STATUTORY INSTRUMENTS

2005 No. 2789

MEDICINES

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

Made - - - -	*10th October 2005*
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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...

3. Where it is necessary for an animal which has been...

PART 3 — STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO BCG VACCINES

1. The licence holder shall provide separate premises or separate parts...
2. The licence holder shall ensure that any procedure which involves...
3. The licence holder shall ensure that all media, glassware and...
4. The licence holder shall not permit animals to be in...
5. (1) The licence holder shall arrange for all persons engaged...
6. The licence holder shall ensure that no person who has...

PART 4 — STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO TOXINS

1. The licence holder shall provide separate premises or separate parts...
2. Nothing in paragraph 1 shall operate so as to restrict...
3. The licence holder shall ensure that any procedure which in...

PART 5 — STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A MANUFACTURER'S LICENCE WHICH RELATES TO SERA

1. The licence holder shall ensure that blood used in the...
2. The licence holder shall ensure that an adequate system of...
3. Before an animal is used in the production of any...
4. The licence holder shall notify the licensing authority if any...
5. The licence holder shall notify the licensing authority if any...
6. The licence holder shall ensure that laboratories in which any...
7. The licence holder shall provide such number of sterilizers as...
8. Without prejudice to any other requirements to keep records, the...
9. Nothing in this Part shall operate so as to restrict...

SCHEDULE 4 — STANDARD PROVISIONS WHICH MAY BE INCORPORATED IN A WHOLESALE DEALER'S LICENCE

1. The licence holder shall not use any premises for the...
2. The licence holder shall provide such information as may be...
3. (1) Where and insofar as the licence relates to relevant...
4. The licence holder shall take all reasonable precautions and exercise...

SCHEDULE 5 — CONSEQUENTIAL AND OTHER AMENDMENTS OF ENACTMENTS

PART 1 — AMENDMENTS TO THE ACT

1. (1) Section 8 of the Act (provisions as to manufacture...
2. In section 14 of the Act (exemption for re-exports) ,...
3. Section 20 of the Act (grant or refusal of licence)...
4. (1) Section 24 of the Act (duration and renewal of...
5. For section 30 of the Act (variation of licence on...
6. Section 49A of the Act is repealed.
7. After section 49 of the Act (postponement of restrictions in...
8. In section 67 of the Act (offences under Part III)—...
9. In section 111 of the Act (rights of entry)—
10. In section 132 (general interpretation provisions)— (a) In the definition...

PART 2 — AMENDMENTS TO ORDERS AND REGULATIONS

1. Amendments to the Standard Provisions Regulations
2. Amendments to the Applications Regulations

Changes to legislation:
There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005. Any changes that have already been made by the team appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Sch. 2 para. 7(8) words revoked by S.I. 2010/1882 reg. 10(b)(i)
- Sch. 4 para. 3(8) words revoked by S.I. 2010/1882 reg. 10(b)(ii)
- Regulations revoked by S.I. 2012/1916 Sch. 35
- reg. 1(2) words substituted by S.I. 2010/1882 reg. 10(a)
- reg. 8(3) substituted by S.I. 2009/1164 reg. 4