
STATUTORY INSTRUMENTS

1995 No. 2808

MEDICINES

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

Made - - - - - *27th October 1995*
Laid before Parliament *6th November 1995*
Coming into force *8th December 1995*

THE MEDICINES (EXEMPTION FROM
LICENCES) (CLINICAL TRIALS) ORDER 1995

1. Citation and commencement
2. Interpretation
3. Exemption from licences in respect of clinical trials
4. Conditions
5. Coming into effect, duration and termination of exemption
6. Amendment of Order
Signature

SCHEDULE 1 — PARTICULARS AND SUMMARIES WHICH ARE TO
ACCOMPANY A NOTICE GIVEN OR SENT UNDER ARTICLE
4(1)(a)

1. The name and address of the supplier and any other...
2. (a) The name and address of any person taking part,...
3. The name or proposed name of the medicinal product or,...
4. The chemical structural formula for each active constituent or, where...
5. A description of the pharmaceutical form in which the medicinal...
6. The specification of the medicinal product including a statement of...
7. In respect of each constituent, whether active or not—
8. A description of the containers used for the medicinal product...
9. The proposed dosage and its duration, and the methods and...
10. A description of the proposed clinical trial including the duration...
11. (a) A summary of pharmaceutical data in respect of the...
12. (a) Where a specification has been established for a constituent—...
13. A summary of pharmaceutical data in respect of—

Status: This is the original version (as it was originally made).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

14. Summaries of reports and evaluations of any experimental and biological...

SCHEDULE 2 — INFORMATION TO BE CONTAINED IN USAGE GUIDELINE

1. The name or proposed name of the medicinal product or,...
2. A description of each clinical use to be investigated and,...
3. The minimum and maximum ages, and the maximum number, of...
4. The criteria for the selection of patients for, and the...
5. A description of how safety will be monitored during the...

SCHEDULE 3 — MATTERS IN RESPECT OF WHICH THE LICENSING
AUTHORITY SHALL FORTHWITH BE INFORMED OF
CHANGES

1. (a) The name and address of any person taking part,...
2. The active or inactive constituents, or the method of manufacture...
3. The method of synthesis of any active constituent where such...
4. Information in the usage guideline.

Explanatory Note