STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

[F1PART 12A

Sale of medicines to the public at a distance

[F1Variation of a person's entry on the list on the application of that person

256L.—(1) This regulation applies if a person entered on the list applies to the competent authority of a member State for a variation of the person's entry on the list.

(2) The application must—

(a) be in writing;

(b) specify the variation requested;

(c) be signed by or on behalf of the applicant; and

(d) be accompanied by such information as may be required to enable the competent authority of a member State to consider the application.

(3) The competent authority of a member State must vary a person's entry on the list or refuse to vary it within 30 days beginning with the day after the date when that competent authority receives the application.

(4) The competent authority of a member State may give a notice to the applicant requiring the applicant to supply further information in connection with the application within the period specified in the notice.

(5) If a notice under paragraph (4) requires the applicant to provide the competent authority of a member State with information, the information period is not to be counted for the purposes of paragraph (3).

(6) In paragraph (5), the "information period" means the period—

(a) beginning with the day on which notice under paragraph (4) is given; and

(b) ending with the day on which the competent authority of a member State receives the information or the applicant shows to that competent authority's satisfaction that the applicant is unable to provide it.

(7) Nothing in this regulation affects the powers conferred by regulations 256I and 256K.**]**

Textual Amendments

F1 Pt. 12A inserted (coming into force in accordance with reg. 1(2) of the amending S.I.) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(2), **28**