

SUBSIDIARY LEGISLATION 458.50

MEDICINAL PRODUCTS (PACKAGE LEAFLETS AND LABELLING)(TRANSITIONAL ARRANGEMENTS) REGULATIONS

19th December, 2006

LEGAL NOTICE 325 of 2006, as amended by Legal Notice 253 of 2010.

1. (1) The title of these regulations is the Medicinal Products (Package Leaflets and Labelling) (Transitional Arrangements) Regulations.
- (2) The transitional arrangements made in these regulations shall, subject to any amendments that may be made thereto, apply until the 31st December, 2014 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, or a parallel import licence is granted.
- (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.
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.
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.
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.
- Citation, duration and applicability.
Amended by:
L.N. 253 of 2010.
- S.L. 458.34
- Interpretation.
- Language requirements for medicinal products to be placed on the market in Malta.
- Licensing Authority may order package leaflet to be in both languages.
- Documentation required by the Medicines Authority.