SCHEDULE 8

The Veterinary Medicines Regulations 2013: new provisions

PART 1

New Schedule 1A

"SCHEDULE 1A Regulation 4(4)

Converted EU marketing authorisations

1. In this Schedule—

"converted EU marketing authorisation" means an EU marketing authorisation to which paragraph 2 applies;

"EU marketing authorisation" means a marketing authorisation for a veterinary medicinal product granted by the European Commission in accordance with Title 3 of Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency(**1**).

2. This paragraph applies to an EU marketing authorisation which—

(a) was granted before exit day, and

(b) remains in force immediately before exit day.

3. A converted EU marketing authorisation has effect on and after exit day for the purposes of these regulations as if it were a marketing authorisation granted by the Secretary of State under these Regulations on the date it was originally granted—

(a) on the terms which were in force immediately before exit day,

(b) with the benefit of any periods of data marketing exclusivity from which the holder benefited immediately before exit day, and

(c) subject to any suspension or post-authorisation obligations which were in force immediately before exit day.

4. Without prejudice to the generality of paragraph 3—

(a) the holder of a converted EU marketing authorisation is subject to the annual fee as set out in paragraph 26 of Schedule 7;

(b) a converted EU marketing authorisation is to be treated as having been granted in accordance with regulation 4(3) and Schedule 1 for the purposes of Regulation (EC) No 469/2009."

(**1**) OJ No L 136, 30.4.2004, p 1, as last amended by Regulation (EU) No 1027/2012 (OJ No L 316, 14.11.2012, p 38).