DRAFT STATUTORY INSTRUMENTS

2018 No.

The Patents (Amendment) (EU Exit) Regulations 2018

PART 8

SUPPLEMENTARY PROTECTION CERTIFICATES FOR MEDICINAL PRODUCTS – AMENDMENTS TO REGULATION (EC) No 469/2009

52.—(1) Article 1 (interpretation) is amended as follows.

(2) In paragraph (e) for "Article 36 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use", substitute "regulation 58A(3) of the Human Medicines Regulations 2012(**1**)".

(3) After paragraph (e) insert—

"(f) 'comptroller' means the Comptroller-General of Patents, Designs and Trade Marks;

(g) 'court' is to be interpreted in accordance with Article 1A;

(h) "EEA authorisation" means an authorisation to place a medicinal product on the market which has effect in an EEA state in accordance with Directive 2001/83/EC or Directive 2001/82/EC;

(i) 'patent' means a patent which has effect in the United Kingdom;

(j) 'UK authorisation' means, in relation to a product, an authorisation to place that product on the market as a medicinal product granted in accordance with—

(i) Part 5 of the Human Medicines Regulations 2012; or

(ii) regulation 4(3) of, and Schedule 1 to, the Veterinary Medicines Regulations 2013(**2**).".

(**1**) S.I. 2012/1916. Regulation 58A is inserted by S.I. 2018/xxxx , reg. [ ].
(**2**) S.I. 2013/2033.