SCHEDULE 1

Amendment of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

Amendment of Schedule 6 (insertion of Schedule 12A into the 2012 Regulations)

9. In Schedule 6, in Part 8 of inserted Schedule 12A to the 2012 Regulations (periodic safety update reports), in paragraph 27 (format of periodic safety update reports)—

(a) re-number the existing paragraph as sub-paragraph (1) of paragraph 27; and

(b) insert at the end—

"(2) In this paragraph, "signal evaluation" means the process of further evaluating a validated signal taking into account all available evidence, to determine whether there are new risks causally associated with the active substance or medicinal product, or whether known risks have changed, and that process—

(a) may include non-clinical and clinical data; and

(b) must be as comprehensive as possible regarding the sources of information used for that process.".

Commencement Information

I1 Sch. 1 para. 9 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019, Paragraph 9.