AN ORDINANCE
TO AMEND THE LAW RELATING TO
AGRICULTURAL FERTILIZERS

T.W. RIMMER
ADMINISTRATOR

21st October 2002.

BE it enacted by the Administrator of the Sovereign Base Areas of Akrotiri and Dhekelia as follows:-

1. This Ordinance may be cited as the Agricultural Fertilizers Ordinance 2002.

2. In this Ordinance -
   "the principal Ordinance" means the Agricultural Fertilizers Ordinance 2000.

3. Section 2 of the principal Ordinance shall be amended as follows -
   (a) in the definition of "appropriate Republican law" for "N.124" there shall be substituted "No.124(1)/99";
   (b) for the definition of "nutrients" there shall be substituted the following -
       "nutrients" means those elements of the periodic table which are essential to plant life;"
   (c) in the definition of "regulations" for "section 14" there shall be substituted "section 12".

4. For section 3 of the principal Ordinance there shall be substituted the following -
   "Permit to manufacture fertilizers. 3. A person shall not manufacture any fertilizer, except in accordance with the conditions of a written permit granted to him for this purpose by the Board."

5. For subsection (1) of section 7 of the principal Ordinance there shall be substituted the following -
“(1) An Inspector may at any reasonable time enter any premises other than a dwelling, where fertilizers are manufactured, stored or exposed for sale, for the purpose of ascertaining whether the provisions of this Ordinance and of any regulations made under it are being complied with, and for this purpose he shall have power to take samples for qualitative analysis by the Republican Agricultural Chemist. The procedure for the taking of samples and the method of analysis shall be prescribed.”.

6. For section 8 of the principal Ordinance there shall be substituted the following—

8. - (1) Following the analysis of a sample of fertilizer the Republican Agricultural Chemist shall prepare and send to the Board a certificate of analysis in duplicate, of which one copy shall be sent by the Board to the owner of the sample. It shall be stated in such certificate whether or not the quality of the fertilizer corresponds with the particulars of its registration. Such a certificate shall constitute prima facie evidence of the particulars stated therein in any legal or other proceedings.

(2) If an importer, manufacturer or seller of fertilizers wishes to dispute the certificate of the Republican Agricultural Chemist relating to any fertilizer, he shall have the right, after paying the prescribed fee, to require the Inspector to make arrangements for a sample of the fertilizer to be sent to the Republican Analyst for analysis. The Republican Analyst, after analysing the sample, shall prepare and send to the person who requested the analysis a report and a copy of it to the Board.”.

7. For the avoidance of doubt it is hereby declared that the Agricultural Fertilizers Ordinance which was published as Cap.26 (Laws of Cyprus) (“the previous Ordinance”) became spent on 29th September 2000, being the date that the principal Ordinance came into force, and accordingly the previous Ordinance was repealed with effect from that date.

21st October 2002
(195/2/1)

D.J. BONNER,
Chief Officer.
ORDINANCE 25 OF 2002

AN ORDINANCE

TO PROVIDE FOR THE ELIMINATION OF UNFAVOURABLE TREATMENT OF PART-TIME EMPLOYEES

T.W. RIMMER

ADMINISTRATOR

21st October 2002.

BE it enacted by the Administrator of the Sovereign Base Areas of Akrotiri and Dhekelia as follows:-

1. This Ordinance may be cited as the Employment Rights (Part-time Employees) Ordinance 2002.

2. In this Ordinance, unless the context otherwise requires -

“comparable full-time employee” means a full-time employee who –

(a) works in the same undertaking as a part-time employee;

(b) has the same kind of employment contract or relationship with the employer as the part-time employee has; and

(c) carries out duties which are the same as, or similar to those carried out by the part-time employee, having regard to other considerations such as seniority, qualifications and skills;

“employee” means a person who works for another person under a contract of service or in such other circumstances as to lead to the conclusion that there exists a relationship of employer and employee; and the term “employer” shall be construed accordingly;

“part-time employee” means an employee whose hours of work, calculated on a weekly basis or as an average over a period of employment of one year, are fewer than the normal hours of work of a comparable full-time employee;

“principle of pro rata temporis” means the principle whereby any remuneration or other benefit to which a part-time employee is entitled is directly proportional to the remuneration or other
benefit to which a comparable full-time employee is entitled, based on a comparison of the number of hours worked each week by the part-time employee and the comparable full-time employee respectively.

3. The purposes of this Ordinance are –

(a) to eliminate discrimination against part-time employees and to improve the quality of part-time work;

(b) to promote the development of part-time work on a voluntary basis and to contribute to the flexible organisation of working time in a manner which takes into account the needs of employers and employees.

4. - (1) Subject to subsection (2) below, this Ordinance shall apply to all part-time employees.

(2) The following categories of employees shall be excluded from the scope of application of this Ordinance –

(a) part-time employees who work on a casual basis, as prescribed by regulations;

(b) full-time employees affected by partial unemployment, that is to say, by a collective and temporary reduction of their normal working hours for financial, technical or structural purposes.

(3) Any exclusions prescribed by regulations, in accordance with paragraph (a) of subsection (2) above shall be re-examined periodically by the Chief Officer, in order to determine whether the objective reasons which existed when such exclusions were prescribed still exist.

5. Where there is no comparable full-time employee in an undertaking, any comparison required to be made under this Ordinance shall be made by reference to any specific collective agreement or, if no specific collective agreement exists, in accordance with relevant legislation, or any general collective agreement or practice.

6. - (1) In respect of terms and conditions of employment, a part-time employee shall not be treated less favourably than a comparable full-time employee by reason only that he works part-time, unless different treatment is justified on objective grounds.

(2) Where appropriate, the principle of pro rata temporis shall apply.

(3) Where justified on objective grounds, the Chief Officer, after consultation with representatives of employers and employees in accordance with relevant legislation, collective agreements and practice, or representatives of employers and employees may, where appropriate, make the application of particular conditions of employment subject to a specified period of service by an employee, the length of an employee’s employment or an employee’s qualifications based on his earnings.

(4) The conditions subject to which particular conditions of employment are to apply to part-time employees shall be reviewed periodically having regard to the principle of non-discrimination.
7. - (1) Subject to section 6, a part-time employee shall be entitled to equal terms and conditions of employment and to equal treatment and shall be afforded the same protection as that given to a comparable full-time employee, in particular with regard to –

(a) salary and benefits:

Provided that any cash allowances and allowances for part-time employees shall be fixed in proportion by reference to the number of hours worked, earnings or contributions, or other methods, according to relevant legislation, collective agreements and practice;

(b) the social insurance scheme:

Provided that any contributions by, and payment of allowances to, or in relation to, a part-time employee shall be fixed in accordance with the provisions of the Social Insurance (Facilitation of Republican Social Insurance Scheme) Ordinance 1980;

(c) the termination of employment:

Provided that any part-time employee who works fewer hours in a week than the number of hours mentioned in paragraph 1(2)(a) of the Second Schedule to the Termination of Employment (Consolidation) Ordinance 1980 shall be excluded;

(d) protection of maternity;

(e) annual leave with pay and paid public holidays;

(f) parental leave;

(g) sick leave.

(2) A part-time employee shall be entitled to equal treatment to, and enjoy the same protection as, that afforded to a full-time employee in relation to –

(a) the right to join and participate in the activities of a union, the right to collective negotiations and the right to act as an employees’ representative;

(b) health and safety at work;

(c) protection from unfavourable discrimination in employment and occupation.

8. - (1) An employer shall ensure that the transfer of an employee from full-time to part-time employment, or from part-time to full-time employment, in the event of any vacancies in the undertaking is done on a voluntary basis.

(2) The refusal of an employee to be transferred from part-time to full-time employment or from full-time to part-time employment shall not in itself constitute a reason for the termination of his employment, without prejudice to his employer’s right to terminate the employee’s employment in accordance with relevant legislation, collective agreements and practice, for other reasons such as may arise from the operational requirements of the undertaking concerned.
9. An employer shall, as far as possible, examine the following:

(a) requests of employees in relation to their transfer from full-time to part-time employment that becomes available in the undertaking;

(b) requests of employees in relation to their transfer from part-time to full-time employment or for an increase in their working time should the opportunity arise;

(c) provision of timely information on the availability of part-time and full-time positions in the undertaking in order to facilitate transfers from full-time to part-time employment and from part-time to full-time employment;

(d) measures to facilitate access to part-time employment at all levels of the undertaking, including skilled and administrative positions and, where appropriate, to facilitate access by part-time employees to vocational training to enhance career opportunities and occupational mobility;

(e) provision of appropriate information to bodies representing employees about part-time employees working in the undertaking.

10. (1) The Chief Officer may, after consultation with representatives of employers and employees, in accordance with relevant legislation, collective agreements and practice, identify, deal with and, where necessary, eliminate obstacles of a legal or administrative nature which may limit the opportunities for part-time employment.

(2) Representatives of employers and employees, acting within their respective spheres of competence and in accordance with the procedures set out in collective agreements, shall identify, deal with and, where necessary, eliminate obstacles of a legal or administrative nature which may limit the opportunities for part-time employment.

(3) Within three months from the coming into force of this Ordinance, the Chief Officer shall invite the organisations representing employers and employees respectively to examine and review, within a fixed period of time to be determined by him, existing collective employment agreements with a view to amending such agreements in order to remove any provisions in them which limit free choice or opportunities for part-time employment.

11. (1) Subject to the provisions of this section, the Industrial Disputes Tribunal shall have exclusive jurisdiction to determine any dispute of a civil nature (including any ancillary or incidental matter relating to such a dispute) arising from the provisions of this Ordinance.

(2) Part III of the Citizens of the Republic (Jurisdiction of Courts) Ordinance 1960 shall apply to disputes of a civil nature arising from the provisions of this Ordinance, and for such purpose—

(a) any proceedings in connection with such a dispute shall be treated as civil proceedings and, as appropriate, as an action or an appeal;

(b) the Industrial Disputes Tribunal shall be treated as a Court of the Areas, and the Industrial Disputes Court of the Republic shall be treated as a District Court of the Republic; and
(c) any corporation, company or other body corporate established in the Republic under the provisions of any Law of the Republic, shall be treated as a Cypriot.

(3) An award by the Industrial Disputes Tribunal or by the Industrial Disputes Court of the Republic under the provisions of this Ordinance shall be recoverable as a civil debt.

12. Any employer who contravenes any provision of this Ordinance shall be guilty of an offence and shall be liable, on conviction, to a fine not exceeding two thousand pounds.

13. The Chief Officer may appoint inspectors and such other officials as he may deem necessary for the more effective application of this Ordinance.

14. - (1) The Administrator may make regulations for the more effective application of the provisions of this Ordinance or in relation to any matter which this Ordinance provides as requiring to be prescribed by regulations.

(2) Without prejudice to the generality of subsection (1) above, any regulations may in particular prescribe –

(a) the categories of employees working on a casual basis who, in accordance with the provisions of paragraph (a) of subsection (2) of section 4, are excluded from the scope of application of this Ordinance;

(b) the duties or powers of inspectors or other officials appointed pursuant to section 13.

15. This Ordinance shall come into force on 1st January 2003.

21st October 2002
(107/4/3/1) D.J. BONNER,
Chief Officer.
AN ORDINANCE
TO AMEND THE PROTECTION OF MATERNITY
ORDINANCE 1999

ADMINISTRATOR

BE it enacted by the Administrator of the Sovereign Base Areas of Akrotiri and Dhekelia as follows:-

1. This Ordinance may be cited as the Protection of Maternity (Amendment) Ordinance 2002 and shall be read as one with the Protection of Maternity Ordinance 1999 (hereinafter referred to as “the principal Ordinance”).

2. Section 4 of the principal Ordinance shall be amended as follows -

(a) the present section 4 shall be numbered as subsection (1); and

(b) after subsection (1) (as numbered in accordance with paragraph (a) above) there shall be added the following new subsection, to be numbered subsection (2) -

“(2) Where an employer gives notice of termination of employment to a female employed person during the period mentioned in subsection (1) above, he shall state his reasons for doing so in writing:

Provided that the failure of an employer to fulfil this obligation shall not in itself affect the effect of the notice of termination of employment.”.

3. Immediately after section 5 of the principal Ordinance there shall be inserted the following new section, to be numbered section 5A –

“5A. Any female employed person who is entitled to maternity leave under section 3(1) shall also be entitled to time off work, without loss of pay, in order to attend ante-natal examinations, provided that such examinations have to take place during the female employed person’s working hours and the following conditions are fulfilled –
(a) the female employed person produces a certificate relating to the ante-natal examinations from a medical practitioner; and

(b) the female employed person gives timely notice to her employer.”.

4. For section 6 of the principal Ordinance there shall be substituted the following -

“6. The protection of the health and safety of female employed persons who -

(a) are expecting a childbirth;
(b) have recently given birth; or
(c) are breastfeeding,

shall be ensured by appropriate regulations made under the Health and Safety at Work Ordinance 1999.”.

5. Section 9 of the principal Ordinance shall be amended by substituting for the words “sections 3, 4, 5, 6 or 7” the words “section 3, 4, 5, 5A or 7”.

6. This Ordinance shall come into force on the day of its publication in the Gazette.

21st October 2002
(195/9)

D.J. BONNER,
Chief Officer.
ORDINANCE 27 OF 2002

AN ORDINANCE

TO AMEND THE SOCIAL INSURANCE
(FACILITATION OF REPUBLICAN SOCIAL
INSURANCE SCHEME) ORDINANCE 1980.

T.W. RIMMER
ADMINISTRATOR

21st October 2002.

BE it enacted by the Administrator of the Sovereign Base Areas of Akrotiri and Dhekelia as follows:-

1. This Ordinance may be cited as the Social Insurance (Facilitation of Republican Social Insurance Scheme) (Amendment) Ordinance 2002 and shall be read as one with the Social Insurance (Facilitation of Republican Social Insurance Scheme) Ordinance 1980 (hereinafter referred to as “the principal Ordinance”).

2. For Part II of the Second Schedule to the principal Ordinance there shall be substituted the following -

“PART II
EXCEPTED EMPLOYMENT

Agricultural occupation where the person so occupied is under the age of sixteen years and lives with his parents.”.

21st October 2002

D.J. BONNER,
Chief Officer.
THE VETERINARY MEDICINAL PRODUCTS ORDINANCE 2002

ARRANGEMENT OF SECTIONS

PART I
PRELIMINARY PROVISIONS

Section
1. Short title.
2. Interpretation.

PART II
MARKETING OF VETERINARY MEDICINAL PRODUCTS

5. Labelling.
6. Package leaflets.
7. Labelling of and package leaflet for homeopathic veterinary medicinal products.
8. Further provisions concerning labelling.

PART III
PROHIBITION ON THE MANUFACTURE OR IMPORTATION OF VETERINARY MEDICINAL PRODUCTS

9. Prohibition on manufacture and importation.

PART IV
ADVERTISING OF VETERINARY MEDICINAL PRODUCTS

10. Meaning of advertising.
11. Scope of Part IV.
12. Restrictions on advertising.
13. Examination of advertisements by Council for Veterinary Medicinal Products.
14. Applications to the Court by Council for Veterinary Medicinal Products.
15. Applications to the Court by other parties.
CLASSIFICATION, WHOLESALE, RETAIL SALES AND PRICES OF VETERINARY MEDICINAL PRODUCTS

17. Classification of medicinal products.
18. Wholesale distribution.
19. Obligations and duties of a wholesaler.
20. Retail sales.
21. Maximum permissible prices not to be exceeded.
22. Retail price to be indicated.

ADMINISTRATION OF VETERINARY MEDICINAL PRODUCTS TO ANIMALS

23. Restrictions on administering veterinary medicinal products.

MEDICATED ANIMAL FEEDING STUFFS

24. Restrictions on manufacture, importation or supply.

MISCELLANEOUS PROVISIONS

25. Authorised Inspectors.
26. Imposition of administrative penalties.
27. Collection of administrative penalties.
28. Offences.
29. Liability of individuals for offence by body corporate.
30. Consent of Attorney General and Legal Adviser to any prosecution.
32. Civil and criminal liability unaffected by marketing authorisation.
33. Regulations.
34. Repeal.
35. Commencement.
AN ORDINANCE
TO PROVIDE FOR THE CONTROL OF QUALITY,
REGISTRATION, MARKETING, MANUFACTURE,
ADMINISTRATION AND USE OF VETERINARY
MEDICINAL PRODUCTS AND RELEVANT MATTERS

T.W. Rimmer
18th October 2002.

ADMINISTRATOR

BE it enacted by the Administrator of the Sovereign Base Areas of Akrotiri and Dhekelia as follows:—

PART I
PRELIMINARY PROVISIONS

1. This Ordinance may be cited as the Veterinary Medicinal Products Ordinance 2002.

2. - (1) In this Ordinance, unless the context otherwise requires -

“active substance” means any substance intended for treatment, prevention or diagnosis, restoration, improvement or modification of organic functions in animals;

“adverse reaction” means any harmful and unwanted reaction occurring in doses of a veterinary medicinal product normally used in animals, for the prophylaxis, diagnosis or treatment of a disease or the modification of a physiological function;

“allergenic product” means a product intended for the identification or causing of a special acquired modification in the immunological response to any allergenic agent;

“animal” includes mammals, birds, reptiles, insects, amphibians, fish, crustacea and molluscs;

“animal feeding stuffs additive” means any substance which after being mixed and integrated in any animal feeding stuff improves its composition or the production of animals and is safe for the health of humans and animals, and includes the

227
substances referred to in the Schedule to Republican Law No. 13(I)/1993 (which relates to animal feeding stuffs and animal feeding stuffs additives);

"Authorised Inspector" means any person appointed as, or deemed to be, an Authorised Inspector under section 25(1) of this Ordinance;

"Commission" means the Commission of the European Union;

"Committee for Veterinary Medicinal Products" means the Committee which is part of the European Agency for the Evaluation of Medicinal Products;

"common name" in relation to any veterinary medicinal product means its international name as recommended by the World Health Organisation or, if there is none, its usual common name;

"corresponding Republican Law" means Republican Law No. 116(1)/2001 and includes any Law amending or substituting that Law and any subordinate legislation made under that Law;

"Council" (except in the expression "Council for Veterinary Medicinal Products") means the Council of the European Union;

"Council for Veterinary Medicinal Products" means the Council established in accordance with the provisions of section 4 of the corresponding Republican law;

"Court" means a Court of competent jurisdiction;

"dispensing of a prescription" means the supply of any veterinary medicinal product on any prescription provided that such prescription has been issued by a registered veterinary surgeon;

"dosage of the veterinary medicinal product" means the content in active substances, expressed as quantity per unit, per unit volume or per unit weight, depending on how the product is presented;

"European Agency for the Evaluation of Medicinal Products" means the Agency which was founded under Council Regulation (EEC) No. 2309/93 of 22nd July 1993;

"food-producing animal" means an animal which produces products which are usually used for human consumption;

"homeopathic veterinary medicinal product" means any veterinary medicinal product derived from products, substances or compositions called homeopathic sources, manufactured by a method described in the European Pharmacopoeia, or in the absence of a method so described, by a method described in the pharmacopoeia used officially in member States; a homeopathic veterinary medicinal product may also contain more than one active substance;

"immediate packaging" means packaging which is in direct contact with a veterinary medicinal product;

"marketing" in relation to veterinary medicinal products means any activity relating to the possession, offer, distribution or placing on the market and cognate expressions shall be construed accordingly;
"medicinal product" means any medicament manufactured in advance which is marketed under a special name and in a special packaging;

"medicament" means any substance or composition of substances described as having therapeutic or preventive properties against diseases of humans or animals or which may be administered to humans or animals for purposes of medical diagnosis, restoration, improvement or modification of organic functions of humans or animals and includes the immunological products which comprise vaccines, toxins, serums or allergenic products and homeopathic products;

"medicated animal feeding stuff" means any mixture of a veterinary medicinal product and animal feeding stuff which is placed on the market ready-made and is intended for administration to animals without further processing, due to the pharmaceutical and preventive properties thereof or other properties of the veterinary medicinal product;

"member State" means a member State of the European Union;

"name of the veterinary medicinal product" means the name which may be either an invented, common or scientific name accompanied by a trade mark, or the corporate name of the manufacturer; an invented name must not be liable to cause confusion with the common name;

"outer packaging" means the packaging into which immediate packaging is placed;

"package leaflet" means the information document for the user which accompanies a veterinary medicinal product;

"pre-mix" means any veterinary medicinal product manufactured in advance for the further manufacture of medicated animal feeding stuffs;

"registered" means –

(a) in relation to a veterinarian, a practitioner as defined by section 2 of the Veterinary Surgeons Ordinance 1964;

(b) in relation to a pharmacist, a pharmacist as defined by section 2 of the Pharmacy and Poisons Ordinance 1964;

"ready-made veterinary medicinal product" means any veterinary medicinal product manufactured in advance which may be used without further processing, but without being marketed in a special packaging and under a special name;

"retail sale" means a sale made directly to a consumer;

"third country" means any country or territory other than the Areas or the Republic, which is not a member State;

"vaccines, toxins or sera" include in particular –

(a) agents used for the causing of active immunity (such as the enterotoxemia vaccine and the smallpox vaccine of sheep and goats);
(b) agents used for diagnosing the degree of immunity, including in particular the tuberculin PPD, the toxins used for the Schick and Dick tests and brucellin;

(c) agents used for the causing of passive immunity (like the tetanic antitoxin);

"veterinary medicinal product" means any medicinal product which is intended exclusively for administering to animals, but does not include any animal feeding stuffs additives;

"wholesale" in relation to a veterinary medicinal product means any activity of purchase, sale, import, export or any other commercial activity in relation to veterinary medicinal products whether or not aiming at profit but does not include —

(a) the provision of veterinary medicinal products by a manufacturer of such products which he manufactures himself;

(b) the retail sale of veterinary medicinal products by a retailer; or

(c) the provision of small quantities of veterinary medicinal products from one retailer to another;

"withdrawal period" in relation to any veterinary medicinal product means the requisite period of time between the last administering of the veterinary medicinal product to animals, under normal conditions of use, and the production of foodstuffs from such animals, so that such foodstuffs do not contain residues from the veterinary medicinal product administered, or products from the reconstitution and general chemical conversion of such veterinary medicinal product, which may cause damage to the health of consumers.

(2) Any reference in this Ordinance to any Republican law or to any particular provision of any Republican law shall be construed as including a reference to that law as from time to time amended or substituted.

Scope of Ordinance.

3. Nothing contained in this Ordinance shall apply to -

(a) any veterinary medicinal products manufactured on the basis of radio-active isotopes; or

(b) any inactivated immunological veterinary medicinal products manufactured from pathogens and antigens taken from any animal of a farm unit and used for the treatment of any animal of that unit in the same locality.

PART II
MARKETING OF VETERINARY MEDICINAL PRODUCTS

4. - (1) Subject to subsection (2) below, a person shall not market in the Areas any veterinary medicinal product unless there is in force in relation to that product a valid current marketing authorisation granted by either —

(a) the Council for Veterinary Medicinal Products, in accordance with the relevant provisions of the corresponding Republican Law;
(b) the Commission, in accordance with Council Regulation (EEC) No. 2309/93 as amended or substituted from time to time.

(2) A person may market in the Areas a homeopathic veterinary medicinal product which is for the time being registered by the Council for Veterinary Medicinal Products in the Register of Homeopathic Veterinary Products under section 19(2) of the corresponding Republican law, without a marketing authorisation having been granted in relation to the product.

5. - (1) Subject to the following provisions of this section, the outer packaging and immediate packaging of a veterinary medicinal product shall bear the following particulars –

(a) the name of the veterinary medicinal product followed by the common name where such veterinary medicinal product consists of only one active substance, if any, and whether such name is invented;

(b) the qualitative and quantitative composition of the product in terms of active substances per dose unit or according to the route of administration, for a specific volume or weight, with the use of common names;

(c) the manufacturer’s batch number;

(d) the registration number of the marketing authorisation;

(e) the name and address of the holder of the marketing authorisation;

(f) for each species of animal for which the veterinary medicinal product is intended, the method and route of administration;

(g) the expiry date marked clearly (month/year);

(h) any special precautions necessary for the storage of the veterinary medicinal product;

(i) any special precautions necessary for the disposal of any unused product or of any residues of the product;

(j) the indication ‘for veterinary use’;

(k) the pharmaceutical form and the content in weight, volume or dose units which may appear only on the outer packaging;

(l) the withdrawal period, in relation to a veterinary medicinal product administered to food-producing animals;

(m) information relating to health or safety, including any special precautions to be taken in using the product and any other warnings deemed necessary as a result of the clinical and pharmacological trials carried out for the purposes of obtaining the marketing authorisation for the product or acquired as a result of experience acquired from use of the product;

(n) an indication of the type of product by means of clear and legible characters in relation to homeopathic veterinary medicinal products:

Provided that where there is no outer packaging the above indications shall be stated on the immediate packaging.
(2) The outer packaging and immediate packaging may contain in addition to the particulars described in subsection (1) above, other information which is in conformity with the summary of the product characteristics, and relating to health and safety matters, but none of those particulars may be of a promotional nature.

(3) Where ampoules are concerned, the indications referred to in subsection (1) above shall be stated on the outer packaging whilst the immediate packaging shall bear the following particulars –

(a) the name of the veterinary medicinal product;
(b) the quantity of active substances;
(c) the administration route;
(d) the manufacturer’s batch number;
(e) the expiry date;
(f) the indication ‘for veterinary use’.

(4) Where small immediate packagings are concerned (other than ampoules) containing only one dose and on which it is not possible to include all the indications referred to in subsection (3) above, the particulars referred to in subsection (1) above shall appear only on the outer packaging.

(5) The particulars provided for in subsections (1), (2), (3) and (4) above shall appear in a legible, comprehensible and indelible form.

(6) The particulars provided for in subsections (1), (2), (3) and (4) shall be in either the English or Greek language:

Provided that other languages may be used in addition, on condition that the same particulars appear in all the languages used.

(7) Where under the corresponding Republican law there is a requirement for the price of a veterinary medicinal product to be indicated on its packaging, a like requirement shall apply in the Areas.

6. - (1) A package leaflet must be included in the package of every veterinary medicinal product unless the information referred to in subsections (2) and (3) below appears directly on the outer or immediate packaging of the product.

(2) The package leaflet shall be drawn up in accordance with the summary of the product characteristics and shall include, in the following order –

(a) the name and address of the holder of the marketing authorisation and (where they differ) of the manufacturer;
(b) the name, qualitative and quantitative composition in terms of active substances of the veterinary medicinal product with reference to the common name;
(c) the main therapeutic indications, the contra-indications and appropriate precautions for use of the product;
(d) the species of animal for which the veterinary medicinal product is intended, the dosage for each species, the way and route of administration and where necessary, directions for appropriate administration;
(e) the withdrawal period, in relation to a veterinary medicinal product administered to food-producing animals;

(f) any special precautions necessary for the storage of the veterinary medicinal product;

(g) any special precautions necessary for the disposal of unused product or of residues derived from such product.

3. The package leaflet may include any information consistent with the summary of the product characteristics, useful in terms of information on health and safety matters, but no such information shall be of a promotional nature.

4. The package leaflet shall be worded in a comprehensible and legible manner in either the English or Greek language:

Provided that other languages may be used in addition, if the same information is given in all the languages used.

7. The packaging and the package leaflet (where required) of a homeopathic veterinary medicinal product such as is referred to in section 4(2) shall include the words ‘homeopathic veterinary medicinal product without approved therapeutic indication’, and in addition only the following indications –

(a) the scientific name of the source or sources, accompanied by the degree of dilution, the symbols of the European Pharmacopoeia or, in the absence of these, of the pharmacopoeia in official use in member States;

(b) the name and address of the person in whose name the veterinary medicinal product has been registered and (where they differ) those of the manufacturer;

(c) the way of administration and, where necessary, the route of administration;

(d) the expiry date, clearly marked (month/year);

(e) the pharmaceutical form;

(f) the content of the commercial presentation of the product;

(g) any special precautions necessary for the storage of the product;

(h) any special warning that may be necessary for the specific veterinary medicinal product;

(i) the manufacturer’s batch number;

(j) the registration number;

(k) the species of animal for which the veterinary medicinal product is intended.

8. - (1) Any decision of the Council for Veterinary Medicinal Products to grant a marketing authorisation in respect of a veterinary medicinal product in circumstances where, under the corresponding Republican law, it ought to have refused to grant the marketing authorisation on the grounds that the requirements relating to labelling and the package leaflet were not satisfied in respect of the product, or any decision by the Council for Veterinary Medicinal Products not to oppose any application proposing any amendment to the labelling.
labelling of, or package leaflet for, such veterinary medicinal product, shall not affect any civil liability of the manufacturer of the veterinary medicinal product or of the holder of the marketing authorisation in respect of the veterinary medicinal product.

(2) Where under the corresponding Republican law the Council for Veterinary Medicinal Products disapplies any of the requirements relating to labelling or package leaflets in specified circumstances, then like requirements imposed under this Ordinance shall likewise be disapplied where similar circumstances obtain in the Areas.

PART III
PROHIBITION ON THE MANUFACTURE OR IMPORTATION OF VETERINARY MEDICINAL PRODUCTS

9. - (1) A person shall not manufacture any veterinary medicinal product in the Areas nor import into the Areas any veterinary medicinal product for the purpose of any business carried on or to be carried on by him or any other person.

(2) For the purposes of this section, manufacture includes partial manufacture and the operations of dividing up a veterinary medicinal product or of changing its packaging or presentation, but does not include –

(a) the manufacture, the dividing up or the changing of the packaging or presentation when these activities are carried out by a pharmacist in a shop for the purpose of a retail sale of the veterinary medicinal product; or

(b) the carrying out of the activities described in paragraph (a) above by a registered veterinarian for the purpose of treating a particular animal.

PART IV
ADVERTISING OF VETERINARY MEDICINAL PRODUCTS

10. In this Part, unless the context otherwise requires, the advertising of a veterinary medicinal product includes any form of information about the product supplied to attract buyers, and any canvassing activity or inducement with a view to promoting the prescribing, supply, sale or consumption of the veterinary medicinal product.

11. - (1) The provisions of this Part shall apply in particular to -

(a) the advertising of veterinary medicinal products to the general public;

(b) the advertising of veterinary medicinal products to persons qualified to prescribe or supply veterinary medicinal products;

(c) visits by persons representing the manufacturer, importer or distributor of a veterinary medicinal product to persons qualified to prescribe or supply veterinary medicinal products;

(d) the supply of samples of veterinary medicinal products;
(e) the provision of any inducement to supply or prescribe veterinary medicinal products by the provision, offer or promise of any benefit, whether in money or in kind, unless the intrinsic value of the inducement is insignificant;

(f) sponsorship of promotional meetings attended by persons qualified to supply or prescribe veterinary medicinal products;

(g) sponsorship of scientific conferences attended by persons qualified to supply or prescribe veterinary medicinal products, and in particular the payment of the transport and accommodation costs of such persons.

(2) Nothing included in this Part shall apply to –

(a) the labelling of, and the package leaflets for, veterinary medicinal products covered by the provisions of sections 5 to 8;

(b) correspondence, whether or not accompanied by any other material of a non-promotional nature, which is required in order to reply to specific questions about a particular veterinary medicinal product;

(c) specific information and documents relating to such matters as changes in packaging, warnings about adverse reactions in connection with pharmacovigilance, trade catalogues and price lists, provided that no further information relating to a veterinary medicinal product is included;

(d) statements relating to animal health or animal diseases provided that they do not include any reference to a specific veterinary medicinal product.

12. A person shall not advertise any veterinary medicinal product in the Areas in any manner in which he could not lawfully advertise it in the Republic in accordance with sections 61 to 69 of the corresponding Republican law.

13. - (1) The Council for Veterinary Medicinal Products may, either following a complaint or of its own volition, examine any advertisement which relates to a veterinary medicinal product and which has been published or is imminently to be published, as to whether it is misleading or is otherwise not in conformity with the provisions of this Part.

(2) In exercising the powers conferred on it under this Ordinance, the Council for Veterinary Medicinal Products shall have regard to all interests involved and in particular to the public interest.

14. - (1) Where the Council for Veterinary Medicinal Products, following an examination of an advertisement under section 13, considers that such advertisement is misleading or is otherwise not in conformity with the provisions of this Part, it may apply to the Court by originating summons, requesting the issue of an injunction or mandatory order, including an interim order against any person whom it considers to be involved or is likely to be involved in the issue or publication of the advertisement.

(2) The Council for Veterinary Medicinal Products shall give to a complainant a reasoned decision in writing as to whether or not it intends to apply for the issue of an order as provided in subsection (1)
above in relation to any advertisement that it has examined in accordance with the provisions of this Part.

15. Any person who, or any lawfully established organisation which under any Ordinance or under its articles of association has a sufficient legal interest for the prohibiting of any misleading advertisements or more generally of advertisements which are not in conformity with the provisions of this Part, shall have a right to apply to the Court for the issue of an injunction or mandatory order, including an interim order against any person who is involved in the issue or publication of the advertisement.

16. - (1) The Court before which an application is submitted, in accordance with section 14 or 15, may, subject to the Civil Procedure Ordinance, the Courts Ordinance and Civil Procedure Rules, issue an injunction or mandatory order on such conditions as it deems appropriate, on being satisfied that the advertisement in respect of which the application was submitted is misleading or is otherwise not in conformity with the provisions of this Part. Before issuing such an order the Court shall have regard to all interests involved and in particular to the public interest.

(2) The Court may, where it deems the following measures necessary for the protection of any interests involved and in particular of the public interest –

(a) order the cessation of the publication of the advertisement which is misleading or which is otherwise not in conformity with the provisions of this Part; or

(b) prohibit publication of such advertisement where the advertisement in question has not yet been published but is imminently to be published.

(3) The Court may issue an injunction or mandatory order even though neither of the following is proved -

(a) harm or real damage to any person from the publication or proposed publication of the advertisement; or

(b) fraud or negligence on the part of the advertiser.

(4) Further, in order to eliminate the continuing effects of any misleading advertisement or more generally of any advertisement which is not in conformity with the provisions of this Part, where the Court has made a final decision that any further publication of the advertisement should cease, the Court may also order –

(a) the publication of its decision in full or in part, in such form as it deems appropriate; and

(b) the publication of a corrective statement.

(5) Where a Court of the Republic makes any order under the corresponding Republican law to the like effect as any order which could be made by a Court of the Areas under subsections (1) to (4) above, the Order of the Court of the Republic shall have effect in the Areas as if it had been made by a Court of the Areas.
PART V
CLASSIFICATION, WHOLESALE, RETAIL SALES AND PRICES OF VETERINARY MEDICINAL PRODUCTS

17. (1) Any classification of a veterinary medicinal product by the Council for Veterinary Medicinal Products under Part VII of the corresponding Republican law as being either a veterinary medicinal product for which –

(a) a veterinary prescription is required; or

(b) a veterinary prescription is not required,

shall apply in the Areas as it applies in the Republic.

(2) In this Part, a veterinary prescription means a prescription signed by a registered veterinarian.

18. (1) Without prejudice to section 4, a person shall not distribute any veterinary medicinal product by way of wholesale distribution unless he holds a wholesale distribution licence issued to him by the Council for Veterinary Medicinal Products authorising him to distribute by way of wholesale distribution veterinary medicinal products of that description or unless he is otherwise permitted under the corresponding Republican law to distribute by way of wholesale distribution veterinary medicinal products of that description.

(2) For the purposes of this Ordinance a veterinary medicinal product is distributed by way of wholesale distribution in any case where it is distributed otherwise than –

(a) by way of a retail sale; or

(b) in small quantities by one retailer to another.

19. A person who is licensed or otherwise permitted under the corresponding Republican law to distribute any veterinary medicinal product by way of wholesale distribution shall, in relation to like distribution in the Areas, comply with the same obligations and duties in the Areas as he is or would be required to comply with under the corresponding Republican law in relation to such distribution in the Republic.

20. (1) A person shall not sell by way of retail sale any veterinary medicinal product unless he is authorised to do so under the corresponding Republican law, and a person so authorised is hereafter referred to as “a retailer”.

(2) A retailer shall, in relation to his business as a retailer in the Areas, be subject to the same obligations and duties as he is or would be subject to as a retailer in the Republic under the corresponding Republican law.

21. Without prejudice to sections 19 and 20(2), a person shall not sell or offer for sale by way of retail sale or by way of wholesale, any veterinary medicinal product at a price exceeding the maximum retail price, or as the case may require, the maximum wholesale price that may be prescribed for that product, by or under the provisions of the corresponding Republican law.

22. Without prejudice to section 20(2), a retailer shall indicate the selling price in clear figures on the outer packaging, or if there is no such packaging, on the immediate packaging, of any veterinary medicinal product which he offers or exposes for sale.
PART VI
ADMINISTRATION OF VETERINARY MEDICINAL PRODUCTS TO ANIMALS

23. - (1) A person shall not administer any veterinary medicinal product to any animal in the Areas in circumstances where he could not lawfully administer that veterinary medicinal product to that animal in the Republic in accordance with the provisions of the corresponding Republican law.

(2) Without prejudice to subsection (1) above, a person who administers any veterinary medicinal product to an animal in the Areas shall comply with all the same duties and responsibilities as have to be complied with under the corresponding Republican law by a person who administers any veterinary medicinal product to an animal in the Republic.

PART VII
MEDICATED ANIMAL FEEDING STUFFS

24. - (1) A person may not manufacture in the Areas any medicated animal feeding stuff or any pre-mix or intermediate product, nor import into the Areas any medicated animal feeding stuff, pre-mix or intermediate product for the purpose of any business carried on or to be carried on by him or any other person.

(2) A person may only supply a medicated animal feeding stuff, pre-mix or intermediate product in the Areas in similar circumstances and subject to the same conditions, obligations and duties as he may lawfully supply it in the Republic under the corresponding Republican Law.

PART VIII
MISCELLANEOUS PROVISIONS

25. - (1) The Chief Officer may appoint any person to be an Authorised Inspector to exercise powers and perform duties for the effective application of this Ordinance. Any person appointed under section 117 of the corresponding Republican law to exercise powers and perform duties under that law shall be deemed to be an Authorised Inspector for the purposes of this Ordinance.

(2) Any Authorised Inspector shall have the power at any reasonable time to enter any premises other than a dwelling, in which any veterinary medicinal products are controlled, stored, supplied or administered or in which any medicated animal feeding stuffs or intermediate products are controlled, stored, supplied or administered for the purpose of –

(a) establishing whether any manufacturing is taking place contrary to section 9;

(b) inspecting the premises, installations and equipment and checking the registers and any other particulars in relation to the observance of the provisions concerning the wholesale distribution of veterinary medicinal products;

(c) inspecting the registers as well as any other particulars in order to establish whether or not the provisions concerning the retail sale of veterinary medicinal products are being observed;
(d) inspecting the premises, installations and registers as well as any other particulars in order to establish whether or not the provisions concerning the administration to animals of veterinary medicinal products are being observed;

(e) inspecting where veterinary medicinal products are exposed or held for sale;

(f) confiscating any veterinary medicinal products in relation to which it is reasonably believed that any contravention or offence has been committed under this Ordinance and which may be required as evidence:

Provided that where no administrative penalties are imposed or no criminal prosecution is commenced in relation to any contravention or offence within two months from the date of confiscation of the veterinary medicinal products, such veterinary medicinal products shall be returned to their owner, or if the veterinary medicinal products have been destroyed or damaged, reasonable compensation shall be paid to their owner;

(g) establishing whether there is any unlawful manufacture of medicated animal feeding stuffs and inspecting the premises, registers as well as any other particulars relating to the supply of any medicated animal feeding stuffs or intermediate products;

(h) inspecting the laboratories and premises where it is reasonably believed that any medicated animal feeding stuffs or intermediate products are held or stored;

(i) inspecting the laboratories and premises where it is reasonably believed that any medicated animal feeding stuff has been or will be administered to any animal;

(j) taking samples;

(k) confiscating any medicated animal feeding stuffs in respect of which there is reasonable cause to believe that a contravention or offence has been committed under this Ordinance and which may be required as evidence:

Provided that where no administrative penalties are imposed or no criminal prosecution is commenced in relation to any contravention or offence within two months from the date of confiscation of any medicated animal feeding stuffs, such medicated animal feeding stuffs shall be returned to their owner, or if such medicated animal feeding stuffs have been destroyed or damaged, reasonable compensation shall be paid to their owner.

(3) Any person who, whether personally or through an employee of his or other representative, obstructs or impedes an Authorised Inspector in the exercise of any of his duties under subsection (2) above, shall be guilty of an offence and, on conviction, shall be liable to imprisonment not exceeding six months or to a fine not exceeding £1,000 or to both such penalties.

(4) A sample taken in accordance with subsection (2)(j) above shall be sent for testing to the General Laboratory of the Republic or to such other laboratory that the Council for Veterinary Medicinal
Imposition of administrative penalties.

Products may designate. The results of the test shall be notified to the holder of the marketing authorisation for the veterinary medicinal product, who shall be entitled to submit an objection within a period of fifteen days from the notification of the results to him.

(5) Where an objection is submitted against the results of any test carried out under subsection (4) above, a re-examination of the sample may be requested. The holder of the marketing authorisation for the veterinary medicinal product or any representative of his may be present at such re-examination.

26. - (1) The Council for Veterinary Medicinal Products may examine, either following a complaint or of its own volition, whether any person alone or through an employee of his or other representative of his has—

(a) contravened section 5, 6, 7, 12, 18, 19, 20, 21, 22 or 23 of this Ordinance; or

(b) done or not done in the Areas any act or other thing which if he had done or, as the case may require, not done in the Republic would have constituted a contravention of section 13(5), 31(1), 35, 36, 37, 41, 55(1), 55(2), 56, 67, 68, 74, 75, 82(1), 82(2), 85(1), 85(2), 95, 97(5), 97(6), 97(7), 98, 106(1), 108, 109, 110, 111, 112(3), 112(4), 113(6), 113(7), 114 or 115(5) of the corresponding Republican law; or

(c) contravened any regulations or orders made under this Ordinance; or

(d) done or not done in the Areas any act or other thing which if he had done, or as the case may require, not done in the Republic would have constituted a contravention of any regulations or orders which form part of the corresponding Republican law:

Provided that the Council for Veterinary Medicinal Products may not conclude in any such examination that the same act or other thing done or not done by any person falls under both paragraph (a) and paragraph (b) above, or under both paragraph (c) and paragraph (d) above.

(2) If the Council for Veterinary Medicinal Products decides on any examination carried out in accordance with subsection (1) above that there has been a contravention of any of the provisions referred to in that subsection, it shall have the power to do one or more of the following, depending on the nature, duration and seriousness of such contravention—

(a) to order or advise the offender to cease the contravention within a specified period of time and to avoid repeating it in the future, or if the contravention has ceased before the issue of a decision by the Council for Veterinary Medicinal Products, to confirm that a contravention as specified in its decision, has occurred;

(b) to impose an administrative penalty not exceeding £25,000;

(c) to decide that if the contravention continues, an administrative penalty not exceeding £200 shall be imposed for each day that the contravention continues.
(3) The Council for Veterinary Medicinal Products shall give its reasons for its decision in relation to the exercise of any of the powers provided for in subsection (2) above.

27. - (1) The administrative penalties provided for in section 26(2) shall be imposed on an offender by means of a written decision of the Council for Veterinary Medicinal Products giving its reasoning and which shall confirm the contravention after having given the offender an opportunity to make written representations within thirty days of the notification of the decision to impose a penalty.

(2) The amount of an administrative penalty shall be collected by the Council for Veterinary Medicinal Products as follows –

(a) if no appeal has been made to the Senior Judge’s Court within the period of seventy five days starting on the day that the decision to impose the penalty was notified to the offender, immediately after the expiration of that period;

(b) where an appeal has been made and dismissed, immediately following the dismissal of the appeal.

(3) Where a person fails to pay any penalty imposed under this Ordinance by the Council for Veterinary Medicinal Products, the amount of the penalty shall be recoverable as a civil debt.

28. Any person who, whether personally or through an employee or other representative of his –

(a) places on the market of the Areas –

(i) any veterinary medicinal product for which no marketing authorisation has been granted, in contravention of section 4(1),

(ii) any homeopathic veterinary medicinal product which is not for the time being registered in accordance with section 19(2) of the corresponding Republican law,

(iii) any veterinary medicinal product which for any reason other than, one mentioned in sub-paragraph (i) or (ii) above, could not lawfully be marketed in the Republic under the corresponding Republican law; or

(b) manufactures or imports any veterinary medicinal product in contravention of section 9(1);

(c) engages in the wholesale distribution of any veterinary medicinal product otherwise than in accordance with section 18 or 19;

(d) administers any veterinary medicinal product to an animal otherwise than in accordance with section 23;

(e) carries out trials on a veterinary medicinal product in circumstances where if he had carried out the trials in the Republic he would have contravened section 99(1) of the corresponding Republican law;

(f) trades foodstuffs derived from animals which have been used in trials, in circumstances where if he had traded them in the Republic he would have contravened section 100 of the corresponding Republican law;
(g) manufactures or imports any medicated animal feeding stuff, pre-mix or intermediate product contrary to section 24(1) or who supplies any of these in contravention of any condition, obligation or duty imposed upon him under section 24(2);

(h) possesses, uses, supplies or otherwise markets any active substance which can be used as a veterinary medicinal product with anabolic, anti-infective, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties in circumstances where he could not also lawfully do so under the corresponding Republican law,

shall be guilty of an offence and shall be liable, on conviction, to imprisonment not exceeding five years or to a fine not exceeding £50,000 or to both such penalties and, in addition, the Court may order the confiscation of the veterinary medicinal products or other goods in relation to which the offence has been committed.

29. Where any offence under this Ordinance is committed by a body corporate and it is proved that the offence has been committed with the consent, connivance or approval or has been facilitated by the negligence of a consultant, director or secretary of the body corporate (including any other individual who purported to be acting in any such capacity) such consultant, director, secretary or other individual shall also be guilty of a like offence.

30. No criminal prosecution shall be brought under this Ordinance, without the consent of the Attorney General and Legal Adviser.

31. - (1) In any criminal or civil proceedings under this Ordinance the Court may take judicial notice of the whole or part of the corresponding Republican law, and of any document issued by the Council for Veterinary Medicinal Products.

(2) For the purposes of this section the production of a copy of any part of the corresponding Republican law –

(a) contained in any printed collection of laws purporting to be printed and published by an authority of the Republic; or

(b) contained in any issue of the Gazette of the Republic; or

(c) purporting to be printed by the Government Printer of the Republic, by whatever name called,

shall be incontrovertible evidence in Court and for all purposes whatsoever of the due and lawful making of such law.

(3) For the purposes of this section, a version of the whole or any part of the corresponding Republican law in the English language –

(a) purporting to be produced by any authority of the Republic; or

(b) certified as being accurate by any officer of the Administration considered by the Court to have been at the time of such certification a competent and adequate translator into the English language from the language in which the Republican law was published in the Republic; or
(c) given or produced in the course of the oral evidence of any person whom the Court considers to be a competent translator for the purpose; or

(d) stated orally in Court or produced in writing by a Registrar or official Court interpreter,

may be held by the Court to be incontrovertible evidence for all purposes whatsoever that such version is the accurate English version of the corresponding Republican law or part thereof.

(4) For the purposes of this section, the production of –

(a) a copy of a document such as is referred to in subsection (1) above, the accuracy of which is certified in writing by a senior officer of the Council for Veterinary Medicinal Products; or

(b) an English translation of such a document, the accuracy of which is certified in writing by a translator of recognised competence,

may be held by the Court to be incontrovertible evidence for all purposes of the contents of such document.

32. The existence of a marketing authorisation in respect of a veterinary medicinal product shall not affect the civil or criminal liability of either the manufacturer of the veterinary medicinal product or of the holder of the marketing authorisation for the veterinary medicinal product.

33. The Administrator may make regulations in relation to any matter that is required to be or may be prescribed under this Ordinance, and more generally in relation to any matter for the more effective application of the provisions of this Ordinance.

34. The Medicines (Control of Sale, Supply and Manufacture) Ordinance 2000 is repealed so far as it relates to medicinal products for administration to animals.

35. This Ordinance shall come into force on the day of its publication in the Gazette, save that any provision of this Ordinance in relation to which the corresponding provision under the corresponding Republican law is not in force in the Republic on that day, shall not come into force until the day that that corresponding provision comes into force in the Republic.

18th October 2002

D.J. BONNER, (205/2/2)
Chief Officer.