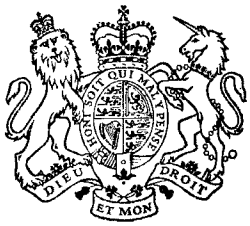

SUPPLEMENT No. 2
TO
THE SOVEREIGN BASE AREAS GAZETTE
No. 1256 of 27th August 2002
LEGISLATION

THE MEDICINES FOR HUMAN USE ORDINANCE 2002.

ARRANGEMENT OF SECTIONS

PART I

PRELIMINARY

PART V

CLASSIFICATION, WHOLESALE DISTRIBUTION AND PROVISIONS ON PRICES OF MEDICINAL PRODUCTS

PART VI

MISCELLANEOUS PROVISIONS

ORDINANCE 20 OF 2002

AN ORDINANCE

TO PROVIDE FOR THE CONTROL OF QUALITY, SUPPLY AND PRICES OF MEDICINES FOR HUMAN USE

D.E. RADCLIFFE
ACTING ADMINISTRATOR

5th August 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 Medicines for Human Use Ordinance 2002. Short title.

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

"adverse reaction" means a reaction which is harmful and unintended and which occurs when a medicine is taken in doses normally used by humans for the prophylaxis, diagnosis or treatment of disease or the restoration, correction or modification of physiological function;

"allergen product" means a product which is intended to identify or to induce a specific acquired alteration of the immunological response to an allergizing agent;

"Authorised Inspector" means a person appointed as an Authorised Inspector under section 96(1) of the corresponding Republican law;

"Commission" means the Commission of the European Union;

"common name" in relation to a medicinal product means its international common name as recommended by the World Health Organisation, or where one has not been recommended, the usual common name of the medicinal product;

"corresponding Republican law" means Republican Law No.70(I)/2001 and includes any legislation of the Republic amending or substituting that Law and any subordinate legislation made under that Law or under any such amending or substituting legislation; and any reference to a particular provision of the corresponding Republican law shall be construed accordingly;

"Council" (except in the expression "Medicines Council") means the Council of the European Union;

"dosage" in relation to a medicinal product means the quantity of active substance which is contained in a dose unit or in a volume or weight unit, depending on the form of presentation of the medicinal product in question;

"European Agency for the Evaluation of Medicinal Products" means the Agency of that name which was established under Council Regulation 2309/93/EEC of July 22nd 1993 and includes any body to which the functions of that Agency might be transferred;

"execution of a prescription" means the supply of any medicine, in accordance with a prescription issued by a registered doctor , dentist or veterinarian;

"galenical preparation outside pharmacopoeia" means any medicine which is prepared in a pharmacy in accordance with a prescription intended for a particular patient;

"galenical preparation of the pharmacopoeia in use at the time" means any medicine which is prepared in a pharmacy in accordance with the prescription of a pharmacopoiea and is intended to be supplied directly to the patients served by the pharmacy in question;

"generator" means any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide, which is obtained by elution or by any other method and is used in a radiopharmaceutical product;

"homeopathic medicinal product" means any medicinal product containing one or more active substances and prepared from products, substances or compositions called homeopathic stocks, in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the member States;

"immediate packing" in relation to a medicinal product means the container or any other form of packing which is in direct contact with the medicinal product;

"kit" means any ready-made preparation which is reconstituted or combined with radionuclides in the final pharmaceutical product, usually prior to its administration;

"label" means the indications on the outer or immediate packing of a medicinal product;

"marketing" in relation to a medicinal product, means any activity consisting of possession, offer, delivery or disposal of the medicinal product in the market and cognate expressions shall be construed accordingly;

"medicinal product derived from human blood or human blood plasma" means any medicine based on blood constituents, which is prepared industrially by private or public establishments and which includes in particular, albumin, coagulating factors, immunoglobulins of human origin;

"medicinal product" or "proprietary medicinal product" means any ready prepared medicine, which is marketed under a special name and in a special package;

"medicine" means any substance or combination of substances presented for treating or preventing disease in human beings or animals and which may be administered to humans or animals with a view to making a medical diagnosis, to restoring or improving or modifying physiological functions in humans or animals, and includes radiopharmaceutical products, medicinal products based on constituents derived from human blood or human blood plasma, immunological products contained in serum toxin vaccines or allergen products or homeopathic medicinal products;

"Medicines Council" means the Medicines Council established in accordance with the provisions of section 4 of the corresponding Republican law;

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

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

"name of the medicinal product" means its brand name or its common or scientific name together with the trade mark or the name of the manufacturer. The brand name must not be such as to be capable of being confused with the common name;

"outer packaging" means the packing in which the immediate packaging of a medicinal product is placed;

"package leaflet" means the information sheet for the user, which accompanies a medicinal product;

"precursor" means any radionuclide other than one in a kit and which is prepared for the radio-labelling of another substance prior to its administration;

"radiopharmaceutical product" means any medicinal product intended for human use, which when ready for use for medical purposes, contains one or more radionuclides (radioactive isotopes);

"registered" means –

(a) in relation to a doctor, a practitioner as defined by section 2 of the Medical Practitioners Ordinance 1964; Ordinance 10/64.

(b) in relation to a dentist, a practitioner as defined by section 2 of the Dentists Ordinance 1964; Ordinance 11/64.

(c) in relation to a veterinarian, a practitioner as defined by section 2 of the Veterinary Surgeons Ordinance 1964; Ordinance 21/64.

(d) in relation to a pharmacist, a pharmacist as defined by section 2 of the Pharmacy and Poisons Ordinance 1964; Ordinances 23/64, 10/70, 4/71, 17/89.

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

"stocks" means substances or preparations used as starting materials or preparations of starting materials;

"substance" means any substance irrespective of its origin which may be –

(a) human, such as human blood and human blood products;

(b) animal, such as micro-organisms, whole animals , parts of organs, animal secretions, toxins, substances produced from extracts, blood products; or

(c) vegetable, such as micro-organisms, plants, parts of plants, plant secretions, substances produced from extracts; or

(d) chemical, such as chemical elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis;

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

"vaccines, toxins or serums" include, in particular –

(a) agents used to induce active immunity (such as anti-cholera vaccine, BCG, anti-polio vaccine, small pox vaccine);

(b) agents used to diagnose the degree of immunity, including tuberculin PPH, toxins for the Schick and Dick tests and brucellin;

(c) agents used to induce passive immunity (such as diphtheria antitoxin, immune cow pox globulin or antilymphocytic globulin).

Scope of Ordinance.

3. - (1) The provisions of this Ordinance shall apply to medicinal products for human use as defined in section 2, which are intended to be placed on the market in the Areas.

(2) This Ordinance shall not apply to-

(a) any galenical preparation;

(b) medicines intended for experiments in relation to research and development;

(c) intermediate products intended for subsequent industrial processing by an authorised manufacturer;

(d) radionuclides used in the form of sealed sources;

(e) radiopharmaceutical products prepared in accordance with the directions of the manufacturer at the time of use, by generators, kits or precursor radiopharmaceutical products, for which a marketing authorisation has been granted;

(f) whole blood, plasma or blood cells of human origin;

(g) homeopathic medicines which are prepared in the form of galenical medicines outside pharmacopoeia or in the form of galenical medicines of the pharmacopoeia in use at the time.

(3) Subject to the provisions of this Ordinance, the Chief Officer may, in order to fulfil special needs and having regard to any advice of the Medicines Council, by a decision published in the Gazette, exclude from the application of the provisions of Parts II to VI, medicines, including homeopathic medicines, supplied in response to a medical prescription, which were prepared in accordance with

the specifications of a registered doctor and which are intended to be administered to his own patients under his direct personal responsibility. In the case of the formulation of allergen mixtures, in particular, it shall not be permissible to prescribe more than four allergens and up to six grasses.

PART II

MARKETING OF MEDICINAL PRODUCTS

Marketing authorisations.

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

(a) the Medicines Council, in accordance with the relevant provisions of the corresponding Republican law; or

(b) the European Agency for the Evaluation of Medicines, in accordance with the provisions of European Council Regulation 2309/93/EEC of 22nd July 1993, as it may be amended or replaced from time to time.

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

Labelling.

5. - (1) Subject to subsections (2) to (8) below, the outer packaging or where there is no outer packaging, the immediate packaging of a medicinal product shall bear the following information -

(a) the name of the medicinal product, followed by the common name where the medicinal product contains only one active substance and where the name is a brand name: where the medicinal product is marketed in several pharmaceutical forms or several strengths (or both), the pharmaceutical form or strength (or both) for babies, children and adults respectively shall be included;

(b) the active substances, expressed qualitatively and quantitatively for a dosage unit or according to the form of administration, for a given volume or weight, using their common names;

(c) the pharmaceutical form and the contents by weight, volume or by number of doses of the medicinal product;

(d) a list of those excipients known to have a recognised action or effect: where, however, the product is injectable, or is a topical or eye preparation, all substances shall be stated;

(e) the method and if necessary the route of administration;

(f) a special warning that the medicinal product must be stored out of the reach of children;

(g) any other special warning, which may be necessary;

(h) the expiry date of the medicinal product in clear terms (month/year);

(i) any special storage precautions in relation to the medicinal product which may be appropriate;

(j) any special precautions in relation to the disposal of any unused product or of waste materials from such product, which may be appropriate;

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

(l) the number of the marketing authorisation;

(m) the manufacturer's batch number;

(n) in relation to a medicinal product which may lawfully be provided without a medical prescription, instructions for its use;

(o) in the case of a homeopathic medicinal product, an indication of its homeopathic character in clear and legible letters.

(2) The outer packaging may include symbols or pictograms designed to clarify certain information referred to in subsection (1) above and other information compatible with the summary description of the product's characteristics and which is useful for health education, but excluding anything of a promotional nature.

(3) Immediate packaging other than that referred to in subsection (4) below shall bear the indications provided for in subsections (1) and (2).

(4) Where immediate packaging is contained in outer packaging, in accordance with the provisions of subsections (1) and (2) then –

(a) if the immediate packaging takes the form of blisters, it shall bear at least the following particulars -

(i) the name of the medicinal product in accordance with the provisions of paragraph (a) of subsection (1),

(ii) the name of the holder of the marketing licence,

(iii) the expiry date of the medicinal product,

(iv) the manufacturer's batch number;

(b) if the immediate packaging is too small to accommodate the particulars listed in subsections (1) and (2) it shall bear the following particulars -

(i) the name of the medicinal product and where appropriate, the dosage,

(ii) the route of administration,

(iii) the expiry date of the medicinal product,

(iv) the manufacturer's batch number,

(v) the contents by weight, volume or units.

(5) The outer carton and the container of a medicinal product containing radionuclides, shall be labelled in accordance with the regulations of the International Atomic Energy Agency for the safe transport of radioactive materials. Furthermore, the labelling shall be in conformity with the following requirements –

(a) the label on the shielding shall contain the particulars referred to in subsections (1) and (2) and explain in full the codings used on the vial and shall indicate, where necessary, for a given date and time, the amount of radioactivity per dose or vial and the number of capsules or, for liquids, the number of millimetres in the container; and

(b) the vial shall be labelled with the following information –

(i) the name or code of the medicinal product including the name or chemical symbol of the radionuclide,

(ii) the batch identification and the expiry date,

(iii) the international symbol of radioactivity,

(iv) the name of the manufacturer,

(v) the amount of radioactivity as referred to in paragraph (a) above.

(6) The particulars provided for in subsections (1), (2), (4) and (5) shall be indicated in a legible, easily comprehensible and indelible manner.

(7) The particulars provided for in subsections (1), (2), (4) and (5) above shall appear either in English or in Greek:

Provided that this provision shall not preclude the required particulars being given additionally in other languages, provided that the same particulars appear in all the languages used.

(8) Where any additional requirements relating to the labelling of medicinal products marketed in the Republic are imposed in accordance with the corresponding Republican law, the like requirements shall also be fulfilled in relation to any medicinal products marketed in the Areas.

Package leaflet.

6. - (1) The inclusion of a package leaflet in the packaging of a medicinal product shall be compulsory unless all the information referred to in subsections (2), (3) and (4) below is directly conveyed either on the outer packaging or on the immediate packaging of the medicinal product.

(2) The package leaflet for a medicinal product shall include, in the following order –

(a) for the identification of the medicinal product –

(i) the name of the medicinal product followed by its common name, if the product contains only one active substance and if its name is a brand name. Where a medicinal product is marketed under several pharmaceutical forms or strengths (or both) the pharmaceutical form or strength (or both) for babies, children, and adults respectively shall be included in the name of the medicinal product,

(ii) a full statement of the active substances and excipients expressed quantitatively and qualitatively, using their common names, for each form of presentation of the medicinal product,

(iii) the pharmaceutical form and the contents by weight, volume or number of each dose of the product for each form of presentation of the medicinal product,

(iv) the pharmacotherapeutic group or the type of activity in terms easily comprehensible to a patient,

(v) the name and the address of the holder of the marketing authorisation and of the manufacturer;

(b) the therapeutic indications, unless under section 36(3) of the corresponding Republican law, the Medicines Council decides that the inclusion of such indications has disadvantages for patients and should for that reason not be given;

(c) a list of the information which any person taking or using the medicinal product needs to know before taking or using it, that is to say -

(i) the contra-indications,

(ii) appropriate precautions for use,

(iii) forms of interactions with other medicinal products and other forms of interactions, for example with alcohol, tobacco or foodstuffs, which may affect the action of the medicinal product,

(iv) any appropriate special warnings.

The above list shall take into account the particular condition of certain categories of users such as children, pregnant or breastfeeding women, elderly persons and persons with specific pathological conditions. Mention, where appropriate, shall be made of the effects of the medicinal product on the ability to drive vehicles or operate machinery and mention shall also be made of excipients, knowledge about which is necessary for the effective and safe use of the medicinal product;

(d) the necessary and usual instructions for common use, in particular –

(i) dosage,

(ii) the method and, where appropriate, the route of administration,

(iii) the frequency of administration, specifying, if necessary, the appropriate time at which the medicinal product may or, as the case may be, should be administered, depending on the nature of the product,

(iv) the period for which the product may be taken or used if this is of limited duration,

(v) the action to be taken in the case of an overdose, for example the indicative symptoms of an overdose and the appropriate emergency procedures to be followed,

(vi) the course of action to be taken if one or more doses have not been taken,

(vii) indication of the risk (if any) of withdrawal effects;

(e) a description of the adverse reactions that may occur under normal use of the medicinal product and the action to be taken in such event. The patient must be expressely invited to communicate to his pharmacist any adverse reaction not mentioned on the package leaflet;

(f) a reference to the expiry date indicated on the label with –

(i) a warning against using a medicinal product after this date,

(ii) where appropriate, special storage precautions in respect of the medicinal product,

(iii) if necessary, a warning against visible signs of deterioration;

(g) the date on which the package leaflet was last revised.

(3) The outer packaging may include symbols or pictograms designed to clarify certain information referred to in subsection (2) above and other information compatible with the summary of product characteristics, which is useful for health education, but excluding anything of a promotional nature.

(4) In relation to a radiopharmaceutical product, generator, kit or precursor, in addition to the matters mentioned in subsections (2) and (3) above, the leaflet shall include any precautions to be taken by the user and the patient during the preparation and administration of the product and special precautions for disposal of the container and any unused contents.

(5) The particulars in a package leaflet shall be legible, clear and comprehensible for the patient and indicated in at least the English or Greek language. Other languages may be used in addition provided that the same information is given in all the languages used.

Homeopathic medicinal products.

7. - (1) In addition to the clear mention of the words "homeopathic medicinal product", the label and the package leaflet of a homeopathic medicinal product which has been registered in the Register for Homeopathic Medicinal Products in accordance with the provisions of section 19 of the corresponding Republican law, shall bear the following, and no other, indications –

(a) the scientific name of the stock or stocks, followed by the degree of de-concentration, making use of the symbols of European pharmacopoeia or in the absence of these, of the symbols of the pharmacopoeias currently in use in member States;

(b) the name and address of the applicant who applies to register the medicinal product and, where appropriate, of the manufacturer;

(c) the method of administration and, where required, the route of administration;

(d) the expiry date in clear terms (month/year);

(e) the pharmaceutical form;

(f) the contents of the sales presentation;

(g) any special storage precautions which may be required;

(h) any special warning that may be necessary in respect of the medicinal product;

(i) the manufacturer's batch number;

(j) the registration number;

(k) the words "medicinal product without approved therapeutic indications";

(l) a warning advising the user to consult a doctor if his symptoms persist during the course of using the medicinal product.

(2) Where, in accordance with the corresponding Republican law, the Medicines Council imposes additional labelling requirements –

(a) that the price of a medicinal product is to be shown;

(b) as to the conditions for any refund of the price by a social security body,

like requirements shall be complied with in the Areas.

Further provisions concerning labelling.

8. - (1) Any decision of the Medicines Council to grant a marketing authorisation in respect of a 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 of the Medicines Council not to oppose any application proposing any amendment to the labelling of, or package leaflet for, such a medicinal product shall not affect any civil liability of the manufacturer of the medicinal product or of the holder of the marketing authorisation in respect of the medicinal product.

(2) Where under the corresponding Republican law the Medicines Council 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 MANUFACTURE OR IMPORTATION OF MEDICINAL PRODUCTS

Prohibition on manufacture or importation of medicinal products.

9. - (1) A person shall not manufacture any medicinal product in the Areas nor import into the Areas any 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 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 the course of dispensing a prescription to an individual; or

(b) the carrying out of any of the activities described in paragraph (a) above by a registered doctor, dentist or veterinarian in the course of any medical diagnosis or in the course of any treatment of a patient.

PART IV

ADVERTISING OF MEDICINAL PRODUCTS

Meaning of advertising.

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

Scope of application of Part IV.

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

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

(b) the advertising of medicinal products to persons qualified to issue prescriptions for, or to supply medicinal products;

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

(d) the supply of samples of medicinal products;

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

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

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

(2) Nothing in this Part shall apply to –

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

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

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

Restrictions on advertising.

12. A person shall not advertise any medicinal product in the Areas in any manner in which he could not lawfully advertise it in the Republic in accordance with sections 62 to 70 of the corresponding Republican law.

Control of advertising.

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

(2) In exercising the powers conferred upon it by the provisions of this Ordinance, the Medicines Council shall have regard to all interests involved and in particular to the public interest.

Applications to the Court by the Medicines Council.

14. - (1) Where the Medicines Council, following an investigation relating to an advertisement in accordance with the provisions of section 13, considers that an advertisement is misleading or is not compatible with the provisions of this Part, it may apply to the Court by originating summons, requesting the issue of a prohibition or mandatory order, including an interim order, against any person believed to be involved or likely to be involved in the issue or publication of the advertisement.

(2) The Medicines Council shall give its reasons adequately and notify them in writing to any complainant of its decision to apply, or, as the case may be, not 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.

Applications to the Court by other parties.

15. The right to apply to the Court for the issue of a prohibition or mandatory order, including an interim order, against any person who is or is likely to be involved in the issue or publication of an advertisement, shall be available to any person or to any lawfully established organisation, which either according to the law or its articles of association, has a sufficient legal interest for the prohibiting of misleading advertisements or more generally of advertisements which are not compatible with the provisions of this Part.

Powers of the Court.

16. - (1) The Court before which an application is made, in accordance with the provisions of section 14 or 15 may, under the Civil Procedure Rules, make a prohibition or mandatory order, with such conditions as it deems necessary, if it is satisfied that the advertisement which is the subject of the application is misleading, or not compatible with the provisions of this Part. The Court shall have regard to all interests involved and in particular to the public interest before making an order.

(2) Where the Court considers that such measures are necessary for the protection of all interests involved and in particular the public interest, it may –

(a) order the cessation of the misleading advertisement and generally of advertising which is not compatible with the provisions of this Part; or

(b) prohibit the publication of a misleading advertisement or of an advertisement which is not compatible with the provisions of this Part and where publication is imminent.

(3) The Court may issue a prohibition or mandatory order even without proof of –

(a) loss or actual damage to any person, resulting from the 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 a misleading advertisement and in general of any advertisement which is not compatible with the provisions of this Part, the cessation of which has been ordered by a final decision, the Court may order –

(a) the publication of that decision in full or in part, in such a 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 DISTRIBUTION AND PROVISIONS ON PRICES OF MEDICINAL PRODUCTS

Classification of medicinal products.

17. - (1) Any classification of a medicinal product by the Medicines Council under Part VII of the corresponding Republican law as being either a medicinal product which is –

(a) subject to medical prescription; or

(b) not subject to medical prescription,

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

(2) Any sub-classification by the Medicines Council under Part VII of the corresponding Republican law of a medicinal product which is subject to medical prescription as being a medicinal product which –

(a) may be supplied on a medical prescription which -

(i) is renewable, or

(ii) is not renewable;

(b) is subject to a special medical prescription; or

(c) may be prescribed for restricted use, that is to say for use in specialised areas,

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

Wholesale distribution.

18. - (1) Without prejudice to section 4, a person shall not distribute any medicinal product in the Areas by way of wholesale distribution unless he holds a wholesale distribution licence granted to him by the Medicines Council authorising him to distribute by way of wholesale distribution medicinal products of that description or unless he is otherwise permitted under the corresponding Republican law to distribute by way of wholesale distribution medicinal products of that description.

(2) For the purposes of this Ordinance a medicinal product is distributed by way of wholesale distribution in any case where it is distributed otherwise than directly to a member of the public.

Obligations and duties of a wholesaler.

19. A person who is licensed or otherwise permitted under the corresponding Republican law to distribute any medicinal products by way of wholesale distribution shall, in relation to such distribution, be subject to the same conditions, obligations and duties in the Areas as he is subject to under the corresponding Republican law.

Maximum permissible prices to be observed.

20. Without prejudice to section 19, a person shall not sell or offer for sale either by way of retail sale or by way of wholesale, any medicinal product at a price exceeding the maximum permissible

retail price, or as the case may require, the maximum permissible wholesale price that may be prescribed for that product by or under the provisions of the corresponding Republican law.

Indication of retail price.

21. A retailer shall indicate the selling price in clear figures on the outer packing, or if there is no such packing, on the immediate packing, of any medicinal product which he offers or exposes for sale.

PART VI

MISCELLANEOUS PROVISIONS

Authorised Inspectors.

22. - (1) An Authorised Inspector shall have the power to enter at any reasonable time any premises other than a dwelling, where medicinal products are controlled, stored, offered for sale or sold, in order to -

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

(b) inspect the places, installations and equipment and auditing records as well as all information concerning compliance with the provisions relating to the wholesale distribution of medicinal products;

(c) inspect the places where medicinal products are displayed or held for sale;

(d) take samples;

(e) confiscate any medicinal products in respect of which there is reasonable cause to believe that an offence or infringement has been committed under this Ordinance and which products may be required as evidence:

Provided that confiscated medicinal products shall be returned to their owner if administrative penalties are not imposed or if criminal proceedings are not commenced in relation to the infringement or offence within two months from the day the medicinal products were confiscated. If the products concerned have been destroyed or damaged, reasonable compensation shall be paid to the owner.

(2) Any person who, whether personally or through an employee of his or other representative, obstructs or prevents an Authorised Inspector from exercising any of his duties in accordance with the provisions of subsection (1) above, shall be guilty of an offence and shall be liable, on conviction, to imprisonment not exceeding six months or to a fine not exceeding £1000 or to both such penalties.

(3) A sample taken in accordance with the provisions of subsection (1)(d) above, shall be sent for testing to the General Government Laboratory of the Republic or to the Laboratory of the Pharmaceutical Services of the Republic or to any other laboratory which may be designated by the Medicines Council. The results of the test shall be communicated to the holder of the marketing authorisation, who shall be entitled to submit an objection within 15 days from the day that the results were notified to him.

(4) Where an objection against the results of any tests has been submitted in accordance with the provisions of subsection (3) above, the person objecting may request the re-testing of the sample in

question. The holder of the marketing authorisation or his representative may be present at the re-testing of the sample.

Imposition of administrative penalties.

23. - (1) The Medicines Council may examine, either following a complaint or of its own volition, whether a person, personally or through an employee of his or other representative of his, has –

(a) contravened section 5, 6, 7, 12, 18, 19, 20 or 21 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 15(3), 31(1), 35, 36, 37, 41, 56(1), 56(2), 57, 68, 69, 75 or 76, 84(1), 84(2), 86(2) or 95 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 Medicines Council 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, on any examination carried out in accordance with the provisions of subsection (1) above, the Medicines Council ascertains that there has been a contravention of any of the provisions referred to in subsection (1) above, it shall have the power to take one or more of the following actions, depending on the nature, duration and seriousness of the contravention –

(a) to order or advise the offender to cease the contravention within a specified period of time, and to refrain from repeating it in the future or, where the contravention has ceased before the Medicines Council has made a decision, to confirm that a contravention 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 due for each day that the contravention continues.

(3) The Medicines Council shall give its reasons for any decision it takes relating to the exercise of any of the powers provided for in subsection (2) above.

Payment and recovery of administrative penalties.

24. - (1) An administrative penalty such as is provided for in section 23(2) shall be imposed on an offender by the Medicines Council following a reasoned decision in writing which confirms the contravention, provided that the Medicines Council gives the offender the opportunity to make representations in writing within 30 days from the day he was notified of the decision to impose a penalty.

(2) The amount of the administrative penalty shall be collected by the Medicines Council as follows –

(a) if no appeal has been made to the Senior Judge's Court within the period of 75 days starting on the day that the decision of the Medicines Council to impose the penalty was notified to the offender, immediately after the expiry of that period;

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

(3) In the case of a failure to pay a penalty imposed by the Medicines Council in accordance with the provisions of this Ordinance, the amount of the penalty shall be recoverable as a civil debt.

Offences.

25. - (1) Any person who, whether personally or through an employee or other representative of his –

(a) places on the market of the Areas –

(i) a medicinal product in respect of which there is no valid current marketing authorisation, in contravention of section 4(1),

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

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

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

(c) engages in the wholesale distribution of a medicinal product otherwise than in accordance with section 14,

shall be guilty of an offence, and shall be liable, on conviction, to imprisonment not exceeding 5 years or to a fine not exceeding £50.000 pounds or to both such penalties. Further, the court judging the case may order the confiscation of the medicinal products in respect of which the offence was committed.

Liability of individuals for offence by body corporate.

26. Where an offence under this Ordinance is committed by a body corporate and it is proved that such 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 the like offence.

Consent of Attorney General and Legal Adviser to any prosecution.

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

Judicial notice.

28. - (1) In any civil or criminal proceedings under this Ordinance the Court may take judicial notice of the whole or any part of the corresponding Republican law, and of any licence or authorisation issued by the Medicines Council.

(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 purported to be printed and published by an authority of the Republic; or

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

(c) purported 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 copy of a licence or authorisation referred to in subsection (1) above or an English translation thereof, the accuracy of which or of its translation is certified in writing by a senior officer of the responsible Government Department of the Republic or by a recognised competent translator, as the case may be, may be held by the Court to be incontrovertible evidence for all purposes of the contents of such document.

Civil and criminal liability unaffected by a marketing authorisation.

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

Regulations.

30. 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.

Repeal.

31. The Medicines (Control of Sale, Supply and Manufacture) Ordinance 2000 is repealed so far as it relates to medicinal products for administration to, or use by, human beings.

Commencement.

32. 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.

5th August 2002 D.J. BONNER,

(205/2/2) Chief Officer.

ORDINANCE 21 OF 2002

AN ORDINANCE TO AMEND AND MODIFY THE TRADE MARKS ORDINANCE

D.E. RADCLIFFE
ACTING ADMINISTRATOR

5th August 2002.

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

Short title.

Cap.268 (Laws of Cyprus) and Ordinances 1/63, 21/91.

1. This Ordinance may be cited as the Trade Marks Ordinance 2002 and shall be read as one with the Trade Marks Ordinance (hereinafter referred to as "the principal Ordinance").

Amendment of section 2 of the principal Ordinance.

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

(a) the expression "mark" and its definition in subsection (1) shall be omitted;

(b) for the definition of the expression "trade mark" in subsection (1) there shall be substituted the following –

" "trade mark" means a mark consisting of any signs capable of being represented graphically (particularly words, including personal names, designs, letters, numerals, the shape of goods or of their packaging, or any combination of these), provided that such signs are capable by their nature of distinguishing the goods or services of an undertaking from those of other undertakings, since such mark is used or is intended to be used for the purposes of so distinguishing;";

(c) after the definition of the expression "limitations" in subsection (1) there shall be inserted the following new definition –

" "Paris Convention for the Protection of Industrial Property" means the convention ratified in the Republic by Republican Laws Nos.63 of 1965 and 66 of 1983; ";

(d) after subsection (2) there shall be added the following new subsection to be numbered subsection (3) –

"(3) For the purposes of this Ordinance, any reference to a trade mark shall be read and interpreted as including a reference to a certification trade mark as defined in section 37A and to a collective trade mark, as defined in section 37B.".

Amendment of section 3 of the principal Ordinance.

3. Subsection (2) of section 3 of the principal Ordinance, which continued the division of the register into Part A and Part B, is hereby repealed and in consequence –

(a) any reference in any other provision of the principal Ordinance to either Part A or Part B of the register shall be construed as a reference to the undivided register; and

(b) subsections (3) and (4) of the principal Ordinance shall be renumbered as subsections (2) and (3) respectively.

Amendment of section 6 of the principal Ordinance.

4. Section 6 of the principal Ordinance shall be amended as follows -

(a) for subsection (1) there shall be substituted the following –

"(1) Subject to the provisions of this section and of sections 9 and 10, the registration of a trade mark in the register, whether before or after the coming into force of this Ordinance, shall give the proprietor of the trade mark the exclusive right to the use of such mark.";

(b) immediately after subsection (1), the following new subsections (2) and (3) shall be inserted and the existing subsections (2), (3) and (4) shall be renumbered as subsections (4), (5) and (6) respectively –

"(2) The proprietor of a trade mark shall have the right to prohibit any third person from using in the course of trade without his consent –

(a) a sign identical with the trade mark, for goods or services identical with the goods and services in respect of which the trade mark has been registered;

(b) a sign which, due to its identity with or similarity to the trade mark and the identity or similarity of the goods or services covered by the trade mark and the sign, there exists a likelihood of confusion on the part of the public, including the likelihood of association of the sign with the trade mark;

(c) a sign identical with or similar to the trade mark for goods or services not similar to the goods and services in respect of which the trade mark has been registered, where such trade mark has a reputation in the Island of Cyprus and where use of that sign, without reasonable cause, would take advantage of, or would be detrimental to, the distinctive character or the repute of the trade mark without any cost.

(3) For the purpose of this section "use of a sign" includes –

(a) affixing the sign to goods or to their packaging;

(b) offering the goods or putting them on the market or stocking them for these purposes under that sign, or offering or supplying services under it;

(c) importing or exporting the goods under the sign;

(d) using the sign on business papers and in advertising;";

(c) after subsection (6), as renumbered in accordance with paragraph (b) above, there shall be added the following new subsection to be numbered (7) –

"(7) The right to the use of a trade mark given by registration, as provided above, shall not entitle the proprietor of such mark to prohibit its use in relation to any goods which have been put on the market in the European Community under the trade mark by the proprietor or with his consent:

Provided that this subsection shall not apply where the proprietor has legitimate reasons to oppose further commercialization of such goods, particularly when the condition of the goods is changed or impaired after they have been put on the market.".

Repeal of section 7 of the principal Ordinance.

5. Section 7 of the principal Ordinance is hereby repealed.

Substitution of section 10 of the principal Ordinance.

6. For section 10 of the principal Ordinance there shall be substituted the following -

"Saving for the use of name, address etc.

10. The registration of a trade mark shall not prohibit a third party from using in the course of trade –

(a) his own name and address;

(b) indications concerning the kind, quality, quantity, intended purpose, value, geographical origin, the time of production of any goods, or of the rendering of any services, or any other characteristics of any goods or services; or

(c) the trade mark, where it is necessary, so as to indicate the intended purpose of a product or service, in particular as accessories or spare parts,

provided that such use is in accordance with honest practices in industrial or commercial matters.".

Substitution of section 11 of the principal Ordinance.

7. For section 11 of the principal Ordinance there shall be substituted the following -

"Absolute reasons for non-registration of a trade mark.

11. - (1) The following shall not be registered as trade marks or, if registered, shall be liable to be declared invalid -

(a) signs which cannot constitute a trade mark in accordance with the definition of that expression given in section 2(1);

(b) trade marks which are devoid of any distinctive character;

(c) trade marks consisting exclusively of signs or indications which may serve, in trade, to designate the kind, quality, quantity, intended purpose, value, geographical origin, or the time of production of any goods or of the rendering of any services, or any other characteristics of any goods or services;

(d) trade marks consisting exclusively of signs or indications which have become customary in current language or in the bona fide and established practices of the trade;

(e) trade marks consisting exclusively of –

(i) the shape which results from the nature of the goods themselves, or

(ii) the shape of goods which is necessary to obtain a technical result, or

(iii) the shape which gives substantial value to the goods;

(f) trade marks which could deceive the public, particularly as to the nature, quality or geographical origin of the goods or services;

(g) trade marks which are to be refused or invalidated pursuant to Article 6 of the Paris Convention for the Protection of Industrial Property;

(h) trade marks which cover a sign of highly symbolic significance, in particular a religious symbol;

(i) trade marks of which the application for registration was made in bad faith by the applicant.

(2) A trade mark shall not be refused registration or be declared invalid in accordance with paragraph (b), (c) or (d) of subsection (1) above, if before the date of application for its registration and following the use which has been made of it, it has acquired a distinctive character.".

Repeal of section 12 of the principal Ordinance.

8. Section 12 of the principal Ordinance is hereby repealed.

Substitution of section 13 of the principal Ordinance.

9. For section 13 of the principal Ordinance there shall be substituted the following -

"Prohibition of registration of scandalous design etc.

13. Any scandalous design or any sign contrary to law or to the accepted principles of morality shall not be registered as a trade mark or part thereof or, if registered, it may be declared invalid.".

Substitution of section 14 of the principal Ordinance.

10. For section 14 of the principal Ordinance there shall be substituted the following -

"Prohibition of registration of identical and similar trade marks.

14. - (1) No trade mark shall be registered or, if registered, it may be declared invalid, if –

(a) it is identical with an earlier trade mark and the goods or services in respect of which the trade mark is applied for or is registered are identical with the goods or services in respect of which the earlier trade mark is protected;

(b) as a result of its identity with or similarity to an earlier trade mark and the identity or similarity of the goods or services covered by such trade mark, there exists a likelihood of confusion on the part of the public, which includes the likelihood of association with the earlier trade mark;

(c) it is identical with or similar to an earlier trade mark and the goods or services in respect of which the trade mark is applied for or is registered are not similar to the goods or services in respect of which the earlier trade mark is protected, where the earlier trade mark has a reputation in the Island of Cyprus and where use of the subsequent trade mark, without reasonable cause, would take advantage of, or would be detrimental to the distinctive character or the repute of the trade mark without any cost;

(d) the use of the trade mark may be prohibited by virtue of an earlier right, apart from the rights provided for by section 14A and especially by virtue of –

(i) a right to a name,

(ii) a right to personal portrayal,

(iii) a copyright,

(iv) a right to industrial property;

(e) the trade mark is identical with, or similar to, an earlier collective trade mark conferring a right which expired within the period of three years immediately preceding the application for registration;

(f) the trade mark is identical with, or similar to, an earlier certification trade mark conferring a right which had expired within the period of three years immediately preceding the application for registration;

(g) the trade mark is identical with, or similar to, an earlier registered trade mark in respect of identical or similar goods or services which earlier registered trade mark had been lost for failure to renew within the period of two years immediately preceding the application for registration, unless the proprietor of the earlier registered trade mark consented to the registration of the subsequent trade mark or, during the period of two years immediately preceding the period of two years mentioned above, the proprietor of such mark did not substantially use his trade mark for goods or services in respect of which it has been registered.

(2) In the case of a bona fide honest simultaneous use, or of other special circumstances which in the opinion of the Court or the Chief Officer make it proper so to do, the Court or the Chief Officer may permit the registration of trade marks that are identical with, or similar to one another in respect of the same goods or description of goods or services by more than one proprietor, subject to such conditions and limitations, if any, as the Court or the Chief Officer, as the case may be, shall think it fit to impose.

(3) Where separate applications are made by different persons to be registered as proprietors respectively of trade marks which are similar or identical in respect of the same goods or description of goods or services, the Chief Officer may refuse to register any of them, until the respective rights of the persons concerned have been determined by the Court, or have been settled by agreement in a manner approved by the Chief Officer, or, on appeal, by the Court.".

Insertion into the principal Ordinance of sections 14A, 14B and 14C.

11. Immediately after section 14 of the principal Ordinance there shall be inserted the following new sections to be numbered sections 14A, 14B and 14C respectively –

"Earlier trade marks.

14A. - (1) For the purposes of this Ordinance "earlier trade marks" means –

(a) trade marks registered prior to the date of application for registration of a trade mark, taking account of the priorities claimed in respect of those trade marks and which belong to the following categories –

(i) trade marks registered on the register,

(ii) trade marks registered under international arrangements which have effect in the Republic or the Areas,

(iii) Community trade marks registered in the Register of the Office for the Harmonization of the Internal Market;

(b) applications for registration of trade marks of categories (i) to (iii) in paragraph (a) above on the condition of their registration;

(c) trade marks which, at the date of the application for their registration are "commonly known" in the Republic or the Areas within the meaning of Article 6 of the Paris Convention for the Protection of Industrial Property.

(2) For the purposes of this section "Office for the Harmonization of the Internal Market" means the Office of Harmonization within the Internal Market provided for in Commission Regulation (EEC) No. 2868/95 of 13th December 1995 for the application of Council Regulation (EEC) No. 40/94 on the Community mark.

Consent of the proprietor of an earlier mark.

14B. A trade mark shall be registered and, if already registered, shall not be declared invalid, if the proprietor of the earlier registered trade mark or earlier right consents to the registration of the subsequent trade mark.

Loss of right because of acquiescence.

14C. Where the proprietor of an earlier trade mark has acquiesced for a continuous period of five years in the use of a subsequently registered trade mark, he shall no longer be entitled on the basis of the earlier trade mark either to apply for a declaration that the subsequent trade mark is invalid, or to oppose the use of the subsequent registered trade mark in respect of the goods or services for which the subsequent trade mark has been used, unless registration of the

subsequent trade mark was applied for in bad faith:

Provided that the proprietor of a subsequent registered trade mark shall not be entitled to oppose the use of the earlier right, even though that right may no longer be invoked against the subsequent trade mark.".

Repeal of section 17 of the principal Ordinance.

12. Section 17 of the principal Ordinance is hereby repealed.

Amendment of section 19 of the principal Ordinance.

13. Subsection (3) of section 19 of the principal Ordinance is hereby repealed and subsections (4), (5), (6) and (7) of that section shall be renumbered as subsections (3), (4), (5) and (6) respectively.

Amendment of section 20 of the principal Ordinance.

14. For the proviso to subsection (1) of section 20 of the principal Ordinance there shall be substituted the following –

"Provided that the Chief Officer may cause an application to be advertised before its acceptance, if he deems it expedient so to do, and where an application has been so advertised in the prescribed manner, the Chief Officer may, if he thinks fit, advertise it again when it has been accepted, but shall not be bound so to do.".

Substitution of section 28 of the principal Ordinance.

15. For section 28 of the principal Ordinance there shall be substituted the following -

"Reasons for removal from register.

28. - (1) A registered trade mark may be removed from the register in respect of any goods or services in respect of which it is registered, on the application to the Court by any aggrieved person, or, at the option of the applicant and subject to the provisions of section 49, to the Chief Officer, if –

(a) for a continuous period of five years the proprietor for the time being has not put the trade mark to genuine use in connection with those goods or services in respect of which it is registered and there exists no reasonable cause for non-use thereof;

(b) after the date of registration, the trade mark has become the common name in the trade for a product or service in respect of which it is registered, in consequence of acts or inactivity of any proprietor thereof;

(c) in consequence of the use made of it by the proprietor of the trade mark, or with his consent in connection with the goods or services in respect of which it is registered, it is likely to mislead the public, particularly as to the nature, quality or geographical origin of such goods or services.

(2) A registered trade mark shall not be taken off the register by virtue of paragraph (a) of subsection (1) above if, during the interval between the expiry of the continuous period of five years provided for in the said paragraph and the filing of the application for the removal thereof, genuine use of the trade mark has commenced or been resumed:

Provided that the commencement or resumption of the use within three months before the application for removal, which application shall not have effect before the completion of the continuous period of five years of non-use, shall not be taken into account, where the preparatory actions for the commencement or resumption of the use occurred after the proprietor was informed of the possibility of an application for removal being filed.".

Insertion into the principal Ordinance of section 28A.

16. Immediately after section 28 of the principal Ordinance there shall be inserted the following new section to be numbered section 28A:

"Sanctions on grounds of non-use

28A. Where within five years from the date of registration of a trade mark on the register, any proprietor for the time being has not made substantial use of the mark or part of the mark in connection with the goods or services in respect of which the trade mark is registered, or if he has interrupted the use of the trade mark for a continuous period of five years, the trade mark shall be subject, in relation to the goods or services in respect of which it has not been used, and unless a reasonable cause exists for the non-use, to the following limitations –

(a) it may not be invoked in order to declare an opposing subsequent trade mark invalid;

(b) it may not be invoked in order to oppose the registration of an opposing subsequent trade mark;

(c) subject to the application of section 28 in the case of opposing an application for removal from the register, the trade mark may not validly be invoked in proceedings for infringement, if it is proved, after any objection, that the said trade mark may be removed from the register under paragraph (a) of subsection (1) of section 28.".

Amendment of section 29 of the principal Ordinance.

17. Section 29 of the principal Ordinance shall be amended as follows -

(a) in subsection (1) the words "but subject to a degree of control by the registered proprietor" shall be omitted;

(b) in subsection (2) for the words "section 28" there shall be substituted the words "sections 28 and 28A";

(c) for subsection (5) there shall be substituted the following –

"(5) When the Chief Officer is satisfied that the requirements of subsection (4) above have been complied with, he shall register the proposed registered user as a registered user in respect of the goods or services as to which he is satisfied.";

(d) subsection (6) shall be repealed;

(e) subsections (7), (8), (9), (10), (11) and (12) shall be renumbered as subsections (6), (7), (8), (9), (10) and (11) respectively.

Amendment of section 30 of the principal Ordinance.

18. Subsection (2) of section 30 of the principal Ordinance is hereby repealed and subsections (3) and (4) of that section shall be renumbered as subsections (2) and (3) respectively.

Insertion into the principal Ordinance of section 32A.

19. Immediately after section 32 of the principal Ordinance there shall be inserted the following new section to be numbered section 32A –

"Use of trade mark.

32A. For the purposes of this Ordinance –

(a) the use of a registered trade mark shall include its use in a different form as to the particulars which do not alter the distinctive character of the trade mark in the form it is registered;

(b) the use of a registered trade mark with the consent of its proprietor or, in the case of a collective or certification trade mark, the use by persons authorised to use a collective or certification trade mark shall be deemed to be use by the proprietor.".

Amendment of section 33 of the principal Ordinance.

20. Subsection (5) of section 33 of the principal Ordinance is hereby repealed.

Insertion into the principal Ordinance of sections 37A and 37B.

21. Immediately after section 37 of the principal Ordinance there shall be inserted the following new sections to be numbered sections 37A and 37B respectively –

"Certification trade marks.

37A. - (1) A certification trade mark is a trade mark indicating that the goods or services in respect of which it is used are certified by the proprietor of the said mark as to their quality, precision or other characteristics, including the origin, constituents or, in respect of goods, as to the method of their manufacture and, in respect of services, as to the way that they are performed.

(2) The provisions of this Ordinance shall apply to certification trade marks subject to the provisions of the First Schedule.

First Schedule.

Collective trade marks.

37B. - (1) A collective trade mark is a trade mark which distinguishes the goods or services of members of an association which is the proprietor of such mark from the goods or services of other undertakings.

(2) For the purposes of this section the term association includes public corporations, clubs, institutions, co-operative societies and in general, unions and organisations of persons, which, in accordance with the relevant legislation may, under their own name, have rights and obligations, do legal acts, conclude contracts, sue and be sued.

(3) No association shall be registered as a proprietor of a collective trade mark, unless the members of such association deal with the construction, production, manufacturing or trade of goods or with the provision of services.

(4) The provisions of this Ordinance shall apply to collective trade marks, subject to the provisions of the Third Schedule.". Third Schedule.

Insertion into the principal Ordinance of section 54A.

22. Immediately before section 55 of the principal Ordinance there shall be inserted the following new section to be numbered section 54A –

"Reasons for part only of goods or services being unacceptable, removed or invalid.

54A. If the reasons for a trade mark being found to be unacceptable or being removed from the register or declared invalid concern only part of the goods or services in respect of which the trade mark is sought to be or is registered, the finding that the trade mark is unacceptable or its removal from the register or the declaration that it is invalid shall cover only that part of the goods or services in question.".

Amendment of section 59 of the principal Ordinance.

23. Section 59 of the principal Ordinance shall be amended by inserting before the word "Schedule" the word "Second".

Addition of the First Schedule to the principal Ordinance.

24. Immediately after section 60 of the principal Ordinance there shall be added the following Schedule to be called the First Schedule –

"FIRST SCHEDULE

(Section 37A)

CERTIFICATION TRADE MARKS

1. The provisions of this Ordinance shall apply to certification trade marks subject to the following provisions of this Schedule.

2. In relation to a certification trade mark, the definition of the expression "trade mark" in section 2(1) shall be read as if for the words "the goods or services of an undertaking from those of other undertakings" there were substituted the words "goods or services which are certified from similar goods or services which are not so certified".

3. Notwithstanding the provisions of section 11(1)(c), it shall be permissible to register a certification trade mark consisting of signs or indications which may be used in trade to declare the geographical origin of a product or service:

Provided that the proprietor of a certification trade mark consisting of signs or indications of the kind referred to in this paragraph shall not be entitled to prohibit the use of the said signs or indications, when such signs or indications are used in accordance with the accepted principles of trade and industry, particularly when used by a person entitled to use a geographical name.

4. - (1) Notwithstanding the provisions of section 11(1), a certification trade mark shall not be registered or, if registered, it may be declared invalid, if the public is likely to be deceived as to the character or the meaning of the said mark, especially if such mark may be perceived as being something other than a certification trade mark.

(2) The Chief Officer may require that a certification trade mark shall include an indication that it is a trade mark of such nature.

5. - (1) The person applying for the registration of a certification trade mark shall submit to the Chief Officer, together with the application, regulations governing the use of such mark so that the Chief Officer may examine the following –

(a) whether the applicant is the appropriate person to certify the goods or services in respect of which the mark is to be registered;

(b) whether the regulations are satisfactory; and

(c) whether under all the circumstances the registration required is in the public interest.

(2) The Chief Officer may, after examining an application –

(a) reject the application; or

(b) admit the application and approve the regulations, either without any amendment and without conditions, or subject to such conditions or restrictions on, or subject to such amendments or alterations to the application or regulations as he deems necessary, having regard to any of the above matters.

6. The regulations submitted to the Chief Officer in relation to a certification trade mark shall regulate the use of such mark and shall include provisions as regards the cases where the proprietor certifies goods or services and authorises the use of the certification trade mark and shall also include provisions conferring a right to appeal to the Chief Officer against any refusal of the proprietor thereof to certify goods or services or to authorise the use of the certification trade mark in accordance with the regulations. The regulations so submitted shall be subject to inspection in the same way as is the register.

7. The regulations submitted in relation to a certification trade mark may, on the application of the registered proprietor, be amended with the consent of the Chief Officer and in such a case the provisions of section 20 shall apply, with appropriate modifications.

8. - (1) The Chief Officer may, on application in the prescribed manner of any affected person, issue such order as he may think fit for the removal or amendment of any entry in the register referring to a certification trade mark or for the amendment of the regulations submitted, for any of the following reasons –

(a) that the proprietor is no longer fit, in relation to any goods or services in respect of which the certification trade mark is registered, to certify such goods or services;

(b) that the proprietor has failed to comply with a provision of the regulations submitted, which he was required to comply with;

(c) that it is no longer in the public interest that the certification mark remains registered; or

(d) that it is necessary in the public interest that the regulations be amended, if the trade mark remains registered.

(2) The Chief Officer shall correct the register and the regulations submitted in such manner as may be necessary for the application of an order made under subparagraph (1) above.

9. A certification trade mark shall not be assigned or transferred in any way other than with the consent of the Chief Officer.

10. The following provisions of this Ordinance shall not apply in relation to a certification trade mark, that is to say subsections (4) to (8) of section 24, sections 28 to 30 and section 55.".

Original Schedule to the principal Ordinance renamed the Second Schedule.

25. The Schedule immediately following the First Schedule to the principal Ordinance shall be renamed "SECOND SCHEDULE" and for the words "(section 61)" immediately below the words "SECOND SCHEDULE" there shall be substituted the words "(section 59)".

Addition of the Third Schedule to the principal Ordinance.

26. The principal Ordinance shall be amended by adding immediately after the Second Schedule, the following new Schedule –

"THIRD SCHEDULE

(Section 37B)

COLLECTIVE TRADE MARKS

General

1. The provisions of this Ordinance shall apply to collective trade marks subject to the following provisions of this Schedule.

Signs and indications of which a collective trade mark may consist

2. In relation to a collective trade mark, the definition of the expression "trade mark" in section 2(1) shall be read as if for the words "the goods or services of an undertaking from those of other undertakings" there were substituted the words "goods or services of the members of the association which is the proprietor of the collective trade mark from similar goods or services of other undertakings".

3. Notwithstanding the provisions of section 11(1)(c), it shall be permissible to register a collective trade mark consisting of signs or indications which can be used in trade to declare the geographical origin of a product or service:

Provided that the proprietor of a collective trade mark consisting of signs or indications of the kind referred to in this paragraph shall not be allowed to prohibit the use of the said signs or indications, when these are used in accordance with the accepted principles of trade and industry, particularly when such signs or indications are used by a person entitled to use a geographical name.

A collective trade mark shall not be misleading as to its character or meaning

4. - (1) Notwithstanding the provisions of section 11(1), a collective trade mark shall not be registered or, if registered, it may be declared invalid, if the public is likely to be deceived as to the character or meaning of the said mark, especially if such mark is likely to be perceived as being something other than a collective trade mark.

(2) The Chief Officer may require that a collective trade mark shall include an indication that it is a trade mark of such nature.

Regulations governing the use of a collective trade mark

5. - (1) The person applying for the registration of a collective trade mark shall submit to the Chief Officer, together with the application, regulations governing the use of such mark.

(2) The regulations shall prescribe the persons authorised to use the trade mark, the terms and conditions that they must satisfy in order to be members of the association and, if any, the terms for the use of the trade mark, including any penalties against any illegal use of it.

Approval of the regulations by the Chief Officer

6. A collective trade mark shall not be registered or, if registered, it may be declared invalid, unless the regulations governing the use of such mark –

(a) satisfy the requirements of paragraph 5(2) above; and

(b) are not contrary to public order and the accepted principles of morality.

7. - (1) The Chief Officer shall examine whether the requirements referred to in paragraph 6 are satisfied.

(2) If the Chief Officer is of the opinion that the said requirements are not satisfied, he shall inform the applicant and shall afford to him the opportunity, within such reasonable period as the Chief Officer may determine, to make representations or to submit amended regulations.

(3) If the applicant fails to satisfy the Chief Officer that such requirements are satisfied, or if he does not submit amended regulations which satisfy the requirements, or if he does not respond before the end of the period mentioned in subparagraph (2) above, the Chief Officer shall reject the application.

(4) If the Chief Officer is of the opinion that the said requirements and all other requirements for registration are satisfied, he shall accept the application.

Regulations shall be open for inspection

8. The regulations which govern the use of a registered collective trade mark shall be open to public inspection in the same way as is the register.

Amendment of regulations

9. -(1) An amendment to the regulations which govern the use of a registered collective trade mark shall be of no effect if the amended regulations are not submitted to the Chief Officer and accepted by him.

(2) The Chief Officer may, before accepting any amending regulations, if he deems it expedient, order the publication of such regulations.

(3) If the Chief Officer orders the publication of the regulations, a notice of objection may be given in relation to the matters referred to in paragraph 6 above.

Reasons for removal from the register

10. - (1)The Chief Officer may, on the application, in the prescribed manner, of any affected person, remove a collective trade mark from the register for any of the following reasons –

(a) that the proprietor had failed to comply with, or to ensure compliance with the regulations governing the use of a trade mark; or

(b) that there has been an amendment to the regulations, so that the regulations –

(i) no longer satisfy the requirements of paragraph 5(2) above, or

(ii) are contrary to public order or the accepted principles of morality.

11. In addition to the reasons for invalidity that may arise due to a contravention of the provisions of section 11, 13 or 14, the registration of a collective trade mark may also be declared invalid for the reason that the mark was registered in contravention of the provisions of paragraph 6 above.".

Commencement.

27. This Ordinance shall come into force on the day of its publication in the Gazette save for section 4(c) which shall not come into force unless the Republic becomes a member State of the European Union in which event section 4(c) shall come into force on the first day that the Republic becomes such a member State.

5th August 2002 D.J. BONNER,

(173/14) Chief Officer.

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