STATUTORY INSTRUMENTS

2019 No. 801

The Patents (Amendment) (EU Exit) Regulations 2019

PART 7

COMPULSORY LICENSING OF PHARMACEUTICAL PATENTS - AMENDMENTS TO REGULATION (EC) NO 816/2006

37. Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems is amended as set out in this Part.

38.—(1) Article 1 (scope) is amended as follows.

(2) For "Member States", substitute "The competent authority".

39.—(1) Article 2 (definitions) is amended as follows.

(2) For the definition of "competent authority" in paragraph (4), substitute—

""competent authority" for the purposes of Articles 1 to 11, 16 and 17 means the Comptroller-General of Patents, Designs and Trade Marks;".

(3) After paragraph (4), insert—

"(5) "patent" means "a patent under the Patents Act 1977;

(6) "supplementary protection certificate" means a supplementary protection certificate issued under Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products".

(4) Omit Article 3 (competent authority).

40. In Article 4 (eligible importing countries), for "Commission", substitute "United Kingdom".

41.—(1) Article 5 (extension to least-developed and developing countries which are not members of the WTO) is amended as follows.

(2) In paragraph (a), for "Commission", substitute "Secretary of State".

(3) In paragraph (c), omit "or on its own initiative if national law allows the competent authority to act on its own initiative,".

42.—(1) Article 6 (application for a compulsory licence) is amended as follows.

(2) For paragraph 1, substitute—

"**1.** Any person may submit an application for a compulsory licence under this Regulation to the competent authority in a case where that person's intended activities of manufacture and sale for export are covered by a patent or a supplementary protection certificate.".

(3) In paragraph 2, for "each application", substitute "the application made to the competent authority".

(4) Omit paragraph 4.

43. In Article 8 (verification), for "Commission", wherever it occurs, substitute "United Kingdom".

44.—(1) Article 10 (compulsory licence conditions) is amended as follows.

(2) In paragraph 5, for "Member States", substitute "United Kingdom".

(3) In paragraph 8, omit "or on its own initiative, if national law allows the competent authority to act on its own initiative.".

45.—(1) Article 12 (notification) is amended as follows.

(2) For "Member State", substitute "Secretary of State".

(3) Omit "through the intermediary of the Commission".

46. In Article 13 (prohibition of importation), in paragraph 1, for "Community", substitute "United Kingdom".

47.—(1) Article 14 (action by customs authorities) is amended as follows.

(2) In paragraph 1—

(a) for "Community" substitute "United Kingdom"; and

(b) omit "Member States shall ensure that a body has the authority to review whether such importation is taking place".

(3) In paragraph 2, for "national provisions on", substitute "the law relating to".

(4) In paragraph 3, for "Community", substitute "United Kingdom".

(5) In paragraph 4, omit ", in accordance with national legislation,".

(6) Omit paragraph 6.

48.—(1) Article 16 (termination or review of the licence) is amended as follows.

(2) In paragraph 2, for "through the intermediary of the Commission", substitute "by the Secretary of State".

(3) In paragraph 3, omit—

(a) "or any other body appointed by the Member State"; and

(b) "or by another body appointed by the Member State,".

49. Omit Articles 17 to 19. (appeals, safety and efficacy of medicinal products and review)

50. After Article 20 (entry into force), omit "This Regulation shall be binding in its entirety and directly applicable in all Member States".