STATUTORY INSTRUMENTS

1993 No. 2538

MEDICINES

The Medicines (Applications for Grant of Product Licences—Products for Human Use) Regulations 1993

Made - - - -	*21st October 1993*
Laid before Parliament	*28th October 1993*
Coming into force	*29th November 1993*

THE MEDICINES (APPLICATIONS FOR GRANT OF PRODUCT LICENCES—PRODUCTS FOR HUMAN USE) REGULATIONS 1993

13. Brief information about the educational background, training and occupational experience...
14. One or more samples or mock-ups of the sales presentation,...
15. A statement of the number of volumes of documentation submitted...
16. A statement as to any samples provided.
17. Where the applicant is, by virtue of paragraph 8 above,...
18. Where the applicant is, by virtue of paragraph 8 above,...
19. A statement indicating— (a) which of the following should apply...
20. If the product is already authorised in other countries—
21. In relation to any generator to which Article 3 of...
22. Where the applicant, in relation to all or any particular...
23. Where the licence applied for is required solely for the...
24. A statement indicating that the applicant agrees that the licence...
25. All other information which is relevant to the evaluation of...

SCHEDULE 2 — EXCEPTIONS TO THE REQUIREMENT TO PROVIDE PARTICULARS OF THE RESULTS OF TESTS AND TRIALS REFERRED TO IN PARAGRAPH 8 OF SCHEDULE 1

1. Subject to paragraphs 2 to 4 below, the applicant shall...
2. Notwithstanding paragraph 1 above, the applicant shall provide particulars of...
3. Where the product is a new medicinal product containing known...
4. The applicant shall not be entitled by virtue of the...
5. Subject to compliance with paragraphs 19(a) and 22 of Schedule...
6. The applicant shall not be required under paragraph 8 of...

SCHEDULE 3 — CIRCUMSTANCES IN WHICH CERTAIN PARTICULARS MAY BE PROVIDED BY A MANUFACTURER (OTHER THAN THE APPLICANT) OF CERTAIN ACTIVE INGREDIENTS

1. In the case of— (a) an active ingredient not described...
2. Paragraph 1 of this Schedule shall not apply unless the...

Explanatory Note