STATUTORY INSTRUMENTS

1986 No. 1180

MEDICINES

The Medicines (Exemptions from Licences and Animal Test Certificates) Order 1986

Made - - - -	*8th July* 1986
Laid before Parliament	*11th July* 1986
Coming into Operation	*1st August* 1986

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 powers conferred by sections 15(1) and (2) and 35(8)*(b)* and (9) of the Medicines Act 1968(**a**) and now vested in them (**b**) 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 the said 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) Order 1986, and shall come into operation on 1st August 1986.

Interpretation

2.— (1) In this order—

(a) "the Act" means the Medicines Act 1968;

"approved name", means in relation to an ingredient, either the name of the substance or article which appears in the current edition of the list prepared by the appropriate body (in accordance with section 100 of the Act) and published by the Ministers on the recommendation of the Medicines Commission or the international non-proprietary name recommended by the World Health Organisa-

(**a**) 1968 c. 67.

(**b**) In the case of the Secretaries of State concerned with health in England and 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 section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36) and section 1(3) of, and paragraph 2(1)*(b)* of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

tion notice of which has been given by the Director-General of that organisation in the World Health Organisation Chronicle;

"immunological veterinary drug" means a veterinary drug which when administered to an animal produces an immune response;

"monograph" means a monograph in the current edition of—

(i) the European Pharmacopoeia, or

(ii) any compendium, published by the Ministers under section 99 of the Act, of the British Pharmacopoeia, or

(iii) the British Pharmaceutical Codex;

"monograph name" means, in relation to an ingredient, the name which appears at the head of the relevant monograph;

"notice" means a notice in writing;

"supplier" means a person selling, supplying or importing, or procuring the sale, supply, manufacture or assembly of, a veterinary drug for the purpose of a medicinal test on animals;

"veterinary drug" means any medicinal product which is manufactured, sold, supplied, imported or exported for the purpose of being administered to animals, but not for the purpose of being administered to human beings, and includes any substance or article for administration to animals specified in an order made under section 104 or 105(1)*(b)* of the Act which is for the time being in force and which directs that sections 32 and 35(8) and (9) shall have effect in relation to that substance or article; and

(b) a reference to a numbered Article or Schedule is to the Article of, or Schedule to, this order bearing that number and a reference in an Article to a numbered paragraph is to the paragraph of that Article bearing that number.

(2) Section 127 of the Act applies to any notice required or authorised to be given by any provision of this order as it applies to any notice required or authorised to be given by any provision of the Act.

Exemptions from licences and certificates in respect of medicinal tests on animals

3. Subject to the conditions contained in Article 4 and to the provisions of Articles 5 and 6, the restrictions imposed by sections 7 and 32 of the Act (restrictions as to dealings in medicinal products and restrictions on such dealings for medicinal tests on animals) shall not apply—

(a) to the sale, supply or importation, or procuring the sale, supply, manufacture or assembly of a veterinary drug for the purpose of a medicinal test on animals, or

(b) to the administration by a person in the course of a business carried on by him of a veterinary drug to an animal by way of a medicinal test on animals, or the procuring of such a drug to be so administered.

Conditions

4.— (1) The exemption conferred by Article 3*(a)* is subject to the conditions that—

(a) the supplier has given to the licensing authority a notice containing or accompanied by—

(i) the particulars and summaries specified in Schedule 1, and

(ii) a certificate signed by a veterinary surgeon or veterinary practitioner who practices in the United Kingdom stating that he is employed by, or is a consultant to, the supplier and that he has satisfied himself as to the accuracy of the summaries of data specified at paragraphs 12 and 13 of Schedule 1 and that, having regard to the contents of those summaries, he is of the opinion that it is reasonable for the proposed medicinal test on animals to be undertaken;

(b) the licensing authority have not, before the end of the specified period, given to the supplier a notice stating that the exemption shall not apply to the activities proposed to be carried out by him in relation to the veterinary drug; and

(c) the supplier has given an undertaking to the licensing authority that he will inform them immediately of—

(i) any adverse reactions or effects associated with the administration of the veterinary drug,

(ii) any other matter coming to his attention which might reasonably cause the licensing authority to think that the veterinary drug could no longer be regarded as a drug which could safely be administered for the purposes of the medicinal test on animals or as a drug which was of satisfactory quality for those purposes,

(iii) any change in respect of any of the matters specified in Schedule 2, and

(iv) the discontinuation of the test and the reasons for such discontinuation.

(2) The exemption conferred by Article 3*(b)* is subject to the following conditions—

(a) where a veterinary drug is administered to an animal by way of a medicinal test on animals or is procured to be so administered by the supplier of such veterinary drug then the conditions in paragraph (1) must have first been fulfilled;

(b) where a veterinary drug is administered to an animal by way of a medicinal test on animals or is procured to be so administered by a person other than the supplier of such veterinary drug such person shall have believed and shall have had reasonable grounds for believing—

(i) that the conditions in paragraph (1) had first been fulfilled, and

(ii) that the exemption conferred by Article 3*(a)* has not expired or been terminated pursuant to Article 6; and

(c) the administration of a veterinary drug shall be in accordance with the medicinal test described by the supplier pursuant to paragraph 1*(a)*(i).

(3) In paragraph (1)*(b)* and Article 6(1), "the specified period" means the period of 35 days from the date on which the licensing authority has sent an acknowledgement in writing to the supplier that they have received the notice referred to in paragraph (1)*(a)*, except that that period may be extended by the licensing authority by such further period, not exceeding 28 days, as they may determine, by a notice given to the supplier within the said period of 35 days stating the duration of the extension.

Application of exemption

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) an immunological veterinary drug; or

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

Application, expiry and termination of exemptions

6.— (1) Subject to the conditions specified in Article 4 the exemption conferred by Article 3*(a)* shall apply in relation to a veterinary drug on the expiry of the specified period and, unless previously terminated under paragraph (2), shall expire at the end of two years from that date.

(2) The licensing authority may, by notice given to the supplier, terminate with effect from a date specified in the notice the exemptions conferred by Article 3 in relation to any description of veterinary drug if it appears to them that—

(a) veterinary drugs of that description can no longer be regarded as drugs which can safely be administered for the purposes of the medicinal test on animals in question or as drugs which are of satisfactory quality for those purposes;

(b) the specification or standards to which veterinary drugs of that description are manufactured can no longer be regarded as satisfactory;

(c) any changes which have been notified in respect of matters specified in Schedule 2 may adversely affect—

(i) the safety of an animal in the medicinal test on animals;

(ii) the safety of a consumer of an animal described in sub-paragraph (i) or of the produce of such an animal;

(iii) the safety of a person administering the veterinary drug to an animal described in sub-paragraph (i); or

(iv) the safety of the community;

(d) any of the matters stated in the notice referred to in Article 4(1)*(a)* or

the documents which accompanied it was false or incomplete in a material particular; or

(e) the supplier is in breach of any part of the undertaking referred to in Article 4(1)*(c)*.

Norman Fowler,
Secretary of State for Social Services.

23rd June 1986.

Gray of Contin,
Minister of State, Scottish Office.

27th June 1986.

Nicholas Edwards,
Secretary of State for Wales.

23rd June 1986.

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 25th June 1986.

L.S.

Michael Jopling,
Minister of Agriculture, Fisheries and Food.

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland this 8th day of July 1986.

L.S.

Miss Z. I. Davies,
Under Secretary.

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 8th day of July 1986.

L.S.

W. H. Jack,
Permanent Secretary.

Article 4(1)(*a*) SCHEDULE 1

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.

2. *(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 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 drug and a statement of any special directions given by the manufacturer for storage and transport.

9. The purpose of the test.

10. 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 safety will be monitored during the test and a description of arrangements for the disposal of test animals.

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

12. A summary of pharmaceutical data in respect of:—

(a) the method of synthesis of each active ingredient and where appropriate, the results of physico-chemical 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;

(b) 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;

(c) 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;

(d) the method of manufacture or assembly of the veterinary drug;

(e) 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 bioavailability for the use intended;

(f) 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.

Article 4(1)(*c*)(iii)

SCHEDULE 2

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.

2. *(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 the method of manufacture or assembly of the veterinary drug where such change will affect either or both the bioavailability and the shelf life of that 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.

EXPLANATORY NOTE

(This Note is not part of the Order.)

This Order grants exemptions from the restrictions imposed by sections 7 and 32 of the Medicines Act 1968 on certain dealings (such as sale, supply and administration) in veterinary drugs without a product licence or an animal test certificate (Articles 3 and 5).

The exemptions, which apply where dealings in certain veterinary drugs are for the purpose of a medicinal test on animals, are subject to conditions specified in the Order. One such condition is that there shall be submitted to the licensing authority particulars relating to the medicinal test on animals including summaries of pharmaceutical data and of reports made and tests performed in relation to the veterinary drugs to be used in that test (Article 4).

Article 6 of the Order provides for the application, expiry and termination of the exemptions.

SI 1986/1180
ISBN 0-11-067180-5