STATUTORY INSTRUMENTS

1977 No. 675

MEDICINES

The Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1977

Made - - - -	*6th April 1977*
Laid before Parliament	*21st April 1977*
Coming into Operation	*12th May 1977*

THE MEDICINES (STANDARD PROVISIONS FOR LICENCES AND CERTIFICATES) AMENDMENT REGULATIONS 1977

Schedules added to the principal regulations

SCHEDULE 4 —

PART I — Standard provisions for manufacturer's licences and manufacturer's licences of right relating to vaccines

1. The licence holder shall ensure that the premises on which...
2. The licence holder shall provide separate premises or separate parts...
3. The licences holder shall ensure that any procedure which, in...
4. The licence holder shall ensure that no person who has...
5. Before an animal is used in the production of vaccine...
6. (1) The licence holder shall ensure that animals used in...
7. The licence holder shall provide a special room capable of...
8. Without prejudice to any other requirements to keep records, where...

PART II — Standard provisions for manufacturer's licences and manufacturer's licences of right relating to smallpox vaccine

1. (1) The licence holder shall ensure that animals used in...
2. Where it is necessary for an animal which has been...

PART III — Standard provisions for manufacturer's licences and manufacturer's licences of right relating to BCG vaccine

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 IV — Standard provisions for manufacturer's licences and manufacturer's licences of right relating to toxins

1. The licence holder shall ensure that the premises on which...
2. The licence holder shall provide separate premises or separate parts...
3. The licence holder shall ensure that any procedure which in...

PART V — Standard provisions for manufacturer's licences and manufacturer's licences of right relating to sera

1. The licence holder shall ensure that the premises on which...
2. The licence holder shall ensure that blood used in the...
3. The licence holder shall ensure that an adequate system of...
4. Before an animal is used in the production of any...
5. The licence holder shall notify the licensing authority if any...
6. The licence holder shall notify the licensing authority if any...
7. The licence holder shall ensure that laboratories in which any...
8. The licence holder shall provide such number of sterilizers as...
9. Without prejudice to any other requirements to keep records, the...

SCHEDULE 5 —

PART I — Standard provisions for product licences including product licences of right relating to medicinal products to which regulation 5 of these regulations applies

1. In this Part of this Schedule “expiry date” means the...
2. The licence holder shall, within 28 days of any request...
3. Until the expiry date and for six months thereafter the...
4. Where the licence holder has supplied the licensing authority with...
5. Where the licence holder has been informed by the licensing...
6. Unless and to the extent that the licensing authority otherwise...
7. (1) Unless the licensing authority otherwise direct in writing, the...
8. The licence holder shall not sell, supply, import or export...
9. The provisions of this Schedule shall not have effect until...

PART II — Tests for sterility

1. In this Part of this Schedule— “batch” means a homogeneous...
2. (1) The test for bacterial sterility shall be applied to...
3. (1) The quantity of the medicinal product required for the...
4. (1) Subject to the provisions of sub-paragraph (2) below, the...
5. In the case of a medicinal product which is itself...
6. Where more than one test is to be performed on...
7. (1) The tests for sterility shall be made on a...
8. (1) The sample shall be applied to the media selected...
9. The tubes or vessels of media to which the sample...
10. (1) If at the examination at the end of the...
11. (1) Notwithstanding the provisions of paragraph 10 above, where the...

PART III — Test for abnormal toxicity

1. (1) The amount of medicinal product as is specified in...
2. Where, by virtue of the nature of any substance used,...

PART IV — Test for pyrogens

1. In this Part of this Schedule— “maximum temperature”, in relation...

2. A test for pyrogenic substances (hereinafter referred to as a...
3. A rabbit shall not be used in a pyrogen test—...
4. (1) The measurement of the temperatures of the rabbits in...
5. A pyrogen test shall be conducted in a quiet room...
6. The rabbits used in the pyrogen test shall not be...
7. (1) A pyrogen test shall be made by—
8. The medicinal product shall be regarded as having satisfied the...

Explanatory Note