STATUTORY INSTRUMENTS

2005 No. 2789

MEDICINES

The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005

Made - - - -	*10th October 2005*
Laid before Parliament	*10th October 2005*
Coming into force	*30th October 2005*

THE MEDICINES FOR HUMAN USE (MANUFACTURING, WHOLESALE DEALING AND MISCELLANEOUS AMENDMENTS) REGULATIONS 2005

SCHEDULE 1 — STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE RELATING TO THE MANUFACTURE AND ASSEMBLY OF RELEVANT MEDICINAL PRODUCTS

1. The manufacturer’s licence holder shall place the quality control system...
2. The manufacturer’s licence holder may use a contract laboratory pursuant...
3. The manufacturer’s licence holder shall provide such information as may...
4. The manufacturer’s licence holder shall inform the licensing authority of...
5. The manufacturer’s licence holder shall— (a) keep readily available for...
6. The manufacturer’s licence holder shall keep readily available for examination...
7. Where the manufacturer’s licence holder has been informed by the...
8. The manufacturer’s licence holder shall ensure that any tests for...
9. Where the manufacturer’s licence relates to the assembly of any...
10. Where— (a) the manufacturer’s licence relates to the assembly of...
11. The licence holder shall keep readily available for examination by...
12. Where— (a) animals are used in the production of any...
13. The licence holder shall take all reasonable precautions and exercise...

SCHEDULE 2 — STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE RELATING TO THE IMPORT OF RELEVANT MEDICINAL PRODUCTS FROM A THIRD COUNTRY

1. The manufacturer’s licence holder shall place the quality control system...
2. The manufacturer’s licence holder may use a contract laboratory pursuant...
3. The manufacturer’s licence holder shall provide such information as may...
4. The manufacturer’s licence holder shall— (a) keep readily available for...
5. Where the manufacturer’s licence holder has been informed by the...
6. The manufacturer’s licence holder shall ensure that any tests for...
7. (1) Where and insofar as the licence relates to relevant...
8. The licence holder shall take all reasonable precautions and exercise...

SCHEDULE 3 — STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO VACCINES, TOXINS OR SERA

PART 1 — STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO VACCINES

1. (1) The licence holder shall provide separate premises or separate...
2. The licence holder shall ensure that any procedure which, in...
3. The licence holder shall ensure that no person who has...
4. Before an animal is used in the production of a...
5. The licence holder shall ensure— (a) that animals used in...
6. The licence holder shall provide a separate room in the...
7. Without prejudice to any other requirements to keep records, where...
8. Nothing in this Schedule shall operate so as to restrict...

PART 2 — STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO SMALLPOX VACCINES

1. The licence holder shall ensure that animals used in the...
2. Should any animal during the 28 day period referred to...