DRAFT STATUTORY INSTRUMENTS

2022 No.

The Human Medicines (Amendments Relating to the Early Access to Medicines Scheme) Regulations 2022

Amendment of regulation 8

4. In regulation 8(1)(**1**) (general interpretation), at the appropriate places insert—

""EAMS medicinal product" means a medicinal product that—

(a) has been included in the Early Access to Medicines Scheme by means of the licensing authority issuing an EAMS scientific opinion in respect of it; and

(b) remains in the scheme by virtue of the EAMS scientific opinion not ceasing to have effect in respect of it by virtue of regulation 167D;";

""EAMS scientific opinion" is to be construed in accordance with regulation 167C(2)(b);";

""EAMS scientific opinion holder" means the holder of a EAMS scientific opinion, and accordingly, is the person who places on the market the product to which the opinion relates;";

""Early Access to Medicines Scheme" means the scheme of that name established and operated under regulation 167C(1);"; and

""EU Clinical Trials Regulation" means Regulation EU No. 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products, and repealing Directive 2001/20/EC(**2**);".

(**1**) Amended by S.I. 2013/1855 and 2593, 2015/534 and 1503, 2016/186, 190 and 696, 2017/715, 2018/199, 2019/62, 593, 703, 775 and 1094, 2020/349 and 1125 and 2021/1452.

(**2**) OJ L 158, 27.5.2014, p. 1.