STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 1

General

Classification of medicinal products

5.—(1) In these Regulations references to a medicinal product subject to general sale are to a product that is not a prescription only medicine or a pharmacy medicine but is—

(a) a product that is covered by an authorisation of which it is a term that the product is to be available on general sale; or

(b) a product that—

(i) is covered by an EU marketing authorisation, and

(ii) is not classified in the authorisation as a prescription only medicine, and

(iii) the licensing authority has determined should be available on general sale.

(2) In paragraphs (1)(a) and (5)(a) "authorisation" means—

(a) a UK marketing authorisation;

(b) a certificate of registration;

(c) a traditional herbal registration; or

(d) an Article 126a authorisation.

(3) In these Regulations references to a prescription only medicine are to any of the following—

(a) a medicinal product that is covered by an authorisation of which it is a term that the product is to be available only on prescription;

(b) a medicinal product that—

(i) is covered by an EU marketing authorisation, and

(ii) is classified in the authorisation as a prescription only medicine;

(c) a medicinal product that is a prescription only medicine by virtue of Part 1 of Schedule 1; or

(d) a medicinal product that is the result of—

(i) the assembly, or

(ii) the reformulation (including the combining with other substances),

of a medicinal product that is a prescription only medicine by virtue of sub-paragraph (a) or (b).

(4) In paragraph (3)(a) "authorisation" means—

(a) a UK marketing authorisation; or

(b) an Article 126a authorisation.

(5) In these Regulations references to a pharmacy medicine are to a medicinal product that is not a prescription only medicinal product or a medicinal product subject to general sale but is—

(a) covered by an authorisation of which it is a term that the product is to be available only from a pharmacy;

(b) a product that—

(i) is covered by an EU marketing authorisation, and

(ii) is not classified in the authorisation as a prescription only medicine,

other than a product to which paragraph (1)(b)(iii) applies;

(c) available only from a pharmacy by virtue of Part 2 of Schedule 1; or

(d) the result of—

(i) the assembly, or

(ii) the reformulation (including the combining with other substances),

of a medicinal product that is a pharmacy medicine by virtue of sub-paragraph (a) or (b).