

L.N. 72 of 2005

**MEDICINES ACT, 2003
(ACT NO. III OF 2003)**

**Medicines (Marketing Authorisation) (Amendment) Regulations,
2005**

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

Citation.

L.N. 387 of 2004.

Amends regulation
2 of the principal
regulations.

1. The title of these regulations is the Medicines (Marketing Authorisation) (Amendment) Regulations, 2005 and they shall be read and construed as one with the Medicines (Marketing Authorisation) Regulations, 2004, hereinafter referred to as “the principal regulations”.

2. Regulation 2 of the principal regulations, shall be amended as follows –

(a) after the definition “the Authority”, there shall be inserted the following new definition:-

““generic medicinal product” means a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and, or efficacy. In such cases, additional information providing proof of the safety and, or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines;” and

(b) after the definition “Member State” there shall be inserted the following: -

“ “reference medicinal product” means a medicinal product authorised under regulation 4(1) and in accordance with the provisions of regulations 5 and 6;”.

3. For regulation 7 of the principal regulations there shall be substituted the following:

Substitutes
regulation 7 of the
principal
regulations.

“ (1) By way of derogation from regulation 5 and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that:

(a) the medicinal product is essentially similar to another already authorised in Malta, and that the holder of the marketing authorisation of such similar product has consented to the toxicological, pharmacological and, or clinical references contained in the file of such product being used for the purpose of examining the application in question; or

(b) the constituent or constituents of the medicinal product have a well-established medicinal use, with recognised efficacy and an acceptable level of safety by means of a detailed scientific bibliography; or

(c) the medicinal product is a generic of a reference medicinal product which is or has been authorized under regulation 4(1) of these regulations for not less than six years in a Member State or in the Community:

Provided that –

(i) subregulation (c)(i) shall also apply if the reference medicinal product was not authorised in accordance with articles 4(1) of these regulations, in which case the applicant shall indicate in the application form the name of the Member State in which the reference medicinal product is or has been authorised;

(ii) a generic medicinal product authorised pursuant to this provision shall not be placed on the market until the established period for data exclusivity has elapsed from the initial authorisation of the reference product;

(iii) in cases where the medicinal product does not fall within the definition of a generic medicinal product or where the bioequivalence cannot be demonstrated through bioavailability studies or in case of changes in any active substance, therapeutic indications, strength, pharmaceutical form or route of administration, vis-à-vis the reference medicinal product, the results of the appropriate pre-clinical tests or clinical trials shall be provided;

(iv) where a biological medicinal product which is similar to a reference biological product does not meet the conditions in the definition of generic medicinal products owing to, in particular, differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference biological medicinal product, the results of appropriate pre-clinical tests or clinical trials relating to these conditions must be provided. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex I of EU directive 2003/63 and the related detailed guidelines. The results of other tests and trials from the reference medicinal product's dossier shall not be provided.

(2) In the case of new medicinal products containing known constituents not hitherto used in combination for therapeutic purposes, the results of toxicological and pharmacological tests and of clinical trials relating to that combination must be provided, but it shall not be necessary to provide references relating to each individual constituent:

Provided that conducting the necessary studies and trials with a view to the application of subregulation (1) and (2) and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.”.