STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 3

[[F1]Manufacture and distribution of medicinal products and active substances**]**

[[F1]CHAPTER 4

Importation, manufacture and distribution of active substances

[[F1]Provision of information**

45P.—(1) In this regulation—

"R" means a person who is, or has applied to the licensing authority to become, a registered importer, manufacturer or distributor of active substances;

"reporting year" means a period of twelve months ending on 31st March.

(2) On or before the date specified in paragraph (3), R must submit a report to the licensing authority which—

(a) includes a declaration that R has in place an appropriate system to ensure compliance with regulations 45N, 45O and this regulation; and

(b) details the system which R has in place to ensure such compliance.

(3) The date specified for the purposes of this paragraph is—

(a) in relation to any application made before 31st March 2014, the date of the application; and

(b) in relation to each subsequent reporting year, 30th April following the end of that year.

(4) R must without delay notify the licensing authority of any changes to the matters in respect of which evidence has been supplied in relation to paragraph (2) which might affect compliance with the requirements of this Chapter.

(5) Any report or notification to the licensing authority under paragraph (2) or (4) must be accompanied by the appropriate fee in accordance with the Fees Regulations.

(6) The licensing authority may give a notice to R, requiring R to provide information of a kind specified in the notice within the period specified in the notice.

(7) A notice under paragraph (6) may not be given to R unless it appears to the licensing authority that it is necessary for the licensing authority to consider whether the registration should be varied, suspended or removed from the active substance register.

(8) A notice under paragraph (6) may specify information which the licensing authority thinks necessary for considering whether the registration should be varied, suspended or removed from the active substance register.**]**

Textual Amendments

F1 Pt. 3 Chs. 3, 4 inserted (20.8.2013) by The Human Medicines (Amendment) Regulations 2013 (S.I. 2013/1855), regs. 1(1), **16**

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Section 45P.