
STATUTORY INSTRUMENTS

2013 No. 1855

The Human Medicines (Amendment) Regulations 2013

PART 2

Amendment of the Human Medicines Regulations 2012

Amendment of regulation 206

23.—(1) Regulation 206 (infringement notices) is amended as follows.

(2) For paragraph (1) substitute—

“(1) If an enforcement authority has objective grounds for considering that any person (“P”) has contravened any relevant provision, it may serve upon P a notice in writing (referred to in this Part as an “infringement notice”)—

- (a) informing P of the authority’s grounds for considering that P has contravened one or more relevant provision;
- (b) specifying the relevant provision;
- (c) specifying the measures which P must take in order to ensure that the contravention does not continue or, as the case may be, does not recur;
- (d) requiring P to take those measures, within such period as may be specified in the notice;
- (e) specifying the further action (if any) that the enforcement authority may take.”

(3) After paragraph (3) insert—

“(4) In this regulation “relevant provision” means a provision of—

- (a) this Part;
- (b) Chapter 3 of Title II of Regulation [\(EC\) No 726/2004](#); or
- (c) the Implementing Regulation.”