STATUTORY INSTRUMENTS

2018 No. 1055

The Misuse of Drugs (Amendments) (Cannabis and Licence Fees) (England, Wales and Scotland) Regulations 2018

Amendment of regulation 2 of the 2001 Regulations

3. In regulation 2(1) of the 2001 Regulations(**1**) (interpretation) at the appropriate places insert—

""cannabis-based product for medicinal use in humans" means a preparation or other product, other than one to which paragraph 5 of part 1 of Schedule 4 applies, which—

(a) is or contains cannabis, cannabis resin, cannabinol or a cannabinol derivative (not being dronabinol or its stereoisomers);

(b) is produced for medicinal use in humans; and—

(c) is—

(i) a medicinal product, or

(ii) a substance or preparation for use as an ingredient of, or in the production of an ingredient of, a medicinal product;";

""clinical trial" has the same meaning as in the Medicines for Human Use (Clinical Trials) Regulations 2004(**2**);";

""dronabinol" does not include any substance which—

(a) has the international non-proprietary name dronabinol (recommended by the World Health Organisation); and

(b) is derived from cannabis, cannabis resin or their constituents,

and stereoisomers of dronabinol are to be construed accordingly;; and"; and

""medicinal product" has the same meaning as in the Human Medicines Regulations 2012(**3**);".

(**1**) Regulation 2 has been amended by S.I. 2003/1653, 2003/2429, 2004/1771, 2005/271, 2005/2864, 2006/986, 2006/1450, 2006/2178, 2007/2154, 2011/2581, 2012/973, 2012/1916, 2013/235, 2015/891 and 2018/682.
(**2**) S.I. 2004/1031. See the definition of "clinical trial" in regulation 2.
(**3**) S.I. 2012/1916. See the definition of "medicinal product" in regulation 2.