STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 11

Pharmacovigilance

Application of this Part and interpretation

177.—(1) This Part and Schedule 33 apply, except to the extent set out in paragraph (4)(b), in relation to medicinal products that are the subject of—

(a) a UK marketing authorisation;

(b) a traditional herbal registration; or

(c) an Article 126a authorisation.

(2) References in this Part to a "holder" are to the holder of—

(a) a UK marketing authorisation;

(b) a traditional herbal registration; or

(c) an Article 126a authorisation,

and, in relation to such references, "product" means the product to which the authorisation or registration relates.

(3) References to an "authorisation or registration" in this Part and in Schedule 33 are references to—

(a) a UK marketing authorisation;

(b) a traditional herbal registration; or

(c) an Article 126a authorisation

and "authorised or registered" is to be read accordingly.

(4) The following provisions of this Part and Schedule 33 apply in relation to medicinal products that are the subject of an EU marketing authorisation—

(a) regulation 206 (infringement notices); and

(b) regulation 210 (offences relating to pharmacovigilance obligations under Regulation (EC) No 726/2004), and paragraphs 2 and 4 of Schedule 33 (transitional arrangements: pharmacovigilance), but that regulation and those paragraphs do not apply in relation to the medicinal products specified in paragraph (1).

(5) In this Part and in Schedule 33—

"co-ordination group" means the group of that name established under Article 27 of the 2001 Directive;

"Eudravigilance database" means the database and data-processing network set up and maintained by the EMA under Article 24 of Regulation (EC) No 726/2004;

"infringement notice" has the meaning given to it in regulation 206 (infringement notices);

"relevant competent authorities" means the competent authority of each EEA state other than the United Kingdom which has granted in relation to a medicinal product—

(a) an authorisation in accordance with Chapter 1 of Title III to the 2001 Directive (marketing authorization);

(b) an authorisation in accordance with Chapter 4 of Title III to the 2001 Directive (mutual recognition and decentralised procedure);

(c) a registration in accordance with Chapter 2a of Title III to the 2001 Directive (traditional use registration for herbal medicinal products); or

(d) an authorisation in accordance with Article 126a of the 2001 Directive;

"relevant post-authorisation safety study" means a post-authorisation safety study which—

(a) is non-interventional;

(b) is initiated, managed or financed by the holder voluntarily or pursuant to conditions imposed under regulation 59 (conditions of a UK marketing authorisation: general) or 61 (conditions of a UK marketing authorisation: new obligations post-authorisation); and

(c) involves the collection of safety data from patients or health care professionals; and

"UK web-portal" has the meaning given in regulation 203 (obligations on licensing authority in relation to national medicines web-portal).