Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products

Official Journal L 317, 06/11/1981 pp.0001 - 0015

THE COUNCIL OF THE EUROPEAN COMMUNITIES,
Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,
Having regard to the proposal from the Commission (1) ,
Having regard to the opinion of the European Parliament (2) ,
Having regard to the opinion of the Economic and Social Committee (3) ,
Whereas the primary purpose of any rules for the production and distribution of veterinary medicinal products must be the safeguarding of public health;
Whereas, however, this objective must be achieved by means which will not hinder the development of industry and trade in medicinal products within the Community;
Whereas, in so far as the Member States already have certain provisions laid down by law, regulation or administrative action governing veterinary medicinal products, such provisions differ in essential principles ; whereas this results in the hindering of trade in medicinal products within the Community, thereby directly affecting the establishment and functioning of the common market;
Whereas such hindrances must, accordingly, be removed ; whereas this entails approximation of the relevant provisions;
Whereas the provisions of this Directive which concern veterinary medicinal products are, although appropriate, not adequate for veterinary medicinal products used to confer active immunity, to diagnose the state of immunity and to confer passive immunity or for medicinal products based on radioactive isotopes ; whereas it is therefore advisable not to prescribe their application to such products for the present;
Whereas medicated feedingstuffs do not come within the scope of this Directive ; whereas, however, it is necessary, for both public health and economic reasons, to prohibit the use of unauthorized medicinal products in the manufacture of medicated feedingstuffs;
Whereas marketing authorization shall be refused where a medicinal product lacks therapeutic effect or where there is insufficient proof of such effect ; whereas the concept of therapeutic effect must be understood as being the effect promised by the manufacturers;
Whereas such authorization shall also be refused where the withdrawal period indicated is not long enough to eliminate health hazards arising from residues;
Whereas, in order gradually to achieve freedom of movement of veterinary medicinal products, the granting of marketing authorizations in several Member States for the same medicinal product should be made easier;
Whereas, for this purpose, a Committee for Veterinary Medicinal Products, composed of representatives of the Member States and of the Commission, should be set up and should be responsible for giving an opinion on whether a particular veterinary medicinal product complies with the requirements set out in this Directive;
Whereas this Directive is only one stage in the achievement of the aim of freedom of movement of veterinary medicinal products ; whereas, for this purpose, new measures will prove necessary, in the light of experience gained - especially within the said Committee - for the removal of the remaining barriers to freedom of movement;
Whereas, in order to facilitate the movement of veterinary medicinal products and to prevent the checks carried out in one Member State from being repeated in another, minimum requirements for manufacture and imports from third countries and the grant of authorization relating thereto, should be applied to veterinary medicinal products, as specified in Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or

administrative action relating to proprietary medicinal products (1) ,
HAS ADOPTED THIS DIRECTIVE:

CHAPTER I Definitions and scope
Article 1
1. The definitions laid down in Article 1 of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (2) shall apply to this Directive.
2. For the purposes of this Directive, the following definitions shall apply: - " veterinary medicinal product" shall mean any medicinal product intended for animals,
- " ready-made veterinary medicinal product" shall mean any veterinary medicinal product prepared in advance which does not comply with the definition of proprietary medicinal products and which is marketed in a pharmaceutical form which may be used without further processing,
- " pre-mix for medicated feedingstuffs" shall mean any veterinary medicinal product prepared in advance with a view to the subsequent manufacture of medicated feedingstuffs,
- " medicated feedingstuffs" shall mean any mixture of a veterinary medicinal product or products and feed or feeds which is ready prepared for marketing and intended to be fed to animals without further processing, because of its curative or preventive properties or other properties as a medicinal product covered by Article 1 (2) of Directive 65/65/EEC.

3. Until Community rules are adopted for medicated feedingstuffs, Member States may lay down that this term shall include semi-finished products which are manufactured from a pre-mix for medicated feedingstuffs for which an authorization pursuant to Article 4 of this Directive has been issued and feedingstuffs, where such semi-finished products are intended to be processed by further mixing with feedingstuffs to become medicated feedingstuffs ready for use. Member States shall ensure that such semi-finished products are subject to the control of the competent authorities and that they are used exclusively for the manufacture of medicated feedingstuffs under the conditions which governed the marketing authorization for the pre-mix for medicated feedingstuffs.
4. Additives covered by Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (3) , as subsequently amended, where they are incorporated in animal feedingstuffs and supplementary animal feedingstuffs in accordance with that Directive, shall not be considered as veterinary medicinal products for the purposes of this Directive.
5. Member States shall take any necessary steps to ensure that antibiotics and hormone substances which may be used for the preparation of veterinary medicinal products are made available to p. 1. natural or legal persons duly authorized to be in possession of them under national laws.

Article 2
1. The provisions of this Directive shall apply to veterinary medicinal products offered for sale inter alia in the form of proprietary medicinal products, ready-made veterinary medicinal products or premixes for medicated feedingstuffs.
2. The provisions of this Directive shall not apply to: - medicated feedingstuffs,
- veterinary medicinal products used in order to produce active immunity, diagnose the state of immunity and produce passive immunity,
- veterinary medicinal products based on radioactive isotopes,
- veterinary medicinal products not prepared in advance and intended for one particular animal or a small number of animals,
- homeopathic medicinal products.

3. However, medicated feedingstuffs may be prepared only from pre-mixes which have been

authorized under this Directive. Within two years of the notification of this Directive, the Council shall, on the basis of a Commission report accompanied if necessary by appropriate proposals, deliberate on a list of pharmacological molecules which may be used for preparing pre-mixes and on the procedure for drawing up this list.

Article 3
Member States may permit exemptions from the provisions of Article 4 (1) on their territory in respect of veterinary medicinal products intended solely for aquarium fish, cage birds, homing pigeons, terrarium animals and small rodents, provided that such products do not contain substances the use of which requires veterinary control and that all possible measures have been taken to prevent unauthorized use of the products for other animals.

CHAPTER II Application for marketing authorization for veterinary medicinal products
Article 4
1. No veterinary medicinal product may be marketed in a Member State unless authorization has previously been issued by the competent authority in that Member State.
2. No veterinary medicinal product may be administered to animals unless the authorization referred to above has been issued, except for tests of veterinary medicinal products referred to in point 10 of Article 5.

Article 5
For the purpose of obtaining the marketing authorization provided for in Article 4, the person responsible for marketing shall lodge an application with the competent authority of the Member State.
The following particulars and documents shall be appended to the application: 1. name or corporate name and permanent address or registered place of business of the person responsible for marketing and of the manufacturer, if different;
2. name of the veterinary medicinal product (brand name, non-proprietary name, with or without a trade-mark or name of the manufacturer ; scientific name of formula, with or without a trade-mark or name of the manufacturer) ;
3. qualitative and quantitative particulars of all the constituents of the veterinary medicinal product, using the usual terminology but not empirical chemical formulae and giving the international non-proprietary name recommended by the World Health Organization, if such a name exists;
4. brief description of the method of preparation;
5. therapeutic indications, contra-indications and side-effects;
6. dosage for the various species of animal for which the veterinary medicinal product is intended, its pharmaceutical form, method and route of administration and proposed shelf life if less than three years;
7. reasons for the precautionary and safety measures to be taken when using the veterinary medicinal product, if applicable;
8. indication of the withdrawal period necessary between the last administration of the veterinary medicinal product to animals under normal conditions of use and the production of foodstuffs from such animals in order to ensure that such foodstuffs do not contain any residues which might constitute a health hazard to the consumer;
9. description of the control testing methods employed by the manufacturer (qualitative and quantitative analysis of the constituents and the finished product, specific tests, e.g. sterility tests, tests for the presence of pyrogens, for the presence of heavy metals, stability tests, biological and toxicity tests, tests on intermediate products) ;
10. results of: - physico-chemical, biological or microbiological tests,
- toxicological and pharmacological tests,

- clinical trials.

The results of the toxicological and pharmacological tests must relate more particularly to the metabolism of the active ingredients in the animal and as far as possible to the mode and duration of their elimination, if such data are important for the purpose of checking the indicated withdrawal period.
However, (a) a copy of the published references relating to the toxicological and pharmacological tests and clinical trials and the data concerning the withdrawal period may be substituted for the relevant test results in the case of: (i) a veterinary medicinal product with an established use, which has been adequately tested on animals so that its effects, including side-effects, are already known and are included in the published references;
(ii) a new veterinary medicinal product, in which the active ingredients are identical to those of a known medicinal product with an established use;
(iii) a new veterinary medicinal product containing only known constituents that have already been used together in comparable proportions in adequately tested medicinal products with an established use;
(b) in the case of a new veterinary medicinal product containing known constituents not hitherto used together for therapeutic purposes, references to published data may be substituted for the tests on such constituents;
11. one or more specimens or mock-ups of the sales presentation of the veterinary medicinal product together with a package insert where a package insert is required;
12. a document showing that the manufacturer is authorized in his own country to produce veterinary medicinal products;
13. any marketing authorization for the relevant veterinary medicinal product which may have been obtained in another Member State or in a third country.

Article 6
Member States shall make all necessary arrangements to ensure that the documents and particulars listed in points 8, 9 and 10 of the second paragraph of Article 5 are drafted by experts with the requisite technical or professional qualifications before being submitted to the competent authorities.
These documents and particulars shall be signed by the experts in question.

Article 7
According to their particular qualifications, the role of the experts shall be: 1. to carry out such work as falls within their particular discipline (analysis, pharmacology and similar experimental sciences, clinical trials) and to describe objectively the results obtained in both quantitative and qualitative terms;
2. to describe their findings in accordance with Council Directive 81/852/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicologial and clinical standards and protocols in respect of the testing of veterinary medicinal products (1) , and in particular to state: (a) in the case of analysts, whether the product conforms with the stated composition, providing any reasons for the control testing methods which the manufacturer is to use;
(b) in the case of pharmacologists and appropriately qualified specialists: - the toxicity of the product and the pharmacological properties observed,
- whether, after administration of the veterinary medicinal product under normal conditions of use and observance of the recommended withdrawal period, foodstuffs obtained from the treated animals contain residues which might constitute a health hazard to the consumer;

(c) in the case of clinicians, whether they have found in animals treated with the product effects

corresponding to the information furnished by the manufacturer pursuant to Article 5, whether the product is well tolerated, what dosage they recommend and what are the contra-indications and side-effects, if any;

3. to give reasons for the use of the references to published data referred to in point 10 (a) and (b) of the second paragraph of Article 5, according to the conditions laid down by Council Directive 81/852/EEC.

The experts' detailed reports shall form part of the documentation which the applicant shall lodge with the competent authorities.

CHAPTER III Examination of applications for authorization - Authorization - Renewal of authorization

Article 8

Member States shall take all appropriate measures to ensure that the procedure for granting marketing authorization is completed within 120 days after the date of submission of the application.

In exceptional cases this time limit may be extended for a further 90 days. The applicant shall be notified of such extension before the expiry of the initial time limit.

Article 9

In order to examine the application submitted pursuant to Article 4, the competent authorities of the Member States: 1. shall check that the documentation submitted in support of the application complies with Article 5 and, on the basis of the reports drawn up by the experts pursuant to Article 7, ascertain whether the conditions for the issue of the marketing authorization have been fulfilled;

2. may submit the medicinal product for testing by a State laboratory or a laboratory designated for this purpose, in order to ensure that the control testing methods employed by the manufacturer and described in the application documents, in accordance with point 9 of the second paragraph of Article 5, are satisfactory;

3. may, where appropriate, require the applicant to provide further information as regards the items listed in Article 5. Where the competent authorities take this course of action, the time limits specified in Article 8 shall be suspended until the further data required have been provided. Similarly, these time limits shall be suspended for any period which the applicant may be given to provide oral or written explanations.

Article 10

Member States shall take all appropriate measures to ensure that: 1. the competent authorities ascertain that the manufacturers and importers of veterinary medicinal products from third countries are able to manufacture them in compliance with the details supplied pursuant to point 4 of the second paragraph of Article 5 and/or to carry out control tests in accordance with the methods described in the application documents under point 9 of the second paragraph of Article 5;

2. the competent authorities may authorize manufacturers and importers of veterinary medicinal products from third countries, where (1) See page 16 of this Official Journal. circumstances so justify, to have certain stages of manufacture and/or certain of the control tests referred to in paragraph 1 carried out by third parties ; in such cases checks by the competent authorities shall also be carried out in the establishments concerned.

Article 11

The authorization provided for in Article 4 shall be withheld if examination of the documents and particulars listed in Article 5 establishes that: 1. the veterinary medical product is harmful under the conditions of use stated at the time of application for authorization, has no therapeutic effect or the applicant has not provided sufficient proof of such effect as regards the species of animal which is to be treated, or its qualitative or quantitative composition is not as stated;
2. the withdrawal period recommended by the applicant is not long enough to ensure that foodstuffs obtained from the treated animal do not contain residues which might constitute a health hazard to the consumer, or is insufficiently substantiated;
3. the veterinary medicinal product is offered for sale for a use prohibited under other Community provisions. However, pending Community rules, the competent authorities may refuse to grant authorization for a veterinary medicinal product where such action is necessary for the protection of public health, consumer or animal health.

Authorization shall also be withheld if the application documents submitted to the competent authorities do not comply with Articles 5, 6 and 7.

Article 12
The authorization provided for in Article 4 may require the person responsible for marketing to indicate on the container and/or the outer wrapping and the package insert, where the latter is required, other particulars essential for safety or health protection, including any special precautions relating to use and any other warnings resulting from the clinical and pharmacological trials prescribed in point 10 of Article 5 or from experience gained during the use of the veterinary medicinal product once it has been marketed.
The authorization may also require the inclusion of a tracer substance in the veterinary medicinal product.

Article 13
The granting of authorization shall not diminish the general legal liability of the manufacturer and, where appropriate, of the person responsible for marketing.

Article 14
The person responsible for marketing shall modify the control test method provided for in point 9 of Article 5 in accordance with technological and scientific progress, if such modification is needed to enable the veterinary medicinal product to be controlled with a greater degree of security.
The person responsible for marketing shall forthwith inform the competent authorities of any new information which might entail amendment of the particulars and documents referred to in Article 5 or further examination and, in particular, of any prohibition or restriction imposed by the competent authorities of the States in which the veterinary medicinal product is marketed.
The person responsible for marketing shall immediately inform the competent authorities, with a view to authorization, of any alteration he proposes to make to the particulars and documents referred to in Article 5.

Article 15
Authorization shall be valid for five years and shall be renewable for five-year periods, on application by the holder at least three months before the date of expiry.

CHAPTER IV Committee for Veterinary Medicinal Products
Article 16
1. In order to facilitate the adoption of a common position by the Member States with regard to

marketing authorizations, a Committee for Veterinary Medicinal Products, hereinafter called " the Committee" , is hereby set up ; it shall be composed of representatives of the Member States and of the Commission.
2. The Committee shall, when so requested by a Member State, examine questions relating to the implementation of Articles 11, 36 and 49, in accordance with Articles 17 to 22.
3. The Committee shall draw up its own rules of procedure.

Article 17
1. A Member State which has issued a marketing authorization shall forward a copy of the application and of the authorization, together with the particulars and documents mentioned in Article 5, to the Committee and to the competent authorities of the Member States specified, if the person responsible for marketing has requested that they be forwarded to at least five other Member States.
2. Such forwarding shall be deemed equivalent to the lodging, within the meaning of Article 5, of an application for marketing authorization with the said authorities.
3. The Committee shall forthwith inform the Member States concerned that the case has been referred to the Committee.

Article 18
1. If, within a period of 120 days after the date of forwarding of the information referred to in Article 17 (2) , no objection has been notified to the Committee by the competent authorities of the Member States specified, the Committee shall formally record the fact and forthwith inform the Member States concerned.
2. Where a Member State considers that it is unable to grant marketing authorization, it shall forward its reasoned objection based on Article 11 within the said period of 120 days.

Article 19
1. In the cases referred to in Article 18 (2) , the Committee shall consider the matter and shall deliver its reasoned opinion within 60 days from the expiry of the time limit laid down in Article 18.
2. The opinion of the Committee shall deal with the compliance of the veterinary medicinal product with the conditions set out in Article 11.
The Committee shall forthwith inform the Member States concerned of its opinion or, in the event of dissension, of the opinions of its members.
3. The Member States concerned shall reach a decision on the application for marketing authorization not later than 30 days after the date on which the information provided for in Article 18 (1) or paragraph 2 hereof is given. They shall forthwith inform the Committee of their decision.

Article 20
1. If several applications have been submitted in accordance with Article 5 for marketing authorization for the same veterinary medicinal product and one or more Member States have granted such authorization while one or more of the other Member States have withheld it, one of the Member States concerned may bring the matter before the Committee.
The same shall apply where one or more Member States have suspended or withdrawn marketing authorization while one or more of the other Member States have not done so.
2. The Committee shall consider the matter and shall deliver its reasoned opinion within 120 days at the latest.
3. The opinion of the Committee shall deal only with the grounds on which authorization was refused, suspended or withdrawn.
The Committee shall forthwith inform the Member States concerned of its opinion or, in the

event of dissension, of the opinions of its members.
4. The Member States concerned shall give notice, within 30 days, of the action they intend to take following the Committee' s opinion.

Article 21
The Committee may set itself a time limit for a fresh examination on the basis of particulars relating to the conditions laid down in Articles 11, 27 or 41 obtained in the meantime by Member States, and in particular by those which have authorized the veterinary medicinal product.

Article 22
The competent authorities of Member States may, in specific cases where the interests of the Community are involved, refer the matter to the Committee before reaching a decision on an application for marketing authorization, its suspension or withdrawal.
A Member State also may refer matters to the Committee when there are grounds for believing that a medicinal product should not be authorized for use in veterinary medicine because of its importance in human therapy.

Article 23
1. The Commission shall report to the Council annually on the operation of the procedure laid down in this Chapter and its effects on the development of intra-Community trade ; it shall make its first report two years after the entry into force of this Directive.
2. In the light of experience the Commission shall, not later than four years after the entry into force of this Directive, submit to the Council a proposal containing all appropriate measures for the abolition of any remaining barriers to the free movement of veterinary medicinal products. The Council shall take a decision on the Commission proposal not later than one year after its submission.

CHAPTER V Manufacture of veterinary medicinal products - Imports from third countries
Article 24
1. Member States shall take all appropriate measures to ensure that the manufacture of veterinary medicinal products is subject to the holding of an authorization.
2. The authorization referred to in paragraph 1 shall be required both for total and partial manufacture and for the various processes of dividing up, packaging or presentation. However, such authorization shall not be required for preparation, dividing up, changes in packaging or presentation where these processes are carried out solely for retail supply by pharmacists in dispensing pharmacies or by persons legally authorized in the Member States to carry out such processes.
3. The authorization referred to in paragraph 1 shall also be required for imports from third countries into a Member State ; this Chapter and Article 36 shall apply to such imports in the same way as to manufacture.

Article 25
In order to obtain the authorization referred to in Article 24, the applicant shall meet at least the following requirements: (a) he shall specify the veterinary medicinal products and pharmaceutical forms which are to be manufactured or imported and also the place where they are to be manufactured and/or controlled;
(b) he shall have at his disposal, for the manufacture or import of the above, suitable and sufficient premises, technical equipment and control facilities complying with the legal requirements which the Member State concerned lays down as regards both manufacture and control and the storage of products, in accordance with Article 10 (1) ;
(c) he shall have at his disposal the services of at least one qualified person within the meaning

of Article 29.

The applicant shall provide particulars in his application to establish his compliance with the above requirements.

Article 26
1. The competent authority of the Member State shall not issue the authorization referred to in Article 24 until it has established the accuracy of the particulars supplied pursuant to Article 25 by means of an inquiry carried out by its representatives.
2. In order to ensure that the requirements referred to in Article 25 are complied with, authorization may be made conditional on the fulfilment of certain obligations imposed either when authorization is granted or at a later date.
3. The authorization shall apply only to the premises specified in the application and to the veterinary medicinal products and pharmaceutical forms specified in that application.

Article 27
The holder of an authorization referred to in Article 24 shall at least be obliged to: (a) have at his disposal the services of staff complying with the legal requirements existing in the Member State concerned as regards both manufacture and controls;
(b) dispose of the authorized veterinary medicinal products only in accordance with the legislation of the Member States concerned;
(c) give prior notice to the competent authority of any changes which he may wish to make to any of the particulars supplied pursuant to Article 25 ; the competent authority shall, in any event, be immediately informed if the qualified person referred to in Article 29 is replaced unexpectedly;
(d) allow the representatives of the competent authority of the Member State concerned access to his premises at any time;
(e) enable the qualified person referred to in Article 29 to carry out his duties, particularly by placing at his disposal all the necessary facilities.

Article 28
1. The Member States shall take all appropriate measures to ensure that the time taken for the procedure for granting the authorization referred to in Article 24 does not exceed 90 days from the day on which the competent authority receives the application.
2. If the holder of the authorization requests a change in any of the particulars referred to in Article 25 (a) and (b) , the time taken for the procedure relating to this request shall not exceed 30 days. In exceptional cases, this period of time may be extended to 90 days.
3. Member States may require from the applicant further information concerning both the particulars supplied pursuant to Article 25 and the qualified person referred to in Article 29 ; where the competent authority concerned exercises this right, application of the time limits referred to in paragraphs 1 and 2 shall be suspended until the additional data required have been supplied.

Article 29
1. Member States shall take all appropriate measures to ensure that the holder of the authorization referred to in Article 24 has permanently and continuously at his disposal the services of at least one qualified person who fulfils the conditions laid down in Article 31 and is responsible, in particular, for carrying out the duties specified in Article 30.
2. If he personally fulfils the conditions laid down in Article 31, the holder of the authorization may himself assume the responsibility referred to in paragraph 1.

Article 30
1. Member States shall take all appropriate measures to ensure that the qualified person referred to in Article 29 is, without prejudice to his relationship with the holder of the authorization referred to in Article 24, responsible, in the context of the procedures referred to in Article 33, for ensuring that: (a) in the case of veterinary medicinal products manufactured within the Member State concerned, each batch of veterinary medicinal products has been manufactured and checked in compliance with the laws in force in that Member State and in accordance with the requirements of the marketing authorization;
(b) in the case of veterinary medicinal products coming from third countries, each production batch imported has undergone in the importing country a full qualitative analysis, a quantitative analysis of at least all the active ingredients and all the other tests or checks necessary to ensure the quality of veterinary medicinal products in accordance with the requirements of the marketing authorization.

Batches of veterinary medicinal products which have undergone such controls in a Member State shall be exempt from the above controls if they are imported into another Member State, accompanied by the control reports signed by the qualified person.
A Member State may relieve the qualified person of responsibility for the controls prescribed under (b) for imported veterinary medicinal products which are to remain in that Member State, if appropriate arrangements have been made with the exporting country to ensure that these controls have been carried out in the exporting country. Where these products are imported in the packaging in which they are to be sold by retail, Member States may allow exceptions to the requirements laid down in Article 25.
2. In all cases, and particularly where the veterinary medicinal products are released for sale, the qualified person shall certify, in a register or equivalent document provided for the purpose, that each production batch satisfies the provisions of this Article ; the said register or equivalent document shall be kept up to date as operations are carried out and shall remain at the disposal of the representatives of the competent authority for the period specified in the provisions of the Member State concerned and, in any event, for at least five years.

Article 31
Member States shall ensure that the qualified person referred to in Article 29 fulfils the following minimum conditions of qualification. (a) Possession of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course of study, or a course recognized as equivalent by the Member State concerned, extending over a period of at least four years of theoretical and practical study in one of the following scientific disciplines : pharmacy, medicine, veterinary science, chemistry, pharmaceutical chemistry and technology, biology.
However: - the minimum duration of the university course may be three and a half years where the course is followed by a period of theoretical and practical training of at least one year and includes a training period of at least six months in a pharmacy open to the public, corroborated by an examination at university level,
- where two university or recognized equivalent courses co-exist in a Member State and where one of these extends over four years and the other over three years, the diploma, certificate or other evidence of formal qualifications awarded on completion of the three-year university course or its recognized equivalent shall be considered to fulfil the condition of duration referred to in (a) in so far as the diplomas, certificates or other evidence of formal qualifications awarded on completion of both courses are recognized as equivalent by the State in question.

The course shall include theoretical and practical tuition bearing upon at least the following basic subjects: - experimental physics,
- general and inorganic chemistry,
- organic chemistry,
- analytical chemistry,
- pharmaceutical chemistry, including analysis of medicinal products,
- general and applied biochemistry (medical) ,
- physiology,
- microbiology,
- pharmacology,
- pharmaceutical technology,
- toxicology,
- pharmacognosy (study of the composition and effects of the active principles of natural substances of plant and animal origin) .

Tuition in these subjects should be so balanced as to enable the person concerned to fulfil the obligations specified in Article 30.
In so far as certain diplomas, certificates or other evidence of formal qualifications mentioned in (a) do not fulfil the criteria laid down above, the competent authority of the Member State shall ensure that the person concerned provides evidence that he has, in the subjects involved, the knowledge required for the manufacture and control of veterinary medicinal products.
(b) Practical experience for at least two years, in one or more undertakings which are authorized manufacturers, in the activities of qualitative analysis of medicinal products, of quantitative analysis of active principles and of the testing and checking necessary to ensure the quality of veterinary medicinal products.
The duration of practical experience may be reduced by one year where a university course lasts for at least five years and by a year and a half where the course lasts for at least six years.

Article 32
1. A person engaging in the activities of the person referred to in Article 29 in a Member State at the time when this Directive is brought into force in that State but not complying with the provisions of Article 31 shall be eligible to continue to engage in those activities in the State concerned.
2. The holder of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course - or a course recognized as equivalent by the Member State concerned - in a scientific discipline allowing him to engage in the activities of the person referred to in Article 29 in accordance with the laws of that State may - if he began his course prior to the notification of this Directive - be considered as qualified to carry out in that State the duties of the person referred to in Article 29, provided that he has previously engaged in the following activities for at least two years before the end of the 10th year following notification of this Directive in one or more undertakings authorized pursuant to Article 24 : production supervision and/or qualitative analysis, quantitative analysis of active principles, and the necessary testing and checking under the direct authority of a person as referred to in Article 29 to ensure the quality of veterinary medicinal products.
If the person concerned has acquired the practical experience referred to in the first subparagraph more than 10 years prior to the notification of this Directive, a further one year' s practical experience in accordance with the conditions referred to in the first subparagraph shall be completed by him immediately before he engages in such activities.
3. A person who, at the time this Directive is brought into force, is engaged in direct collaboration with a person referred to in Article 29 in production supervision activities and/or in

qualitative analysis, quantitative analysis of active principles, and the testing and checking necessary to ensure the quality of medicinal products may, for a period of five years thereafter, be considered as qualified to take up in that State the duties of the person referred to in Article 29, provided that the Member State ensures that the person shows evidence of adequate theoretical and practical knowledge and has engaged in the activities mentioned for at least five years.

Article 33
Member States shall ensure that the obligations of qualified persons referred to in Article 29 are fulfilled, either by means of appropriate administrative measures or by making such persons subject to a professional code of conduct.
Member States may provide for the temporary suspension of such a person upon the commencement of administrative or disciplinary proceedings against him for failure to fulfil his obligations.

CHAPTER VI Supervision and sanctions
Article 34
The competent authority of the Member State concerned shall ensure, by means of inspection, that the legal requirements relating to veterinary medicinal products are complied with.
Such inspections shall be carried out by authorized representatives of the competent authority who shall be empowered to: 1. inspect manufacturing or trading establishments and any laboratories entrusted by the holder of the authorization referred to in Article 24 (1) , with the task of carrying out control tests pursuant to Article 10 point 2;
2. take samples;
3. examine any documents relating to the object of the inspection, subject to current provisions in the Member States at the time of notification of this Directive which place restrictions on these powers with regard to the description of the method of preparation.

Article 35
Member States shall take all appropriate measures to ensure that the person responsible for marketing and, where appropriate, the holder of the authorization referred to in Article 24 (1) furnish proof of the control tests carried out on the finished product and/or on the constituents and intermediate products of the manufacturing process, in accordance with the methods laid down for the purposes of marketing authorization.

Article 36
The competent authorities of the Member States shall suspend or withdraw marketing authorization when it is clear that: 1. the veterinary medicinal product proves to be harmful under the conditions of use stated at the time of application for authorization or subsequently, the veterinary medicinal product does not have any therapeutic effect or its qualitative and quantitative composition is not as stated;
2. the recommended withdrawal period is inadequate to ensure that foodstuffs obtained from the treated animal do not contain residues which might constitute a health hazard to the consumer;
3. the veterinary medicinal product is offered for sale for a use which is prohibited by other Community provisions. However, pending Community rules, the competent authorities may refuse to grant authorization for a veterinary medicinal product where such action is necessary for the protection of public, consumer or animal health;
4. the information given in the application documents pursuant to Articles 5 and 14 is incorrect;
5. the control tests referred to in Article 35 have not been carried out;

6. the obligation referred to in the second paragraph of Article 12 has not been fulfilled.

The veterinary medicinal product shall be deemed to have no therapeutic effect if it is established that it does not produce therapeutic results in the species of animal for which the treatment is intended.
Authorization may also be suspended, or withdrawn where it is established that: - the particulars supporting the application, as provided for in Article 5, have not been amended in accordance with the first and third paragraphs of Article 14,
- any new information as referred to in the second paragraph of Article 14 has not been communicated to the competent authorities.

Article 37
1. Without prejudice to Article 36, Member States shall take all necessary measures to ensure that supply of a veterinary medicinal product is prohibited and that the medicinal product concerned is withdrawn from the market where: (a) it is clear that the veterinary medicinal product is harmful under the conditions of use stated at the time of the application for authorization or subsequently, pursuant to the third paragraph of Article 14;
(b) the veterinary medicinal product has no therapeutic effect on the species of animal for which the treatment was intended;
(c) the qualitative and quantitative composition of the veterinary medicinal product is not as stated;
(d) the recommended withdrawal period is inadequate to ensure that foodstuffs obtained from the treated animal do not contain residues which might constitute a health hazard to the consumer;
(e) the control tests referred to in Article 35 have not been carried out, or any other requirement or obligation relating to the grant of the authorization referred to in Article 24 (1) has not been complied with.

2. The competent authority may confine the prohibition on supply and withdrawal from the market solely to the contested production batches.

Article 38
1. The competent authority of a Member State shall suspend or withdraw the authorization referred to in Article 24 for a category of preparations or for all preparations if any of the requirements laid down for obtaining this authorization is no longer met.
2. The competent authority of a Member State may, in addition to the measures provided for in Article 37, either suspend manufacture or imports of veterinary medicinal products from third countries or suspend or withdraw the authorization referred to in Article 24 for a category of preparations or for all preparations in the event of non-compliance with the provisions regarding manufacture or imports from third countries.

Article 39
Member States shall take all appropriate measures to ensure that the competent authorities concerned communicate to each other such information as is appropriate to secure compliance with the requirements for the authorization referred to in Article 24 (1) or for marketing authorization.

Article 40

All decisions taken pursuant to Articles 11, 36, 37 and 38, all negative decisions taken pursuant to Article 10 point 2 and Article 19 (3) of this Directive and all decisions to withhold authorization to manufacture or to import from third countries or to suspend or withdraw manufacturing authorization shall state in detail the reasons on which they are based. Such decisions shall be notified to the party concerned who shall at the same time be informed of the remedies available to him under current legislation and the time allowed for seeking such remedies.
Marketing authorizations and revocations of such authorizations shall be published by each Member State in its official gazette.

Article 41
No decision to: - withhold, withdraw or suspend marketing authorization,
- prohibit the supply of a veterinary medicinal product or have it withdrawn from the market,
- withhold, withdraw or suspend authorization to manufacture or to import veterinary medicinal products from third countries,
- suspend manufacture of imports of veterinary medicinal products from third countries

may be taken on grounds other than those set out in this Directive.

Article 42
Each Member State shall take all appropriate measures to ensure that the Committee is informed immediately of decisions granting marketing authorization and of all decisions refusing or withdrawing marketing authorization, cancelling a decision refusing or withdrawing marketing authorization, prohibiting supply or withdrawing a product from the market, together with the reasons on which such decisions are based.

CHAPTER VII Labelling and package inserts of veterinary medicinal products
Article 43
The following information, which shall conform with the particulars and documents provided pursuant to Article 5 and be approved by the competent authorities, shall appear in legible characters on containers and outer packages of medicinal products: 1. name of the veterinary medicinal product, which may be a brand name or a non-prprietary name with or without a trade-mark or name of the manufacturer or a scientific name or formula with or without a trade-mark or name of the manufacturer;
2. next to the name of the veterinary medicinal product, its qualitative and quantitative composition expressed in active ingredients per dose-unit or as a percentage, according to the pharmaceutical form and, in the cases referred to in the second paragraph of Article 12, the tracer substances.
The international non-proprietary names recommended by the World Health Organization shall be used wherever they exist;
3. reference number for production identification (manufacturer' s batch number) ;
4. marketing authorization number;
5. name or corporate name and permanent address or registered place of business of the person responsible for marketing and of the manufacturer, if different;
6. the species of animal for which the veterinary medicinal product is intended ; the method and route of administration;
7. the withdrawal period, even if this is nil, in the case of veterinary medicinal products administered to animals intended for human consumption;
8. the date of expiry, if the shelf life is less than three years;
9. special storage precautions, if any;

10. particulars required to be indicated pursuant to the first paragraph of Article 12, if any;
11. the words " For animal treatment only" .

The pharmaceutical form and the contents by weight, volume or number of dose-units need only be shown on the outer package.
The provisions of Part 1, A of the Annex to Council Directive 81/852/EEC, in so far as they concern the qualitative and quantitative composition of veterinary medicinal products in respect of active ingredients, shall apply to the particulars provided for in point 2.

Article 44
As regards ampoules, the particulars listed in the first paragraph of Article 43 shall be given on the outer package. On the containers, however, only the following particulars shall be necessary:
- name of veterinary medicinal product,
- quantity of the active ingredients,
- route of administration,
- reference number for production identification (manufacturer' s batch number) ,
- date of expiry,
- the words " For animal treatment only" .

Article 45
As regards small single-dose containers, other than ampoules, on which it is impossible to give the particulars mentioned in Article 44, the requirements of Article 43 shall apply only to the outer package.

Article 46
Where there is no outer package, all the particulars which should feature on such package pursuant to the preceding Articles shall be shown on the container.

Article 47
The particulars mentioned in points 6, 7, 8, 9, 10 and 11 of the first paragraph of Article 43 and in the third and sixth indents of Article 44 shall appear on the outer package and on the container of the medicinal products in the language or languages of the country in which they are placed on the market.

Article 48
Member States shall take all appropriate measures to ensure that where a package insert is included with a veterinary medicinal product it relates solely to that product.
The package insert shall contain at least the following information, which shall conform with the particulars and documents provided pursuant to Article 5 and be approved by the competent authorities: (a) name or corporate name and permanent address or registered place of business of the person responsible for marketing and of the manufacturer, if different;
(b) name of the veterinary medicinal product and a statement of its active ingredients expressed qualitatively and quantitatively.
The international non-proprietary names recommended by the World Health Organization shall be used wherever they exist;
(c) the main therapeutic indications, contra-indications and side-effects in so far as these particulars are necessary for the use of the veterinary medicinal product;
(d) the species of animal for which the veterinary medicinal product is intended, the dosage for

each species, the method and route of administration and advice on correct administration, if necessary;
(e) the withdrawal period, even if this is nil, in the case of veterinary medicinal products administered to animals intended for human consumption;
(f) special storage precautions, if any;
(g) particulars required to be indicated pursuant to the first paragraph of Article 12, if any.

Such particulars must appear in the language or languages of the country in which the product is marketed. The other information shall be clearly separate from the abovementioned particulars. Member States may require a package insert to be included with veterinary medicinal products.

Article 49
Where the provisions of this Chapter are not observed and a formal notice addressed to the person concerned has been ineffectual, the competent authorities of the Member States may suspend or withdraw marketing authorization.
All decisions taken by virtue of the preceding paragraph shall state in detail the reasons on which they are based. A decision shall be notified to the party concerned, along with the remedies available to him under current legislation and the time allowed for seeking such remedies.

Article 50
The requirements of Member States concerning conditions of supply to the public, the marking of prices on medicinal products for veterinary use and industrial property rights shall not be affected by the provisions of this Chapter.

CHAPTER VIII Implementing provisions and transitional measures
Article 51
Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive within 24 months of its notification and shall forthwith inform the Commission thereof.
Member States shall ensure that the main provisions of national law which they adopt in the field governed by this Directive are communicated to the Commission.

Article 52
1. As regards the authorizations referred to in Article 24 which are issued before the expiry of the time limit laid down in Article 51, Member States may grant an additional period of one year for the undertakings concerned to comply with the provisions of Chapter V.
2. The other provisions of this Directive shall be applied progressively, within 10 years of the notification referred to in Article 51, to veterinary medicinal products placed on the market by virtue of earlier provisions.
3. Member States shall notify the Commission, within three years following the notification of this Directive, of the number of veterinary medicinal products covered by paragraph 2 and, in each subsequent year, of the number of such products for which the marketing authorization referred to in Article 4 has not yet been issued.

Article 53
This Directive is addressed to the Member States.

Done at Brussels, 28 September 1981.
For the Council
The President