STATUTORY INSTRUMENTS

1991 No. 633

MEDICINES

The Medicines (Exemptions from Licences and Animal Test Certificates) (Amendment) Order 1991

Made - - - -	*8th March 1991*
Laid before Parliament	*13th March 1991*
Coming into force - -	*3rd April 1991*

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Scotland and in Wales, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of the powers conferred by sections 15(1) and (2) and 35(8)(b) and (9) of the Medicines Act 1968(**1**) and now vested in them(**2**), and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by the following Order in accordance with section 129(6) of that Act, hereby make the following Order:

Title and commencement

1. This Order may be cited as the Medicines (Exemptions from Licences and Animal Test Certificates) (Amendment) Order 1991 and shall come into force on 3rd April 1991.

Amendments

2. The Medicines (Exemptions from Licences and Animal Test Certificates) Order 1986(**3**) shall be amended in accordance with the following provisions.

3. In article 2 (Interpretation) at the end of paragraph (1)(a) there shall be added the following definition—

> "'withdrawal period' means the period from cessation of medication of an animal with a veterinary drug or immunological veterinary drug to slaughter of that animal for

(**1**) 1968 c. 67; "the appropriate Minisiers" referred to in sections 15 and 35 is defined in section 1 (see also the following footnote).
(**2**) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of S.I.1969/388, in the case of the Secretary of State concerned with agriculture in Wales by virtue of S.I. 1978/272 and in the case of the Northern Ireland Departments by virtue of the Northern Ireland Constitution Act 1973 (c. 36), section 40 and Schedule 5, and the Northern Ireland Act 1974 (c. 28), section 1(3) and Schedule 1, paragraph 2(1)(b).
(**3**) S.I. 1986/1180.

human consumption or to the taking of products derived from such an animal for human consumption.".

4. In article 4(1) (conditions) for sub-paragraph (b) there shall be substituted the following sub-paragraph—

"(b) the licensing authority have issued to the supplier, before the end of the specified period, an animal test (confirmation of exemption) certificate; and".

5. For article 5 (application of exemption) there shall be substituted the following article—

"**5.** The exemption conferred by article 3(a) shall not apply to the sale,supply or importation, or to the procuring of the sale, supply, manufacture or assembly of—

(a) a live immunological veterinary drug, in respect of which a product licence has not been granted; or

(b) a verterinary drug containing an active ingredient being a substance which is not contained in any veterinary drug in respect of which a product licence has been granted (not being a product licence of right) unless the supplier has given to the licensing authority—

(i) a notice stating that the drug is not for use by being administered to animals intended for human consumption or to animals whose produce is intended for human consumption; or

(ii) sufficient toxicological information for the licensing authority to determine whether or not the withdrawal period notified pursuant to paragraph 10 of Schedule 1 is adequate.".

6. For Schedules 1 and 2 to the Order there shall be substituted the two Schedules set out in the Schedule to this Order.

Stephen Dorrell
Parliamentary Under Secretary of State for Health

6th March 1991

Strathclyde
Parliamentary Under Secretary of State, Scottish Office

5th March 1991

David Hunt
Secretary of State for Wales

5th March 1991

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on

L.S.

John Selwyn Gummer
Minister of Agriculture, Fisheries and Food

7th March 1991.

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland this

L.S.

F. A. Elliott
7th day of March 1991. Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this

L.S.

W. J. Hodges
8th day of March 1991. Permanent Secretary

SCHEDULE Article 6

"SCHEDULE 1 Article 4(1)(a)

Particulars and summaries which are to accompany a notice given under Article 4(1)(a).

1. The name and address of the supplier and any other name under which he carries on business.

(a) The name and address of any person taking part, in the course of a business carried on by him, in the manufacture or assembly of the veterinary drug, and

(b) in the case of an imported veterinary drug, the name and address of the manufacturer or assembler of the veterinary drug in the form in which it is to be imported.

3. The name or proposed name of the veterinary drug or where the veterinary drug has not been given a name, the designation by which the supplier identifies that drug.

4. The chemical structural formula for, or, in respect of immunological veterinary drugs, the designation or description of, each active ingredient. Where an active ingredient is the subject of a monograph, the monograph name may be given instead of the formula.

5. A description of the pharmaceutical form in which the veterinary drug is to be administered.

6. The specification of the veterinary drug including a statement of its qualitative and quantitative composition giving the ingredients whether active or not, and including all colouring matter, flavouring agents and perfumes.

7. In respect of each ingredient, whether active or not—

(a) the approved name or the monograph name, or

(b) where there is no approved name or monograph name, a designation other than a laboratory code by which it can be readily identified.

8. A description of the containers used for the veterinary drugs and a statement of any special directions given by the manufacturer for storage and transport. Details of the shelf-life of the veterinary drug and drafts of the product literature and of the labels intended to be used.

9. The purpose of the test.

10. The address of every site involved in the proposed animal test, a description of the proposed animal test including the names and qualifications of each supervisor, the duration of the test, the number of animals involved, a statement of the criteria to be used in the selection for, or exclusion or withdrawal of animals from, the test, a description of how safely will be monitored during the test and a description of arrangements for the disposal of lest animals which, in the case of animals whose meat or whose produce is intended for human consumption, shall include notification of the withdrawal period to be observed.

11. The proposed dosage and its duration, and the methods and routes of administration, of the veterinary drug.

12. A summary of pharmaceutical data—

(a) for immunological veterinary drugs in respect of which a product licence has been granted—

(i) a brief description of the manufacturing procedure with fuller details of the inactivation and purification procedures;

(ii) full details of all substances of animal origin used at any stage in the manufacturing process together with information on inactivation and purification procedures and quality control tests carried out on such substances;

(iii) a summary of the in-process and final product quality control tests approved by the licensing authority prior to the grant of the product licence and details of any additional tests done for the purpose of acquiring an animal test (confirmation of exemption) certificates;

(iv) safety data for each of the proposed recipient classes and species, including overdosage studies;

(b) for immunological veterinary drugs for which a product licence has not been granted the following is required—

(i) full details of the manufacturing procedures, including information on all starting materials, inactivation and purification procedures and quality control tests and on other associated procedures and tests (if any);

(ii) safety data for each of the proposed recipient classes and species, including overdosage studies;

(iii) samples of the product;

(iv) information showing that the site of manufacture has previously been approved by the licensing authority for manufacture of this type of product;

(c) for other drugs—

(i) the method of synthesis of each active ingredient and where appropriate, the results of physicochemical tests to substantiate the structure of the compound. Where the active ingredient is the subject of a monograph, the monograph name may be given instead of those data;

(ii) the specification of each ingredient whether active or not unless a specification has not been established for an ingredient, in which case a batch characterisation for each batch of that ingredient to be used in the test. Where an ingredient is the subject of a monograph, the monograph name may be given instead of the specification;

(iii) in the case of each ingredient, whether active or not, the quality control procedures and methods to be applied to ensure compliance with the specification;

(iv) the nietbod of manufacture or assembly of the veterinary drug;

(v) the procedures and methods employed and specifications used in the process of manufacture or assembly to ensure the uniformity of each veterinary drug. Evidence of the stability of the veterinary drug and of its availability for the use intended;

(vi) the methods to be employed during manufacture for determining the identity, purity and potency of the veterinary drug and the address of the premises where such procedures are to be carried out.

13. Summaries of reports and evaluations of any experimental, biological, clinical or other studies and of other laboratory studies carried out with each veterinary drug or its ingredients, which in the view of the supplier are relevant to the assessment of the safety, quality or efficacy of the veterinary drug, together with references to relevant publications or other animal tests. Any toxicological information supplied pursuant to article 5(b)(ii) shall contain sufficient information to enable the licensing authority to determine the adequacy of the proposed withdrawal period.

SCHEDULE 2 Article 4(1)(c)(iii)

Matters in respect of which the licensing authority shall forthwith be informed of changes.

1. The name or proposed name of the veterinary drug or of the designation by which the veterinary drug is identified.

(a) The name and address of any person in the United Kingdom taking part, in the course of a business carried on by him, in the manufacture or assembly of the veterinary drug; or

(b) in the case of an imported veterinary drug, the name and address of the manufacturer or assembler of the veterinary drug in the form in which it is imported.

3. The dosage or its duration or the methods or routes of administration, of the veterinary drug.

4. The active or inactive ingredients, or starting materials or the method of manufacture or assembly of the veterinary drug, or immunological veterinary drug, where such change will affect either or both the bioavailability and the shelf-life of that veterinary drug or immunological veterinary drug.

5. The method of synthesis of any active ingredient where such change will affect the range or level of impurities produced.

6. The criteria used in connection with the animal test in respect of the selection for, or exclusion or withdrawal of animals from, the test.

7. The supervisor.

8. The nature and purpose of the test.

9. The address of any site or of the number of animals involved in the animal test.”

EXPLANATORY NOTE

(This note is not part of the Order)

This Order amends the Medicines (Exemptions from Licences and Animal Test Certificates) Order 1986 as follows—

(1) applicants for an exemption to carry out medicinal tests on animals were formerly notified by the licensing authority within 35 days that it was acceptable to carry out the tests; now applicants must apply for an animal lest (confirmation of exemption) certificate which will be issued by the licensing authority within the 35 days or such further period as the licensing authority determines (article 4);

(2) the exemption from the need for a licence did not apply to the sale, supply or importation of an immunological veterinary drug: for that type of drug there has been substituted an unlicensed live immunological drug. The request for an exemption from the need for a licence for a veterinary drug containing an active ingredient being a substance which is not contained in any licensed veterinary drug must now be accompanied by sufficient toxicological information for the licensing authority to be able to assess the adequacy of the proposed withdrawal period (article 5);

(3) an applicant for an animal test (confirmation of exemption) certificate has to provide the licensing authority with specified items of information. The information required includes: in respect of immunological veterinary drugs, the designation or description of each active ingredient and specified detailed information according to whether it is or is not a licensed medicinal product; in respect of all veterinary drugs, details of the shelf-life and a draft of the product literature; the address of all sites of testing, the number of animals involved and notification of the withdrawal period to be observed (article 6).