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STATUTORY INSTRUMENTS

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**1995 No. 2808**

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

**Coming into effect, duration and termination of exemption**

5.—(1) The exemption conferred by article 3 shall take effect on the expiry of the specified period and shall continue, if the conditions specified in article 4 are fulfilled, for a period of three years unless it is terminated in accordance with paragraphs (2) and (3).

(2) The licensing authority may, by notice given or sent to the supplier, terminate the exemption conferred by article 3 in relation to any description of medicinal product if it appears to them that—

- (a) medicinal products of that description can no longer be regarded as products which can safely be administered for the purposes of the clinical trial in question; or
- (b) the specification or standards to which medicinal products of that description are manufactured can no longer be regarded as satisfactory; or
- (c) any changes which have been notified in respect of matters specified in Schedule 3 to this Order may adversely affect the safety of a patient taking part in the clinical trial; or
- (d) the notice referred to in article 4(1)(a) or any document which accompanied it was false or incomplete in a material particular; or
- (e) the supplier is in breach of any part of the undertaking referred to in article 4(1)(c).

(3) The date on which the termination referred to in paragraph (2) takes effect shall be such date as may be specified by the licensing authority in the notice referred to in that paragraph.