghti fil-qosor ir-raġunijiet għaliex dik l-ordni ta' konformità tkun harget, hekk li tinnotifika b'dawk ir-raġunijiet lil kull min tkun harget kontri l-ordni ta' konformità u, jekk ikun hemm, lill-entità kwalifikata li fuq it-talba tagħha tkun harget l-ordni ta' konformità.

(3) L-ebda qorti jew tribunal ma ghandhom johorgu xi mandat kawtelatorju jew ordni oħra taht ebda liġi oħra li jzommu jew jirrestringu lill-Awtorità milli tohroġ ordni ta' konformità taht dik l-ordni.

7. (1) Ghandha tkun fid-diskrezzjoni ta' l-Awtorità jekk tohroġx ordni ta' konformità jew le wara li tkun saritilha talba bil-miktub minn entità kwalifikata skond is-subregolament (1) tar-regolament 6.

Diskrezzjoni ta' l-Awtorità li tohroġ ordni ta' konformità.

(2) Jekk l-Awtorità tiddeciedi li ma tohroġx ordni ta' konformità wara li tkun saritilha talba bil-miktub minn entità kwalifikata, hija ghandha tgharraf bil-miktub, fi żmien sebat ijiem mid-data li tkun ittiedet id-deċiżjoni, lill-entità kwalifikata u lil dawk il-persuni li tkun intalbet tohroġ ordni ta' konformità kontra tagħhom, bid-deċiżjoni li tkun hadet u tagħti l-motivi għaliha.

(3) Entità kwalifikata tista', sa hmistax-il ġurnata mid-data tan-notifika li tkun waslitilha bid-deċiżjoni ta' l-Awtorità li ma tohroġx l-ordni ta' konformità, tiftah kawża fil-Qorti ta' l-Appell biex tinhareġ ordni li titlob lill-Awtorità tohroġ ordni ta' konformità skond ir-regolament 6. Dawk il-persuni li tintalab tohroġ l-ordni ta' konformità kontri hom ikunu l-partijiet fil-kawża, u għalhekk l-entità kwalifikata hija fid-dmir li tinfirmahom.

(4) Il-Qorti ta' l-Appell, fil-qadi tal-funzjonijiet tagħha u bis-setgħat mogħtija b'din l-Ordni, ghandha fil-każijiet kollha taġixxi malajr kemm jista' jkun.

8. Ordni ta' konformità mahruġa mill-Awtorità tibda ssehh fil-pront.

Ordni ta' konformità tibda ssehh fil-pront.

9. (1) Min tinhariġlu ordni ta' konformità, jista' sa hmistax-il ġurnata minn meta jkun irċieva n-notifika ta' l-ordni ta' konformità, jappella bil-miktub lill-Qorti ta' l-Appell biex tirrevoka jew temenda l-ordni ta' konformità, billi jagħti raġunijiet dettaljati għal din it-talba. Appell bhal dak jista' jsir biss għal dawn ir-raġunijiet li ġejjin:-

Appell kontra ordni ta' konformità.

(a) fejn l-awtorità kompetenti fid-deċiżjoni tagħha, tkun haddmet hażin xi wiehed mill-provvedimenti li hemm f'dawn ir-regolamenti; jew

(b) id-deċiżjoni ta' l-Awtorità tohloq abbuż ta' diskrezzjoni jew tkun tidher ċar li hi wahda ingusta.

(2) Il-Qorti ta' l-Appell tista' tikkonferma, tibdel jew thassar l-ordni ta' konformità skond dawk il-pattijiet u kundizzjonijiet li tqis li jkunu adatti.

(3) Meta jsir appell skond is-subregolament (1), l-ordni ta' konformità ghandha tibqa' fis-sehh, sakemm l-Qorti ta' l-Appell ma tagħtix ordnijiet speċifiċi li l-ordni ta' konformità tibqa' pendent i sa

ma jkun hemm eżitu mill-appell, bla hsara ghal dawk il-kundizzjonijiet u emendi li tista' tistabbilixxi. Meta jiġri dan, l-Awtorità tista' titlob lill-Qorti ta' l-Appell tohroġ ordni ta' konformità temporanja fejn titlob li l-ordni ta' konformità tibqa' fis-seħh, b'xi tibdiliet li l-awtorità kompetenti tista' tissuggerixxi, sakemm il-każ jiġi fl-ahħar deċiż li jkun inbeda skond is-subregolament (1). Ordni ta' konformità temporanja tiskadi l-każ ikun fl-ahħar deċiż.

(4) Skond dawn ir-regolamenti, il-Qorti ta' l-Appell għandha timxi *mutatis mutandis* skond il-provvedimenti tal-Kodiċi ta' l-Organizzazzjoni u Proċedura Ċivili.

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Ma hemmx għalfejn tingieb prova ta' telf, hsara, eċċ.

**10.** Meta l-Awtorità tohroġ ordni ta' konformità taħt ir-regolament 6, ma jkollhiex bżonn provi ta':-

(a) telf jew hsarat attwali; jew

(b) negliġenza, traskuraġni jew htija attwali ta' min tkun inharġitlu l-ordni ta' konformità.

L-Awtorità tista' teħtieġ li ssir publikazzjoni.

**11.** (1) L-Awtorità tista', biex tgharraf ahjar lill-pubbliku:-

(a) tippubblika kopja shiha jew parti minnha, ta' l-ordni ta' konformità mahruġa kontra t-tali persuna, skond ir-regolament 6; jew

(b) tordna lil dik il-persuna li jkollha liċenzja skond l-Att biex tippubblika stqarrija korrettorja f'dak li għandu x'jaqsam ma' kull kontravvenzjoni ta' dawn ir-regolamenti; jew

(ċ) tiehu ż-żewġ passi msemmija hawn qabel, f'paragrafi (a) u (b).

(2) Il-publikazzjoni magħmula skond is-subregolament (1), għandha ssir mill-persuna li kontriha jkun inhareg l-avviż, għas-spejjeż tagħha, f'mhux anqas minn żewġ gazzetti ta' kuljum, u dan fi żmien sebat ijiem minn meta tirċievi l-avviż. Meta din il-publikazzjoni ma ssirx kif hawn qabel imsemmi, l-Awtorità tista' tahseb biex twettaq hi stess din il-publikazzjoni b'liema mezz thoss li jkun xieraq, u f'dan il-każ ikollha l-jedd tiġbor lura l-ispejjeż li tkun għamlet minghand dak li jkun ingħatalu l-avviż, bhala debitu ċivili li jikkostitwixxi titlu esekuttiv għall-iskopijiet ta' Titlu VII ta' l-Ewwel Taqsima tat-Tieni Ktieb tal-Kodiċi ta' l-Organizzazzjoni u Proċedura Ċivili daqs li kieku l-hlas ta' dik is-somma ta' debitu ċivili kienet ordnata b'sentenza ta' qorti ta' ġurisdizzjoni ċivili.

**12.** L-Awtorità tista' tawtorizza bil-miktub lil kull impjegat tagħha, uffiċjal pubbliku, jew kull persuna ohra sabiex taqdi d-dmirijiet tagħha għall-infurzar ta' dawn ir-regolamenti jew jagħmel użu mis-setgħat mogħtija lilha skond dawn il-provvedimenti. Kull min ikun awtorizzat għaldaqstant għandu, meta jkun meħtieġ, juri l-awtorizzazzjoni bil-miktub u iffirmita mill-Awtorità.

Id-delega tas-setgħat ta' l-Awtorità.

**13.** (1) L-Awtorità biex tkun tista' twettaq il-hidma tagħha skond dawn ir-regolamenti, jista' jkun li jkollha bżonn titlob lil xi persuna tagħti kull xorta ta' tagħrif, mhux l-inqas li:-

Ksib ta' tagħrif.

- (a) twieġeb xi mistoqsijiet, bil-fomm jew bil-miktub; jew
- (b) tintalab iġġib xi haġa jew *data* skond ma' thoss li jkun meħtieġ l-Awtorità; jew
- (ċ) tintalab iġġib xi kotba, dokumenti jew xi *records* skond ma' l-Awtorità thoss li jkun meħtieġ.

(2) Kull min jintalab jagħmel dan, għandu jobdi dik l-ordni minnufih.

**14.** (1) Min ikollu liċenza taht l-Att jista' jehel il-penali amministrattiva kif imfissra fl-artikolu 15, jekk:-

Min ma jobdix dawn ir-regolamenti.

- (a) ma josservax xi disposizzjoni ta' dawn ir-regolamenti;
- (b) ma jimxix skond ordni ta' konformità mahruġa skond dawn ir-regolamenti; jew
- (ċ) jirrifjuta jew jonqos milli jagħti tagħrif kif meħtieġ taht dawn ir-regolamenti jew b'xi mod iehor jagħti informazzjoni qarrieqa jew żbaljata.

(2) Min ikollu liċenza taht l-Att jista' jehel penali amministrattiva jekk huwa:-

- (a) ifixkel apposta, jattakha, jhedded, jirreżisti jew jindahal lill-Awtorità f'dak li tagħmel jew xi hadd delegat minnha skond ir-regolament 12 jew lil xi uffiċjal pubbliku waqt li jkun qed jaqdi dmiru skond dawn ir-regolamenti jew jattenta jagħmel dan; jew
- (b) jindirizza lill-Awtorità kompetenti jew lil xi persuna li tkun delegata minnha b'lingwaġġ ta' theddid abbużiv jew insolenti skond kif hemm fir-regolament 12 jew ukoll lil xi uffiċjal pubbliku fil-qadi ta' dmirijietu.

Penali  
amministrattivi.

**15.** Jekk ikun hemm xi responsabbiltà skond ir-regolament 14, il-Kap Esekuttiv ta' l-Awtorità jista' jitlob lill-Awtorità billi javżaha bil-miktub biex timponi fuq min ikollu liċenzja taht l-Att, il-penali amministrattiva skond l-artikolu 100 ta' l-Att u ghandha *mutatis mutandis* tapplika l-proċedura li hemm f'dak l-artikolu.

Sanzjonijiet ohra  
amministrattivi.

**16.** (1) Ebda haġa f'dawn ir-regolamenti m' ghandha tippregudika jew tnaqqas mis-setgħat ta' l-Awtorità fil-hidmiet tagħha li tiehu l-miżuri amministrattivi jew timponi penali skond l-Att, kontra persuna li jkollu liċenzja taht l-Att u li jkun kiser xi provvedimenti ta' dawn ir-regolamenti jew ma ssodisfax jew ma mexiex skond xi kundizzjoni jew rabta li jistgħu jitolbu minnu l-Att jew ir-Regolamenti ta' l-2005.

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(2) Ebda haġa f'dawn ir-regolamenti ma ghandha tirrestringi jew tnaqqas mill-poteri ta' l-Awtorità taht kull liġi ohra, jew mill-poteri tal-Pulizija taht il-Kodiċi Kriminali jew xi liġi ohra.

Notifika ta'  
ordnijiet jew  
tahrικiet.

**17.** (1) Meta jkun mehtieg li tiġi notifikata xi ordni jew avviz taht dawn ir-regolamenti, in-notifika tista' ssir b'xi wiehed minn dawn il-modi li ġejjin:-

(a) billi titwassal jew tintbagħat bil-posta reġistrata lil min ikun fl-indirizz tiegħu fid-dar fejn jgħix, fl-uffiċċju jew fil-post fejn jahdem; jew

(b) fil-każ ta' enti morali jew xi għaqda ohra ta' nies, billi tinghata lil xi uffiċjal jew impjegat tal-post fl-uffiċċju reġistrat jew f'xi post iehor tan-negozju, jew billi tintbagħat f'ittra reġistrata indirizzata lil xi uffiċċju bħal dawk.

(2) F'kull każ meta fejn ma jkunx raġonevolment possibbli li din tinghata jew titwassal b'xi mod skond is-subregolament (1), in-notifika tista' wkoll issir billi tiġi pubblikata taqsira ta' dak l-avviz fil-Gazzetta.

**L.N. 60 of 2008**

**MEDICINES ACT  
(CAP. 458)**

**Medicines Products (Injunction to Advertising)  
Regulations, 2008**

IN exercise of the powers conferred by articles 31 and 106 of the Medicines Act, the Minister of Health, the Elderly and Community Care, has made the following regulations:-

**1.** (1) The title of these regulations is Medicines Products (Injunction to Advertising) Regulations, 2008 Citation and commencement.

(2) These regulations shall come into force on last of February, 2008.

**2.** In these regulations, unless the context otherwise requires: Interpretation.

“the Act” means the Medicines Act;

“the Authority” means the Medicines Authority established under article 4 of the Act;

“the Commission” means the Commission of the European Community;

“Court of Appeal” means the Court of Appeal sitting in its inferior jurisdiction as constituted in terms of sub-article (6) of article 41 of the Code of Organization and Civil Procedure; Cap. 12.

“the Directive” means the provisions of Directive 98/27/EC of the European Parliament and of the Council of 19th May, 1998 on injunctions for the protection of consumers’ interests;

“EEA State” means any State which is a contracting party to the agreement on the European Economic Area signed at Oporto on the 2nd May, 1992 as amended by the Protocol signed at Brussels on 17th March, 1993 and as amended from time to time;

“European Community” means the organisation established by the Treaty of Rome in 1957 and amended institutionally and

otherwise in 1986 by the Single European Act, in 1993 by the Treaty on European Union, in 1997 by the Treaty of Amsterdam and in 2001 by the Treaty of Nice and as amended by accession agreements and as may be further amended from time to time;

“list of qualified entities” means the list compiled and updated by the Commission and published in the Official Journal of the European Communities listing the qualified entities in Member States and EEA States in accordance with Article 4 of the Directive;

“medicinal products” means medicinals for human use;

“Member State” means a member of the European Community;

“the Minister” means the minister responsible for health;

“qualified entity” means any body or organization which, being properly constituted according to the law of a Member State, has a legitimate interest in ensuring that the provisions referred to in article 3 of this Order are complied with and, without prejudice to the generality of the foregoing, includes:-

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(a) a registered consumer association within the meaning of Part IV of the Consumer Affairs Act;

(b) one or more independent public bodies, having a legitimate interest in ensuring the protection of the collective interests of consumers of medicinal products advertising in other Member States or EEA States in which such bodies exist;

(c) voluntary organisations in other Member States or EEA States whose purpose is to protect the interests referred to in paragraph (a) of this definition in accordance with the criteria laid down by their national law;

(d) organisations recognised by the Authority as collectively representing medicinal products manufacturers, suppliers and distributors; or

(e) any qualified entity from a Member State or EEA State included in the list of qualified entities;

L.N. 380 of 2005.

“the 2005 Regulations” means the “Medicinal Products (Advertising) Regulations, 2005.

(2) Words and expressions used in these regulations which are also used in the Act or in the 2005 Regulations shall have the same meanings as in the Act or in the said regulations.

**3.** The object of these regulations is to implement the provisions of the Directive, as applicable to the advertising of medicinal products contained in Directive 92/28/EEC as transposed by the 2005 Regulations, and shall be interpreted and applied accordingly. Object.

**4.** These regulations apply to any advertising of medicinal products in or from Malta as regulated by Directive 92/28/EEC. Scope.

**5.** (1) Where a qualified entity wishes to seek a compliance order, it shall submit its written application to the Authority. In its application, it shall satisfy the Authority that it has tried to achieve the cessation of the infringement in consultation with either the defendant or both the defendant and another qualified entity of the Member State or EEA State in which the injunction is sought. The Authority shall only entertain a written application if the qualified entity shows to its satisfaction that the cessation of the infringement was not achieved within two weeks after the request for consultation was received. Application for compliance orders by qualified entities

(2) Where the qualified entity is from another Member State or EEA State, the Authority shall treat the list of qualified entities published by the Commission as conclusive proof of the legal capacity of the legal entity to present such written application in Malta.

(3) The Authority shall, at the request of a qualified entity from Malta, communicate to the Commission the name and objects of such entities and that such qualified entity should be added to the list of qualified entities so as to facilitate the redress of inter-community infringements.

(4) Before proceeding for the issue of a compliance order under article 6, the Authority shall, if it considers it to be possible and reasonable to do so, seek first to achieve voluntary compliance by a person licensed under the Act and other persons involved, in accordance with these regulations, the Act or any other law dealing with consumer rights and protection.

(5) For the purposes of these regulations, an infringement occurs when any act is committed contrary to Directive 92/28/EEC as transposed by the 2005 Regulations.

**6.** (1) Where the Authority feels it reasonably appropriate or necessary for the protection of consumers, it may, on a written Issue of compliance orders.

application to it by a qualified entity, issue a compliance order against any person licensed under the Act for one or more of the following purposes:-

(a) ordering any such person to cease any advertisement of a medicinal product which the Authority considers to be in breach of the provisions of the 2005 Regulations;

(b) requiring such person to take any measures specified in such order, within the time specified in the compliance order to ensure that such order is complied with;

(c) requiring such person to cease or desist from committing a breach of these regulations or of the provisions of the Act regulating advertisements or of the 2005 Regulations.

(2) The Authority shall, when issuing a compliance order under these regulations -

(a) serve a copy of the compliance order on each person against whom the order is made;

(b) include with the compliance order, information about the right to institute an action before the Court of Appeal, in accordance with regulation 9; and

(c) briefly state the reasons for issuing the compliance order, which reasons shall be notified to each person against whom the compliance order is issued and, if any, to the qualifying body on whose application the compliance order is issued.

(3) No precautionary warrant or other order under any other law shall be issued by any court or tribunal restraining or restricting the Authority from issuing a compliance order under such order.

Discretion of the Authority to issue a compliance order.

**7.** (1) It shall be at the discretion of the Authority whether or not to issue a compliance order after a written request by a qualified entity has been made to it in terms of sub- regulation (1) of regulation 6.

(2) If the Authority decides not to issue a compliance order after an application has been made to it by a qualified entity, it shall, within seven days from the date of its decision, notify in writing the qualified entity and the persons against whom the compliance order is requested with its decision stating the reasons therefore.

(3) A qualified entity may within fifteen days from the date of notification upon it of the decision of the Authority not to issue a compliance order, institute an action before the Court of Appeal for the issue of an order requiring the Authority to issue a compliance order under regulation 6. The persons against whom the compliance order is requested to be made shall be parties to the suit, and it shall be the duty of the qualified entity to notify such persons accordingly.

(4) In the exercise of its functions and powers under this Order, the Court of Appeal shall in all cases act as expeditiously as possible.

**8.** A compliance order issued by the Authority shall come into force with immediate effect.

Compliance order to take immediate effect.

**9.** (1) A person against whom a compliance order has been made, may, within fifteen days from receipt of notification of the compliance order, appeal in writing to the Court of Appeal for the revocation or amendment of the compliance order, giving detailed grounds for the request. Such appeal may be made only on the following grounds:-

Appeal from a compliance order.

(a) the Authority has, in its decision wrongly applied any of the provisions of these regulations; or

(b) the decision of the Authority constitutes an abuse of discretion or is manifestly unfair.

(2) The Court of Appeal may confirm, change or cancel the compliance order on any terms or conditions it considers appropriate.

(3) Where an appeal is instituted under sub- regulation (1), the compliance order shall remain in force unless the Court of Appeal specifically orders that the compliance order shall be stayed pending the outcome of the appeal, subject to such conditions and amendments as it may determine. In any such instance, the Authority may request the Court of Appeal to make an interim compliance order, ordering that the compliance order shall, subject to such modifications as the Authority may suggest, continue in force pending the final determination of the case instituted in accordance with sub-regulation (1). An interim compliance order shall expire upon the final determination of the case.

(4) Subject to these regulations, the provisions of the Code of Organization and Civil Procedure shall, *mutatis mutandis*, govern appeals to the Court of Appeal.

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No need to prove actual loss, etc.

**10.** The Authority, when issuing a compliance order under regulation 6, shall not be required to prove:-

- (a) actual loss or damage or
- (b) actual recklessness, negligence or fault on the part of the person against whom the order is made.

The Authority may require publication.

**11.** (1) The Authority may, for the better information of the public:-

- (a) publish a copy of the compliance order made under regulation 6 against any such person, in full or in part; or
- (b) order any person licensed under the provisions of the Act to publish a corrective statement in relation to any contravention of these regulations; or
- (c) take both measures mentioned in paragraph (a) and (b) above.

(2) Publication in terms of sub-regulation (1) shall be made at the expense of the against whom the order was issued, in at least two daily newspapers within seven days from receipt of the notice and shall be at the expense of the person served with such notice. Where such publication is not effected as aforesaid, the Authority may proceed to effect publication itself, in which case it shall have the right to recover from the person on whom the notice is served, any expenses incurred, as a civil debt, constituting an executive title for the purposes of Title VII of Part I of Book Second of the Code of Organization and Civil Procedure as if payment of the amount of the civil debt has been ordered by a judgment of a court of civil jurisdiction.

Delegation of powers of the Authority.

**12.** The Authority may in writing authorize any of its employees, a public or other officer or any other person to perform any of its functions in relation to the enforcement of these regulations or exercise any power granted to it under these provisions. Any such authorized person shall, when required, produce the written authorisation signed by the Authority.

Obtaining information.

**13.** (1) The Authority may, for the purpose of discharging its functions under these regulations, require any person to provide any information in any manner, including by:-

- (a) answering any questions, orally or in writing; or

(b) producing any item or data as aforesaid as the Authority may consider to be necessary; or

(c) producing any books, documents or other records as the Authority may consider to be necessary.

(2) Any such person shall promptly comply with any such request.

**14.** (1) A person licensed under the provisions of the Act, shall be liable to an administrative penalty in terms of regulation 15 if such person

Failure to comply with these regulations.

(a) fails to observe any other provision in these regulations;

(b) fails to comply with a compliance order issued under these regulations; or

(c) refuses or fails to furnish information as required under these regulations or else provides false or misleading information.

(2) A person licensed under the provisions of the Act, shall be liable to an administrative penalty if such person:-

(a) wilfully obstructs, assaults, threatens, resists or interferes with the Authority or any person delegated by it in terms of regulation 12 or any public officer in the exercise of his duties under these regulations or attempts so to do; or

(b) uses threatening, abusive or insulting language to the Authority or any person delegated by it in terms of regulation 12 or any public officer in the course of duties.

**15.** (1) In the event of liability arising in terms of article 14 the Chief Executive of the Authority may by notice in writing request the Authority to impose on the person licensed under the provisions of the Act an administrative penalty in terms of article 100 of the Act and the procedure laid down in that article shall mutatis mutandis apply.

Administrative penalties.

**16.** (1) Nothing in these regulations shall prejudice or limit the exercise of the powers of the Authority to take administrative measures or impose penalties under the Act, against a person licensed under the provisions of the Act who has contravened any provisions of these regulations or has failed to satisfy or comply with any obligation or condition to which he may be subject under the Act or the 2005 Regulations.

Other administrative sanctions.

(2) Nothing in these regulations shall be deemed to restrict or detract from the powers of the Authority under any other law, or from the powers of the Police under the Criminal Code or any other law.

**17.** (1) Where an order or notice is required or authorised to be served under these regulations it shall be served in any of the following manners:-

(a) by delivering it, or by sending it by registered mail to the person on whom it is to be served at such person's place of residence, office or place of work; or

(b) in the case of a body corporate or other body of persons, by delivering it to an officer or servant thereof at the registered office or any other place of business, or sending it in a registered letter addressed to any such office.

(2) In any case where it is not reasonably possible to effect service in any manner stated in sub- regulation (1), service may be affected by publishing a summary of such notice in the Gazette.