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STATUTORY INSTRUMENTS

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**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

1. Citation, commencement and interpretation
  2. Requirement that manufacturer's licence holders comply with certain obligations in relation to the manufacture and assembly of relevant medicinal products
  3. Requirement that manufacturer's licence holders comply with certain obligations in relation to the import from a third country of relevant medicinal products
  4. Requirements as to qualified persons
  5. Offence relating to the sale and supply of starting materials for use in the manufacture of relevant medicinal products
  6. Standard provisions for manufacturer's licences
  7. Additional standard provisions for manufacturers licences which relate to vaccines, toxins and sera
  8. Requirement that holders of wholesale dealer's licences comply with certain obligations
  9. Requirement that wholesale dealers deal only with specified persons
  10. Requirement as to responsible persons
  11. Standard provisions for wholesale dealer's licences
  12. Application of these Regulations to manufacturer's and wholesale dealer's licences
  13. Consequential and other amendments to enactments
  14. Revocations
  15. Transitional provisions
- Signature

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), in...
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

3. Amendments to the Medicines (Renewal Applications for Licences and Certificates) Regulations 1974
4. Amendments to the Medicines (Retail Sale or Supply of Herbal Remedies) Order 1977

#### SCHEDULE 6 — TRANSITIONAL PROVISIONS

1. Wholesale dealer's licences granted before 30th October 2005 relating to the import of medicinal products from third countries
2. Applications for wholesale dealer's licences made before 30<sup>th</sup> October 2005
3. Manufacturer's and wholesale dealer's licences granted before 30<sup>th</sup> October 2005

Explanatory Note