
EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Misuse of Drugs Regulations (Northern Ireland) 2002 ([S.R. 2002 No.2](#)) (the “2002 Regulations”) to allow the wider use of cannabis based products for medicinal use in humans, essentially for medical purposes.

The Schedule to the 2002 Regulations in which a controlled drug is placed affects the extent to which the drug can be lawfully imported, exported, produced, supplied or possessed. Regulation 3 inserts the definition of a cannabis based product for medicinal use in humans into the 2002 Regulations. Regulations 6 and 7(b) transfer these products from Schedule 1 to Schedule 2. The rescheduling also applies (as a consequence of existing provisions of Schedule 2) to related products such as stereoisomeric forms, salts and esters of cannabis based products for medicinal use in humans where these related products are also produced for medicinal use in humans (by regulation 7(c)). A synthetic version of a constituent of cannabis, dronabinol, was already listed in Schedule 2, and a new definition is inserted to ensure its position is unchanged (regulation 3(c)).

Additional controls, beyond those generally provided for in relation to drugs specified in Schedule 2 to the 2002 Regulations, are imposed for cannabis based products for medicinal use in humans. Regulation 4 inserts new regulation 16 A to specify requirements for the order and supply of these products for the purpose of administration (whether to humans or animals) and their use. The order (by prescription, direction or otherwise) must be for: a special medicinal product (an existing category of medicines without marketing authorisations) for use in accordance with the prescription or direction of a specialist medical practitioner; an investigational medicinal product for use in a clinical trial in humans; or, a medicinal product with a marketing authorisation. Supply, by administration or for the purpose of administration, must be pursuant to such an order. Additionally, a person is restricted from self-administration of a cannabis based product for medicinal use in humans by way of smoking other than for research purposes. An exception is, however, created for order and supply of such products for administration to animals for research purposes.