STATUTORY RULES OF NORTHERN IRELAND

2018 No. 173

The Misuse of Drugs (Amendment No.2) Regulations (Northern Ireland) 2018

Amendment of regulation 2

- **3.** In regulation 2(2) (interpretation)—
 - (a) 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(1);";

""dronabinol" does not include any substance which-

- (a) has the international non-proprietary name dronabinol (recommended by the World Health Organisation); and
- (b) that is derived from cannabis, cannabis resin or their constituents, and stereoisomers of dronabinol are to be construed accordingly;"; and

[&]quot;"medicinal product" has the same meaning as in the Human Medicines Regulations 2012(2);".

⁽¹⁾ S.I. 2004/1031. See the definition of "clinical trial" in regulation 2.

⁽²⁾ S.I. 2012/1916. See the definition of "medicinal product" in regulation 2.