L.N. **of** 2011

MEDICINES ACT
(CAP. 458)

Medicines (Marketing Authorisation) (Amendment) Regulations, 2010

IN exercise 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:-

Title and scope.

1. (a) The title of these Regulations is "Medicines (Marketing Authorisation) (Amendment) Regulations, 2010".

(b) These Regulations lay out the requirements set in Directive 2009/53/EC amending Directive 2001/83/EC and Regulation 1234/2008 as regards the filing of national variation applications.

Interpretation.

2. For the purpose of these regulations the following definitions shall apply:

(a) 'Variation to the terms of a marketing authorisation' or 'variation' means an amendment to the contents of the particulars and documents referred to in:

(i) Regulations 5, 6, 7 and 8 of the Medicines (Marketing Authorisation) Regulations, 2007 and all amendments made to these regulations.

(b) 'Minor variation of type IA' means a variation which has only a minimal impact or no impact at all, on the quality, safety or efficacy of the medicinal product concerned;

(c) 'Major variation of type II' means a variation which is not an extension and which may have a significant impact on the quality, safety or efficacy of the medicinal product concerned;

(d) ‘Extension’ of a marketing authorisation’ or ‘extension’ means a variation which is listed in Annex I of Regulation 1234/2008/EC and fulfils the conditions laid down therein;

(e) ‘Minor variation of type IB’ means a variation which is neither a minor variation of type IA nor a major variation of type II nor an extension;

(f) ‘Urgent safety restriction’ means an interim change to the product information due to new information having a bearing on the safe use of the medicinal product, concerning in particular one or more of the following terms in the summary of product characteristics: therapeutic indications, posology, contraindications, warnings, target species and withdrawal periods.

These definitions replace the definitions for variations given in the Marketing Authorisation (Fees) Regulations, 2003.

3. Classification of national variations should be in line with Annex II of Regulation 1234/2008/EC.