SCHEDULE

Amendments to Regulations on Supplementary Protection Certificates

PART 2

Amendments to Regulation (EC) 469/2009

Article 1: definitions

11. In Article 1—

(a) after the definition of "UK authorisation" in paragraph (j), as inserted by regulation 52(3) of the Patents (Amendment) (EU Exit) Regulations 2019 and amended by regulation 3(3) of these Regulations, insert—

"(ja) "GB authorisation" means, in relation to a product, an authorisation to place that product on the market in England and Wales and Scotland as a medicinal product granted or having effect as if granted in accordance with—

(i) Part 5 of the Human Medicines Regulations 2012(**1**); or

(ii) regulation 4(3) of, and Schedule 1 to, the Veterinary Medicines Regulations 2013(**2**) as they have effect in England and Wales and Scotland;

(jb) "NI authorisation" means, in relation to a product, an authorisation to place that product on the market in Northern Ireland as a medicinal product granted or having effect as if granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC as they have effect by virtue of the Protocol on Ireland/Northern Ireland in the EU withdrawal agreement;";

(b) After paragraph (k), insert—

"(l) "prescribed" means prescribed by rules under section 123 of the Patents Act 1977(**3**).".

(**1**) S.I. 2012/1916. Regulation 58A is inserted by S.I. 2019/775, reg. 64.
(**2**) S.I. 2013/2033.
(**3**) 1977 c. 37; section 123 was last amended by the Patents Act 2004 c. 16.