
STATUTORY INSTRUMENTS

2006 No. 1952

**The Medicines for Human Use (National Rules
for Homoeopathic Products) Regulations 2006**

Amendment of Schedule 3 to the Marketing Authorisation Regulations

5. In Schedule 3 to the Marketing Authorisation Regulations (offences, penalties etc)—
- (a) in paragraph 6(a), for “or Article 6 of Council Regulation (EEC) No. 2309/93” substitute “, Article 6 of Regulation (EC) No. 726/2004 or, in the case of a holder of an authorization for a national homoeopathic product, Article 8.3 of the 2001 Directive as applied by paragraph 1(3) of Part 1 of Schedule 1A”; and
 - (b) in paragraph 6(cc), for the words after “licensing authority” substitute—
 - “as required by—
 - (i) the third paragraph of Article 23 of the 2001 Directive or, in the case of the holder of an authorization for a national homoeopathic product, that paragraph read in accordance with the modifications in regulation 1(8)(c),
 - (ii) the fourth paragraph of Article 23 of the 2001 Directive, or
 - (iii) the first paragraph of Article 23a of the 2001 Directive.”.