
STATUTORY INSTRUMENTS

1995 No. 2808

**The Medicines (Exemption from
Licences) (Clinical Trials) Order 1995**

Interpretation

2.—(1) In this Order—

(a) “the Act” means the Medicines Act 1968;

“approved name” in relation to a constituent is either the name of the substance or article which appears in the current edition of the list prepared in accordance with section 100 of the Act (lists of names) and published by the Ministers or the international non-proprietary name recommended by the World Health Organisation;

“medicinal product” includes any substance or article for human use specified in an order made under section 104 or 105(1)(b) of the Act (application of Act to certain articles and substances and to certain other substances which are not medicinal products) which is for the time being in force and which directs that sections 31 and 35(8) and (9) of the Act shall have effect in relation to that substance or article⁽¹⁾;

“monograph” means a monograph in the current edition of the European Pharmacopoeia, of any compendium published by the Health Ministers or the Agriculture Ministers under section 99 of the Act (new editions of British Pharmacopoeia and other compendia), of the British Pharmacopoeia or of the British Pharmaceutical Codex;

“monograph name” means, in relation to a constituent, the name which appears at the head of the relevant monograph;

“notice” means notice in writing;

“supplier” means a person selling or supplying, or procuring the sale, supply, manufacture or assembly of, a medicinal product for the purposes of a clinical trial;

“usage guideline” means the notice referred to in article 4(1)(a)(iii) of this Order;

(b) a reference to a numbered article is to the article of this Order bearing that number and a reference in an article to a numbered paragraph is to the paragraph of that article bearing that number.

(2) Section 127 of the Act (service of documents) applies to notices required or authorised to be given or sent by any provision of this Order as it applies to notices required or authorised to be given or sent by any provision of the Act.

(3) For the purposes of calculating any period of days referred to in this Order no account shall be taken of Christmas Day, Good Friday or a bank holiday in England under the Banking and Financial Dealings Act 1971⁽²⁾.

(1) See the Medicines (Surgical Materials) Order 1971 (S.I. 1971/1267), the Medicines (Dental Filling Substances) Order 1975 (S.I. 1975/533) and the Medicines (Specified Articles and Substances) Order 1976 (S.I. 1976/968), each amended by the Medical Devices (Consequential Amendments—Medicines) Regulations 1994 (S.I. 1994/3119).

(2) 1971 c. 80.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.
