

A.L. 325 ta' l-2006

**ATT DWAR IL-MEDIĊINI
(KAP. 458)**

**Regolamenti ta' l-2006 dwar Arranġamenti Transitorji
dwar il-Fuljett ta' Taghrif u Ippakkettjar fi Prodotti Mediċinali**

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

1. (1) It-titolu ta' dawn ir-regolamenti hu Regolamenti ta' l-2006 dwar Arranġamenti Transitorji dwar il-Fuljett ta' Taghrif u Ippakkettjar fi Prodotti Mediċinali. Titolu, żmien u applikabilità.

(2) L-arranġamenti transitorji maghmulin f'dawn ir-regolamenti ghandhom, bla hsara ghal kull emendi li jstgħu jsirulhom, ikunu japplikaw sal-31 ta' Diċembru, 2009 kemm-il darba dawn ma jiġux revokati qabel jew ikollhom il-perjodu ta' applikazzjoni tagħhom mġedded ghal aktar żmien.

(3) L-arranġamenti transitorji maghmulin b'dawn ir-regolamenti ghandhom ikunu japplikaw għall-prodotti mediċinali kollha li jintużaw mill-bniedem u li dwarhom tinhareġ awtorizzazzjoni għat-tqeghid fis-suq, jew xi awtorizzazzjoni li fil-prinċipju tkun skond l-artikolu 4(2) tar-Regolamenti dwar Mediċini (Awtorizzazzjoni għat-Tqeghid fis-Suq) ta' l-2004, jew xi licenza ta' importazzjoni parallela. A.L. 387 ta' l-2004.

(4) L-arranġamenti transitorji maghmulin b'dawn ir-regolamenti m'għandhom b'ebda mod ikunu jippreġudikaw il-htigiet lingwistiċi għar rigward ta' applikazzjonijiet għall-hruġ ta' awtorizzazzjoni għat-tqeghid fis-suq skond il-proċeduri Komunitarji li hemm stipulati fir-Regolament tal-Kunsill (KE) Nru. 726/2004 tal-Parlament Ewropew u tal-Kunsill tal-31 ta' Marzu 2004 li jstabbilixxi proċeduri Komunitarji għall-awtorizzazzjoni u s-sorveljanza ta' prodotti mediċinali li jintużaw mill-bniedem u għal skopijiet veterinarji u li jstabbilixxi Aġenzija Ewropea dwar il-Mediċini. Tifsir. A.L. 393 ta' l-2005.

2. Kull prodott mediċinali awtorizzat jista' jitqiegħed fis-suq f'Malta jekk l-ippakkettjar u l-fuljett ta' taghrif, kif approvati, ikunu jew bl-ilsien Inġliż jew bl-ilsien Malti jew biż-żewġ ilsna flimkien. Htigiet lingwistiċi dwar prodott mediċinali li jitqiegħdu fis-suq f'Malta.

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L-Awtorità dwar il-Liċenzji tista' tordna li l-fuljett ta' tagħrif ikun fiż-żewġ ilsna.

3. L-Awtorità dwar il-Liċenzji tista', fil-każ ta' prodotti speċifiċi, tordna li l-fuljett ta' tagħrif għandu jkun kemm bl-ilsien Inġliż kif ukoll bl-ilsien Malti.

Dokumenti meħtieġa mill-Awtorità dwar il-Mediċini.

4. Fil-każ ta' prodotti mediċinali li dwarhom tkun meħtieġa awtorizzazzjoni sabiex il-prodott ikun jista' jitqiegħed fis-suq, id-dokumenti kollha li jkunu meħtieġa mill-Awtorità dwar il-Mediċini jistgħu jiġu pprezentati bl-ilsien Inġliż u/jew bl-ilsien Malti.

L.N. 325 of 2006

**MEDICINES ACT
(CAP. 458)**

**Medicinal Products (Package Leaflets and Labelling)
(Transitional Arrangements) Regulations, 2006**

BY virtue of the powers conferred by article 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 the Medicinal Products (Package Leaflets and Labelling) (Transitional Arrangements) Regulations, 2006. Citation, duration and applicability.

(2) The transitional arrangements made in these regulations shall, subject to any amendments that may be made thereto, apply until the 31st December, 2009 unless earlier revoked or their period of application is further extended.

(3) The transitional arrangements made in these regulations shall apply for all medicinal products for human use, for which a marketing authorisation, an authorisation in line with article 4(2) of the Medicines (Marketing Authorisation) Regulations, 2004 or a parallel import licence is granted. L.N. 387 of 2004.

(4) Provided that the transitional arrangements made in these regulations shall in no way prejudice the language requirements in relation to applications for the granting of a marketing authorisation in accordance with the community procedures laid down in Council Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. Interpretation.
L.N. 393 of 2005.

2. Any authorised medicinal product may be placed on the market in Malta if the packaging and package leaflet, as approved, are either in the English or Maltese language or both. Language requirements for medicinal products to be placed on the market in Malta.

Licensing Authority may order package leaflet to be in both languages.

3. The Licensing Authority may, in the case of specific products, order that the package leaflet shall be in both the English and Maltese languages.

Documentation required by the Medicines Authority.

4. In the case of medicinal products for which an authorisation is required for placing on the market, all the documentation required by the Medicines Authority may be submitted in the English and, or Maltese language.