Statutory Document No. 0180/13

European Communities (Isle of Man) Act 1973

EUROPEAN UNION (INTELLECTUAL PROPERTY) (NO.2) ORDER 2013

Draft laid before Tynwald:	*21 May 2013*
Draft approved by Tynwald:	*18 June 2013*
Coming into Operation:	*1 July 2013*

The Council of Ministers makes the following Order under section 2A of the European Communities (Isle of Man) Act 1973.

1 Title

This Order is the European Union (Intellectual Property) (No.2) Order 2013.

2 Commencement

This Order comes into operation on 1 July 2013.

3 Application of EU instruments

(1) Subject to paragraphs (2), (3) and (4), the following EU instruments shall apply to the Island as part of the law of the Island—

(a) Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products[1], as amended by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products[2];

(b) Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use[3], as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004

[1] OJ L 311, 28.11.2001, p. 1
[2] OJ L 136, 30.4.2004, p. 58
[3] OJ L 311, 28.11.2001, p. 67

amending Directive 2001/83/EC on the Community code relating to medicinal products for human use[4]; and

(c) Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems[5].

(2) Directive 2001/82/EC applies to the Island only for the purpose of the exemption granted by article 13(6) of that Directive from rights conferred by a patent or a supplementary protection certificate.

(3) Directive 2001/83/EC applies to the Isle of Man only for the purpose of the exemption granted by article 10(6) of that Directive from rights conferred by a patent or a supplementary protection certificate.

(4) Regulation (EC) No 816/2006 applies to the Island subject to—

(a) the modification that the Island shall be treated as part of the United Kingdom; and

(b) the omission of Articles 19 and 20.

4 Amendment

In the Schedule to the European Communities (Intellectual Property) Order 2013[6], paragraph 2(1) is omitted.

MADE 19TH JUNE 2013

W GREENHOW
Chief Secretary

[4] OJ L 136, 30.4.2004, p.34
[5] OJ L 157, 9.6.2006, p.1
[6] SD 0073/13

EXPLANATORY NOTE

(This note is not part of the Order)

This Order applies to the Isle of Man —

(a) Directives 2001/82/EC and 2001/83/EC so far as they grant exemption from patent protection for trials of generic drugs (the 'Roche-Bolar exemption'); and

(b) Regulation (EC) No 816/2006 on the compulsory licensing of pharmaceutical products for export to countries with public health problems.

The Order also amends the European Union (Intellectual Property) Order 2013 (SD 0073/13), so that Directive 2004/48/EC on the enforcement of intellectual property rights will apply to the Isle of Man in relation to patents, trade marks and registered designs as well as unregistered rights such as copyright.

The implementation of these measures will bring the law of the Island on registered intellectual property rights closer into line with that of the United Kingdom and other Member States of the European Union.

As required by section 2A(5) of the European Communities (Isle of Man) Act 1973, a text of the Directives applied by this Order, incorporating the exceptions, adaptations and modifications specified in it, is annexed to this Order.

Annex

EU INSTRUMENTS APPLIED TO THE ISLAND BY THE EUROPEAN UNION (INTELLECTUAL PROPERTY) (NO.2) ORDER 2013

DIRECTIVE 2001/82/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to veterinary medicinal products

(as amended by Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products)

NOTE: *This Directive applies to the Isle of Man only for the purpose of the exemption granted by article 13(6) from rights conferred by a patent or a supplementary protection certificate*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products, Council Directive 81/852/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products, Council Directive 90/677/EEC of 13 December 1990 extending the scope of Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary medicinal products, and Council Directive 92/74/EEC of 22 September 1992 widening the scope of Directive 81/851/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to veterinary medicinal products and laying down additional provisions on homeopathic veterinary medicinal products have been frequently and substantially amended; in the interests of clarity and rationality, the said Directives should therefore be codified by assembling them in a single text.

(2) The primary purpose of any rules for the production and distribution of veterinary medicinal products must be the safeguarding of public health.

(3) However, this objective must be achieved by means which will not hinder the development of industry and trade in medicinal products within the Community.

(4) In so far as the Member States already have certain provisions laid down by law, regulation or administrative action governing veterinary medicinal products, such provisions differ in essential principles. This results in the hindering of trade in medicinal products within the Community, thereby directly affecting the functioning of the internal market.

(5) Such hindrances must, accordingly, be removed; whereas this entails approximation of the relevant provisions.

(6) It is necessary from the point of view of public health and the free movement of veterinary medicinal products for the competent authorities to have at their disposal all useful information on authorized veterinary medicinal products in the form of approved summaries of the characteristics of products.

(7) With the exception of those medicinal products which are subject to the centralised Community authorization procedure established by Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, a marketing authorization in one Member State ought to be recognized by the competent authority of the other Member States unless there are serious grounds for supposing that the authorization of the veterinary medicinal product concerned may present a risk to human or animal health, or to the environment; in the event of a disagreement between Member States about the quality, the safety or the efficacy of a medicinal product, a scientific evaluation of the matter should be undertaken at a Community level, lead to a single decision on the area of disagreement, binding on the Member States concerned. This Decision should be adopted by a rapid procedure ensuring close cooperation between the Commission and the Member States.

(8) For this purpose, a Committee for Veterinary Medicinal Products should be set up in accordance with the European Agency for the Evaluation of Medicinal Products laid down in the aforementioned Regulation (EEC) No 2309/93.

(9) This Directive is only one stage in the achievement of the aim of freedom of movement of veterinary medicinal products. However, for this purpose, new measures will prove necessary, in the light of experience gained - especially within the Committee for Veterinary Medicinal Products - for the removal of the remaining barriers to freedom of movement.

(10) Medicated feedingstuffs do not come within the scope of this Directive. However, it is necessary, for both public health and economic reasons, to prohibit the use of unauthorized medicinal products in the manufacture of medicated feedingstuffs.

(11) The concepts of harmfulness and therapeutic efficacy can be examined only in relation to one another and have only a relative significance, depending on the progress of scientific knowledge and the use for which the medicinal product is intended. The particulars and documents which must accompany an application for marketing authorization must demonstrate that potential hazards are outweighed by the benefits due to efficacy. Failing such demonstration, the application must be rejected.

(12) Marketing authorization should be refused where a medicinal product lacks therapeutic effect or where there is insufficient proof of such effect. The concept of therapeutic effect must be understood as being the effect promised by the manufacturers.

(13) Such marketing authorization should also be refused where the withdrawal period indicated is not long enough to eliminate health hazards arising from residues.

(14) Before an authorization to market an immunological veterinary medicinal product can be granted, the manufacturer must demonstrate his ability to attain batch-to-batch consistency.

(15) The competent authorities should also be empowered to prohibit the use of an immunological veterinary medicinal product when the immunological responses of the treated animal will interfere with a national or Community programme for the diagnosis, eradication or control of animal disease.

(16) It is desirable in the first instance to provide users of homeopathic medicinal products with a very clear indication of their homeopathic character and with sufficient guarantees of their quality and safety.

(17) The rules relating to the manufacture, control and inspection of homeopathic veterinary medicinal products must be harmonised to permit the circulation throughout the Community of medicinal products which are safe and of good quality.

(18) Having regard to the particular characteristics of these homeopathic veterinary medicinal products, such as the very low level of active principles they contain and the difficulty of applying to them the conventional statistical methods relating to clinical trials, it is desirable to provide a special, simplified registration procedure for those traditional homeopathic medicinal products which are placed on the market without therapeutic indications in a pharmaceutical form and dosage which do not present a risk for the animal.

(19) The usual rules governing the authorization to market veterinary medicinal products must be applied to homeopathic veterinary medicinal products marketed with therapeutic indications or in a form which may present risks which must be balanced against the desired therapeutic effect. Member States should be able to apply particular rules for the evaluation of the results of tests and trials intended to establish the safety and efficacy of these medicinal products for pet animals and exotic species, provided that they notify them to the Commission.

(20) In order to better protect human and animal health and avoid any unnecessary duplication of effort during the examination of application for a marketing authorization, Member States should systematically prepare assessment reports in respect of each veterinary medicinal product which is authorized by them, and exchange the reports upon request. Furthermore, a Member State should be able to suspend the examination of an application for authorization to place a veterinary medicinal product on the market which is currently under active consideration in another Member State with a view to recognizing the decision reached by the latter Member State.

(21) In order to facilitate the movement of veterinary medicinal products and to prevent the checks carried out in one Member State from being repeated in another, minimum requirements for manufacture and imports from third countries, and the grant of corresponding authorizations, should be applied to veterinary medicinal products.

(22) The quality of veterinary medicinal products manufactured within the Community should be guaranteed by requiring compliance with the principles of good manufacturing practice for medicinal products irrespective of the final destination of the medicinal products.

(23) Measures should also be taken to ensure that distributors of veterinary medicinal products are authorized by Member States and maintain adequate records.

(24) Standards and protocols for the performance of tests and trials on veterinary medicinal products are an effective means of control of these products and, hence, of protecting public health and can facilitate the movement of these products by laying down uniform rules applicable to tests and the compilation of dossiers, allowing the competent authorities to arrive at their decisions on the basis of uniform tests and by reference to uniform criteria, and therefore helping to obviate differences in evaluation.

(25) It is advisable to stipulate more precisely the cases in which the results of pharmacological and toxicological tests or clinical trials do not have to be provided with a view to obtaining authorization for a veterinary medicinal product which is essentially similar to an innovative product, while ensuring that innovative forms are not placed at a disadvantage. However, there are reasons of public policy for not repeating tests carried out on animals without overriding cause.

(26) Following the establishment of the internal market, specific controls to guarantee the quality of veterinary medicinal products imported from third countries can be waived only if appropriate arrangements have been made by the Community to ensure that the necessary controls are carried out in the exporting country.

(27) In order to ensure the continued safety of veterinary medicinal products in use, it is necessary to ensure that pharmacovigilance systems in the Community are continually adapted to take account of scientific and technical progress.

(28) For public health protection, relevant data on adverse effects in humans related to the use of veterinary medicines should be collected and evaluated.

(29) The pharmacovigilance systems should consider the available data on lack of efficacy.

(30) In addition, collection of information on adverse reactions due to off-label use, investigations of the validity of the withdrawal period and on potential environmental problems may contribute to improve regular monitoring of good usage of veterinary medicines.

(31) It is necessary to take account of changes arising as a result of international harmonisation of definitions, terminology and technological developments in the field of pharmacovigilance.

(32) The increasing use of electronic means of communication of information on adverse reactions to veterinary medicinal products marketed in the Community is intended to allow a single reporting point for adverse reactions, at the same time ensuring that this information is shared with the competent authorities in all Member States.

(33) It is the interest of the Community to ensure that the veterinary pharmacovigilance systems for centrally authorised medicinal products and those authorised by other procedures are consistent.

(34) Holders of marketing authorisations should be proactively responsible for ongoing pharmacovigilance of the veterinary medicinal products they place on the market.

(35) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission.

(36) In order to improve the protection of public health, it is necessary to specify that foodstuffs for human consumption may not be taken from animals which have been used in clinical trials of veterinary medicinal products unless a maximum residue limit has been laid down for residues of the veterinary medicinal product concerned in accordance with the provisions of Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.

(37) The Commission should be empowered to adopt the changes necessary in order to adapt Annex I to scientific and technical progress.

(38) This Directive should be without prejudice to the obligations of the Member States concerning the time-limits for transposition of the Directives set out in Annex II, Part B,

HAVE ADOPTED THIS DIRECTIVE:

TITLE I
DEFINITIONS

Article 1[1]

For the purposes of this Directive, the following terms shall bear the following meanings:

. . .

[2. *Veterinary medicinal product:*

(a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or

(b) any substance or combination of substances which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.]

. . .

4. *Substance:*

Any matter irrespective of origin which may be:

[1] as amended by Directive 2004/28/EC

— human, e.g.
human blood and human blood products;

— animal, e.g.
micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products;

— vegetable, e.g.
micro-organisms, plants, parts of plants, vegetable secretions, extracts;

— chemical, e.g.
elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis.

5. *Pre-mix for medicated feedingstuffs:*
Any veterinary medicinal product prepared in advance with a view to the subsequent manufacture of medicated feedingstuffs.

6. *Medicated feedingstuffs:*
Any mixture of a veterinary medicinal product or products and feed or feeds which is ready prepared for marketing and intended to be fed to animals without further processing, because of its curative or preventive properties or other properties as a medicinal product covered by point 2.

7. *Immunological veterinary medicinal product:*
A veterinary medicinal product administered to animals in order to produce active or passive immunity or to diagnose the state of immunity.

[8. *Homeopathic veterinary medicinal product:*
Any veterinary medicinal product prepared from substances 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 Member States. A homeopathic veterinary medicinal product may contain a number of principles.

9. *Withdrawal period:*
The period necessary between the last administration of the veterinary medicinal product to animals, under normal conditions of use and in accordance with the provisions of this Directive, and the production of foodstuffs from such animals, in order to protect public health by ensuring that such foodstuffs do not contain residues in quantities in excess of the maximum residue limits for active substances laid down pursuant to Regulation (EEC) No 2377/90.

10. *Adverse reaction:*
A reaction to a veterinary medicinal product which is harmful and unintended and which occurs at doses normally used in animals for the prophylaxis, diagnosis or treatment of disease or to restore, correct or modify a physiological function.]

11. *Human adverse reaction:*
A reaction which is noxious and unintended and which occurs in a human being following exposure to a veterinary medicine.

12. *Serious adverse reaction:*
An adverse reaction which results in death, is life-threatening, results in significant disability or incapacity, is a congenital anomaly/birth defect, or which results in permanent or prolonged signs in the animals treated.

13. *Unexpected adverse reaction:*
An adverse reaction, the nature, severity or outcome of which is not consistent with the summary of the product characteristics.

14. *Periodic safety update reports:*
The periodical reports containing the records referred to in Article 75.

15. *Post-marketing surveillance studies:*
Pharmacoepidemiological study or a clinical trial carried out in accordance with the terms of the marketing authorization, conducted with the aim of identifying and investigating a safety hazard relating to an authorized veterinary medicinal product.

16. *Off-label use:*
The use of a veterinary medicinal product that is not in accordance with the summary of the product characteristics, including the misuse and serious abuse of the product.

17. *Wholesale dealing in veterinary medicinal products:*
Any activity which includes the purchase, sale, import, export, or any other commercial transaction in veterinary medicinal products, whether or not for profit, except for:

— the supply by a manufacturer of veterinary medicinal products manufactured by himself,

— retail supplies of veterinary medicinal products by persons entitled to carry out such supplies in accordance with Article 66.

[17a. *Representative of the marketing authorisation holder:*
The person, commonly known as local representative, designated by the marketing authorisation holder to represent him in the Member State concerned.]

[18. *Agency:*
The European Medicines Agency established by Regulation (EC) No 726/2004.]

[19. *Risks relating to use of the product:*
— any risk relating to the quality, safety and efficacy of the veterinary medicinal products as regards animal or human health;

— any risk of undesirable effects on the environment.]

[20. *Risk/benefit balance:*
An evaluation of the positive therapeutic effects of the veterinary medicinal product in relation to the risks as defined above.

21. *Veterinary prescription:*
Any prescription for a veterinary medicinal product issued by a professional person qualified to do so in accordance with applicable national law.

22. *Name of veterinary medicinal product:*
The name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trademark or the name of the marketing authorisation holder.

23. *Common name:*
The international non-proprietary name recommended by the World Health Organisation, or, if one does not exist, the usual common name.

24. *Strength:*
The content of active substances, expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form.

25. *Immediate packaging:*
The container or any other form of packaging that is in direct contact with the medicinal product.

26. *Outer packaging:*
The packaging into which is placed the immediate packaging.

27. *Labelling:*
Information on the immediate or outer packaging.

28. *Package leaflet:*
The leaflet containing information for the user that accompanies the medicinal product.]

TITLE II
SCOPE

Article 2

The provisions of this Directive shall apply to veterinary medicinal products intended to be placed on the market inter alia in the form of medicinal products, ready-made veterinary medicinal products or pre-mixes for medicated feeedingstuffs.

Article 3

This Directive shall not apply to:

1. Medicated feedingstuffs as defined in Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community(10);

However, medicated feedingstuffs may be prepared only from pre-mixes which have been authorized under this Directive;

2. Inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals from a holding and used for the treatment of that animal or the animals of that holding in the same locality;

3. Any medicinal product prepared in a pharmacy in accordance with a prescription for an individual animal (commonly known as the magistral formula);

4. Any medicinal product prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the end-user (commonly known as the officinal formula);

5. Veterinary medicinal products based on radio-active isotopes;

6. Any additives covered by Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs(11), where they are incorporated in animal feedingstuffs and supplementary animal feedingstuffs in accordance with that Directive. Nevertheless, Member States may, when implementing Articles 10(1)(c) and(2) take acount of the medicinal products referred to in points 3 and 4 of the first paragraph.

Nonetheless, Member States may, when implementing Article 10(1)(c) and (2) take account of the medicinal products referred to in points 3 and 4 of the first paragraph.

Article 4

1. Member States may provide that this Directive shall not apply to non-inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals from a holding and used for the treatment of that animal or the animals of that holding in the same locality.

2. Member States may permit exemptions on their territory in respect of veterinary medicinal products intended solely for aquarium fish, cage birds, homing pigeons, terrarium animals and small rodents, from the provisions in Articles 5, 7 and 8, provided that such products do not contain substances the use of which requires veterinary control and that all possible measures have been taken to prevent unauthorized use of the products for other animals.

[Articles 5-12 omitted]

[*Article 13*[2]

1. By way of derogation from point (j) of the first subparagraph of Article 12(3), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of the safety and residue tests or of the pre-clinical and clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 5 for not less than eight years in a Member State or the Community.

A generic veterinary medicinal product authorised pursuant to this provision shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product.

The first subparagraph shall also apply when the reference medicinal product was not authorised in the Member State in which the application for the generic medicinal product is submitted. In this case, the applicant shall indicate in the application the Member State in which the reference medicinal product is or has been authorised. At the request of the competent authority of the Member State in which the application is submitted, the competent authority of the other Member State shall transmit, within a period of one month, confirmation that the reference medicinal product is or has been authorised together with the full composition of the reference product and if necessary other relevant documentation.

However, the ten-year period provided for in the second subparagraph shall be extended to 13 years in the case of veterinary medicinal products for fish or bees or other species designated in accordance with the procedure referred to in Article 89(2).

2. For the purposes of this Article:

(a) ‘reference medicinal product’ shall mean a product authorised within the meaning of Article 5 in accordance with the provisions of Article 12;

(b) ‘generic medicinal product’ shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information intended to provide proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.

3. In cases where the veterinary medicinal product does not fall under the definition of a generic medicinal product set out in paragraph 2(b) or where bio-equivalence cannot be demonstrated through bioavailability studies or in the case of changes to the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration vis-à-vis the reference medicinal product, the results of the appropriate safety and residue tests and pre-clinical tests or clinical trials shall be provided.

4. Where a biological veterinary medicinal product which is similar to a reference biological veterinary medicinal product does not meet the conditions in the definition of generic medicinal products, owing to, in

[2] substituted by Directive 2004/28/EC

particular, differences relating to raw materials or in manufacturing processes of the biological veterinary medicinal product and the reference biological veterinary medicinal product, the results of appropriate pre-clinical tests or clinical trials relating to these conditions must be provided. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex I and the related detailed guidelines. The results of other tests and trials from the reference medicinal product's dossier shall not be provided.

5. In the case of veterinary medicinal products intended for one or more food-producing species and containing a new active substance that has not been authorised in the Community by 30 April 2004 the ten-year period provided for in the second subparagraph of paragraph 1 shall be extended by one year for each extension of the marketing authorisation to another food-producing species, if it is authorised within the five years following the granting of the initial marketing authorisation.

This period shall not, however, exceed a total of 13 years, for a marketing authorisation for four or more food-producing species.

The extension of the ten-year period to 11, 12, or 13 years for a veterinary medicinal product intended for food-producing species shall be granted only if the marketing authorisation holder also originally applied for determination of the maximum residue limits established for the species covered by the authorisation.

6. Conducting the necessary studies, tests and trials with a view to the application of paragraphs 1 to 5 and the consequential practical requirements shall not be regarded as contrary to patent-related rights or to supplementary-protection certificates for medicinal products.]

[Articles 13a to 98 and Annexes omitted]

Done at Brussels, 6 November 2001.

For the European Parliament
The President
N. Fontaine

For the Council
The President
D. Reynders

DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 6 November 2001
on the Community code relating to medicinal products for human use

(as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use)

***NOTE**: This Directive applies to the Isle of Man only for the purpose of the exemption granted by article 10(6) from rights conferred by a patent or a supplementary protection certificate*

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission;

Having regard to the opinion of the Economic and Social Committee,

Acting in accordance with the procedure laid down in Article 251 of the Treaty,

Whereas:

(1) Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products, Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products, Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, Council Directive 89/342/EEC of 3 May 1989 extending the scope of Directives 65/65/EEC and 75/319/EEC and laying down additional provisions for immunological medicinal products consisting of vaccines, toxins or serums and allergens, Council Directive 89/343/EEC of 3 May 1989 extending the scope of Directives 65/65/EEC and 75/319/EEC and laying down additional provisions for radiopharmaceuticals, Council Directive 89/381/EEC of 14 June 1989 extending the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down special provisions for proprietary medicinal products derived from human blood or human plasma, Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human use, Council Directive 92/26/EEC of 31 March 1992 concerning the classification for the supply of medicinal products for human use, Council Directive 92/27/EEC of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets, Council Directive 92/28/EEC of 31 March 1992 on the advertising of medicinal products for human use, Council Directive 92/73/EEC of 22 September 1992 widening the scope

of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down additional provisions on homeopathic medicinal products have been frequently and substantially amended. In the interests of clarity and rationality, the said Directives should therefore be codified by assembling them in a single text.

(2) The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health.

(3) However, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community.

(4) Trade in medicinal products within the Community is hindered by disparities between certain national provisions, in particular between provisions relating to medicinal products (excluding substances or combinations of substances which are foods, animal feeding-stuffs or toilet preparations), and such disparities directly affect the functioning of the internal market.

(5) Such hindrances must accordingly be removed; whereas this entails approximation of the relevant provisions.

(6) In order to reduce the disparities which remain, rules should be laid down on the control of medicinal products and the duties incumbent upon the Member States' competent authorities should be specified with a view to ensuring compliance with legal requirements.

(7) The concepts of harmfulness and therapeutic efficacy can only be examined in relation to each other and have only a relative significance depending on the progress of scientific knowledge and the use for which the medicinal product is intended. The particulars and documents which must accompany an application for marketing authorization for a medicinal product demonstrate that potential risks are outweighed by the therapeutic efficacy of the product.

(8) Standards and protocols for the performance of tests and trials on medicinal products are an effective means of control of these products and hence of protecting public health and can facilitate the movement of these products by laying down uniform rules applicable to tests and trials, the compilation of dossiers and the examination of applications.

(9) Experience has shown that it is advisable to stipulate more precisely the cases in which the results of toxicological and pharmacological tests or clinical trials do not have to be provided with a view to obtaining authorization for a medicinal product which is essentially similar to an authorized product, while ensuring that innovative firms are not placed at a disadvantage.

(10) However, there are reasons of public policy for not conducting repetitive tests on humans or animals without over-riding cause.

(11) The adoption of the same standards and protocols by all the Member States will enable the competent authorities to arrive at their decisions on the basis of uniform tests and by reference to uniform criteria and will therefore help to avoid differences in evaluation.

(12) With the exception of those medicinal products which are subject to the centralized Community authorization procedure established by Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products a marketing authorization for a medicinal product granted by a competent authority in one Member State ought to be recognized by the competent authorities of the other Member States unless there are serious grounds for supposing that the authorization of the medicinal product concerned may present a risk to public health. In the event of a disagreement between Member States about the quality, the safety or the efficacy of a medicinal product, a scientific evaluation of the matter should be undertaken according to a Community standard, leading to a single decision on the area of disagreement binding on the Member States concerned. Whereas this decision should be adopted by a rapid procedure ensuring close cooperation between the Commission and the Member States.

(13) For this purpose, a Committee for Proprietary Medicinal Products should be set up attached to the European Agency for the Evaluation of Medicinal Products established in the abovementioned Regulation (EEC) No 2309/93.

(14) This Directive represents an important step towards achievement of the objective of the free movement of medicinal products. Further measures may abolish any remaining barriers to the free movement of proprietary medicinal products will be necessary in the light of experience gained, particularly in the abovementioned Committee for Proprietary Medicinal Products.

(15) In order better to protect public health and avoid any unnecessary duplication of effort during the examination of application for a marketing authorization for medicinal products, Member States should systematically prepare assessment reports in respect of each medicinal product which is authorized by them, and exchange the reports upon request. Furthermore, a Member State should be able to suspend the examination of an application for authorization to place a medicinal product on the market which is currently

under active consideration in another Member State with a view to recognizing the decision reached by the latter Member State.

(16) Following the establishment of the internal market, specific controls to guarantee the quality of medicinal products imported from third countries can be waived only if appropriate arrangements have been made by the Community to ensure that the necessary controls are carried out in the exporting country.

(17) It is necessary to adopt specific provisions for immunological medicinal products, homeopathic medicinal products, radiopharmaceuticals, and medicinal products based on human blood or human plasma.

(18) Any rules governing radiopharmaceuticals must take into account the provisions of Council Directive 84/466/Euratom of 3 September 1984 laying down basic measures for the radiation protection of persons undergoing medical examination or treatment. Account should also be taken of Council Directive 80/836/Euratom of 15 July 1980 amending the Directives laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation, the objective of which is to prevent the exposure of workers or patients to excessive or unnecessarily high levels of ionizing radiation, and in particular of Article 5c thereof, which requires prior authorization for the addition of radioactive substances to medicinal products as well as for the importation of such medicinal products.

(19) The Community entirely supports the efforts of the Council of Europe to promote voluntary unpaid blood and plasma donation to attain self-sufficiency throughout the Community in the supply of blood products, and to ensure respect for ethical principles in trade in therapeutic substances of human origin.

(20) The rules designed to guarantee the quality, safety and efficacy of medicinal products derived from human blood or human plasma must be applied in the same manner to both public and private establishments, and to blood and plasma imported from third countries.

(21) Having regard to the particular characteristics of these homeopathic medicinal products, such as the very low level of active principles they contain and the difficulty of applying to them the conventional statistical methods relating to clinical trials, it is desirable to provide a special, simplified registration procedure for those homeopathic medicinal products which are placed on the market without therapeutic indications in a pharmaceutical form and dosage which do not present a risk for the patient.

(22) The anthroposophic medicinal products described in an official pharmacopoeia and prepared by a homeopathic method are to be treated, as regards registration and marketing authorization, in the same way as homeopathic medicinal products.

(23) It is desirable in the first instance to provide users of these homeopathic medicinal products with a very clear indication of their homeopathic character and with sufficient guarantees of their quality and safety.

(24) The rules relating to the manufacture, control and inspection of homeopathic medicinal products must be harmonized to permit the circulation throughout the Community of medicinal products which are safe and of good quality.

(25) The usual rules governing the authorization to market medicinal products should be applied to homeopathic medicinal products placed on the market with therapeutic indications or in a form which may present risks which must be balanced against the desired therapeutic effect. In particular, those Member States which have a homeopathic tradition should be able to apply particular rules for the evaluation of the results of tests and trials intended to establish the safety and efficacy of these medicinal products provided that they notify them to the Commission.

(26) In order to facilitate the movement of medicinal products and to prevent the controls carried out in one Member State from being repeated in another, minimum requirements should be laid down for manufacture and imports coming from third countries and for the grant of the authorization relating thereto.

(27) It should be ensured that, in the Member States, the supervision and control of the manufacture of medicinal products is carried out by a person who fulfils minimum conditions of qualification.

(28) Before an authorization to market an immunological medicinal product or derived from human blood or human plasma can be granted, the manufacturer must demonstrate his ability to attain batch-to-batch consistency. Before an authorization to market a medicinal product derived from human blood or human plasma can be granted, the manufacturer must also demonstrate the absence of specific viral contamination, to the extent that the state of technology permits.

(29) The conditions governing the supply of medicinal products to the public should be harmonized.

(30) In this connection persons moving around within the Community have the right to carry a reasonable quantity of medicinal products lawfully obtained for their personal use. It must also be possible for a person established in one Member State to receive from another Member State a reasonable quantity of medicinal products intended for his personal use.

(31) In addition, by virtue of Regulation (EC) No 2309/93, certain medicinal products are the subject of a Community marketing authorization. In this context, the classification for the supply of medicinal products covered by a Community marketing authorization needs to be established. It is therefore important to set the criteria on the basis of which Community decisions will be taken.

(32) It is therefore appropriate, as an initial step, to harmonize the basic principles applicable to the classification for the supply of medicinal products in the Community or in the Member State concerned, while taking as a starting point the principles already established on this subject by the Council of Europe as well as the work of harmonization completed within the framework of the United Nations, concerning narcotic and psychotropic substances.

(33) The provisions dealing with the classification of medicinal products for the purpose of supply do not infringe the national social security arrangements for reimbursement or payment for medicinal products on prescription.

(34) Many operations involving the wholesale distribution of medicinal products for human use may cover several Member States simultaneously.

(35) It is necessary to exercise control over the entire chain of distribution of medicinal products, from their manufacture or import into the Community through to supply to the public, so as to guarantee that such products are stored, transported and handled in suitable conditions. The requirements which must be adopted for this purpose will considerably facilitate the withdrawal of defective products from the market and allow more effective efforts against counterfeit products.

(36) Any person involved in the wholesale distribution of medicinal products should be in possession of a special authorization. Pharmacists and persons authorized to supply medicinal products to the public, and who confine themselves to this activity, should be exempt from obtaining this authorization. It is however necessary, in order to control the complete chain of distribution of medicinal products, that pharmacists and persons authorized to supply medicinal products to the public keep records showing transactions in products received.

(37) Authorization must be subject to certain essential conditions and it is the responsibility of the Member State concerned to ensure that such conditions are met; whereas each Member State must recognize authorizations granted by other Member States.

(38) Certain Member States impose on wholesalers who supply medicinal products to pharmacists and on persons authorized to supply medicinal products to the public certain public service obligations. Those Member States must be able to continue to impose those obligations on wholesalers established within their territory. They must also be able to impose them on wholesalers in other Member States on condition that they do not impose any obligation more stringent than those which they impose on their own wholesalers and provided that such obligations may be regarded as warranted on grounds of public health protection and are proportionate in relation to the objective of such protection.

(39) Rules should be laid down as to how the labelling and package leaflets are to be presented.

(40) The provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information.

(41) The marketing of medicinal products whose labelling and package leaflets comply with this Directive should not be prohibited or impeded on grounds connected with the labelling or package leaflet.

(42) This Directive is without prejudice to the application of measures adopted pursuant to Council Directive 84/450/EEC of 10 September 1984 relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising(17).

(43) All Member States have adopted further specific measures concerning the advertising of medicinal products. There are disparities between these measures. These disparities are likely to have an impact on the functioning of the internal market, since advertising disseminated in one Member State is likely to have effects in other Member States.

(44) Council Directive 89/552/EEC of 3 October 1989 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities prohibits the television advertising of medicinal products which are available only on medical prescription in the Member State within whose jurisdiction the television broadcaster is located. This principle should be made of general application by extending it to other media.

(45) Advertising to the general public, even of non-prescription medicinal products, could affect public health, were it to be excessive and ill-considered. Advertising of medicinal products to the general public, where it is permitted, ought therefore to satisfy certain essential criteria which ought to be defined.

(46) Furthermore, distribution of samples free of charge to the general public for promotional ends must be prohibited.

(47) The advertising of medicinal products to persons qualified to prescribe or supply them contributes to the information available to such persons. Nevertheless, this advertising should be subject to strict conditions and effective monitoring, referring in particular to the work carried out within the framework of the Council of Europe.

(48) Advertising of medicinal products should be subject to effective, adequate monitoring. Reference in this regard should be made to the monitoring mechanisms set up by Directive 84/450/EEC.

(49) Medical sales representatives have an important role in the promotion of medicinal products. Therefore, certain obligations should be imposed upon them, in particular the obligation to supply the person visited with a summary of product characteristics.

(50) Persons qualified to prescribe medicinal products must be able to carry out these functions objectively without being influenced by direct or indirect financial inducements.

(51) It should be possible within certain restrictive conditions to provide samples of medicinal products free of charge to persons qualified to prescribe or supply them so that they can familiarize themselves with new products and acquire experience in dealing with them.

(52) Persons qualified to prescribe or supply medicinal products must have access to a neutral, objective source of information about products available on the market. Whereas it is nevertheless for the Member States to take all measures necessary to this end, in the light of their own particular situation.

(53) Each undertaking which manufactures or imports medicinal products should set up a mechanism to ensure that all information supplied about a medicinal product conforms with the approved conditions of use.

(54) In order to ensure the continued safety of medicinal products in use, it is necessary to ensure that pharmacovigilance systems in the Community are continually adapted to take account of scientific and technical progress.

(55) It is necessary to take account of changes arising as a result of international harmonisation of definitions, terminology and technological developments in the field of pharmacovigilance.

(56) The increasing use of electronic networks for communication of information on adverse reactions to medicinal products marketed in the Community is intended to allow competent authorities to share the information at the same time.

(57) It is the interest of the Community to ensure that the pharmacovigilance systems for centrally authorised medicinal products and those authorised by other procedures are consistent.

(58) Holders of marketing authorisations should be proactively responsible for on-going pharmacovigilance of the medicinal products they place on the market.

(59) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission.

(60) The Commission should be empowered to adopt any necessary changes to Annex I in order to take into account scientific and technical progress.

(61) This Directive should be without prejudice to the obligations of the Member States concerning the time-limits for transposition of the Directives set out in Annex II, Part B.

HAVE ADOPTED THIS DIRECTIVE:

TITLE I
DEFINITIONS

Article 1[3]

For the purposes of this Directive, the following terms shall bear the following meanings:

. . .

[2. *Medicinal product:*

(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.]

3. *Substance:*

Any matter irrespective of origin which may be:

— human, e.g.
human blood and human blood products;

— animal, e.g.
micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products;

— vegetable, e.g.
micro-organisms, plants, parts of plants, vegetable secretions, extracts;

— chemical, e.g.

[3] as amended by Directive 2004/27/EC

elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis.

4. *Immunological medicinal product:*
Any medicinal product consisting of vaccines, toxins, serums or allergen products:

(a) vaccines, toxins and serums shall cover in particular:

(i) agents used to produce active immunity, such as cholera vaccine, BCG, polio vaccines, smallpox vaccine;

(ii) agents used to diagnose the state of immunity, including in particular tuberculin and tuberculin PPD, toxins for the Schick and Dick Tests, brucellin;

(iii) agents used to produce passive immunity, such as diphtheria antitoxin, anti-smallpox globulin, antilymphocytic globulin;

(b) "allergen product" shall mean any medicinal product which is intended to identify or induce a specific acquired alteration in the immunological response to an allergizing agent.

[5. *Homeopathic medicinal product:*
Any medicinal product prepared from substances 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. A homeopathic medicinal product may contain a number of principles.]

6. *Radiopharmaceutical:*
Any medicinal product which, when ready for use, contains one or more radionuclides (radioactive isotopes) included for a medicinal purpose.

7. *Radionuclide generator:*
Any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be obtained by elution or by any other method and used in a radiopharmaceutical.

8. [*Kit*]:
Any preparation to be reconsitituted or combined with radionuclides in the final radiopharmaceutical, usually prior to its administration.

9. *Radionuclide precursor:*
Any other radionuclide produced for the radio-labelling of another substance prior to administration.

10. *Medicinal products derived from human blood or human plasma:*
Medicinal products based on blood constitutents which are prepared industrially by public or private establishments, such medicinal products including, in particular, albumin, coagulating factors and immunoglobulins of human origin.

11. *Adverse reaction:*
A response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function.

12. *Serious adverse reaction:*
An adverse reaction which results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect.

13. *Unexpected adverse reaction:*
An adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics.

14. *Periodic safety update reports:*
The periodical reports containing the records referred to in Article 104.

15. *Post-authorisation safety study:*
A pharmacoepidemiological study or a clinical trial carried out in accordance with the terms of the marketing authorisation, conducted with the aim of identifying or quantifying a safety hazard relating to an authorised medicinal product.

16. *Abuse of medicinal products:*
Persistent or sporadic, intentional excessive use of medicinal products which is accompanied by harmful physical or psychological effects.

17. *Wholesale distribution of medicinal products:*
All activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public. Such activities are carried out with manufacturers or their depositories,

importers, other wholesale distributors or with pharmacists and persons authorized or entitled to supply medicinal products to the public in the Member State concerned.

18. *Public service obligation:*
The obligation placed on wholesalers to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question.

[18a *Representative of the marketing authorisation holder:*
The person, commonly known as local representative, designated by the marketing authorisation holder to represent him in the Member State concerned.]

19. *Medicinal Prescription:*
Any medicinal prescription issued by a professional person qualified to do so.

[20. *Name of the medicinal product:*
The name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorisation holder.]

21. *Common name:*
The international non-proprietary name recommended by the World Health Organization, or, if one does not exist, the usual common name.

22. *Strength of the medicinal product:*
The content of the active substances expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form.

23. *Immediate packaging:*
The container or other form of packaging immediately in contact with the medicinal product.

24. *Outer packaging:*
The packaging into which is placed the immediate packaging.

25. *Labelling:*
Information on the immediate or outer packaging.

26. *Package leaflet:*
A leaflet containing information for the user which accompanies the medicinal product.

[27. *Agency:*
The European Medicines Agency established by Regulation (EC) No 726/2004;]

[28. *Risks related to use of the medicinal product:*
— any risk relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health;

— any risk of undesirable effects on the environment;

28a. *Risk-benefit balance:*
An evaluation of the positive therapeutic effects of the medicinal product in relation to the risks as defined in point 28, first indent.]

TITLE II

SCOPE

[*Article 2* [4]

1. This Directive shall apply to medicinal products for human use intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process.

2. In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a 'medicinal product' and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply.

3. Notwithstanding paragraph 1 and Article 3(4), Title IV of this Directive shall apply to medicinal products intended only for export and to intermediate products.]

Article 3[5]

This Directive shall not apply to:

1. Any medicinal product prepared in a pharmacy in accordance with a medical prescription for an individual patient (commonly known as the magistral formula).

[4] substituted by Directive 2004/27/EC
[5] as amended by Directive 2004/27/EC

[2. Any medicinal product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by the pharmacy in question (commonly known as the officinal formula).]

[3. Medicinal products intended for research and development trials, but without prejudice to the provisions of Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.]

4. Intermediate products intended for further processing by an authorized manufacturer.

5. Any radionuclides in the form of sealed sources.

[6. Whole blood, plasma or blood cells of human origin, except for plasma which is prepared by a method involving an industrial process.]

Article 4

1. Nothing in this Directive shall in any way derogate from the Community rules for the radiation protection of persons undergoing medical examination or treatment, or from the Community rules laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation.

2. This Directive shall be without prejudice to Council Decision 86/346/EEC of 25 June 1986 accepting on behalf of the Community the European Agreement on the Exchange of Therapeutic Substances of Human Origin.

3. The provisions of this Directive shall not affect the powers of the Member States' authorities either as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes, on the basis of health, economic and social conditions.

4. This Directive shall not affect the application of national legislation prohibiting or restricting the sale, supply or use of medicinal products as contraceptives or abortifacients. The Member States shall communicate the national legislation concerned to the Commission.

[*Article 5* [6]

1. A Member State may, in accordance with legislation in force and to fulfil special needs, exclude from the provisions of this Directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised health-care professional and for use by an individual patient under his direct personal responsibility.

2. Member States may temporarily authorise the distribution of an unauthorised medicinal product in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm.

3. Without prejudice to paragraph 1, Member States shall lay down provisions in order to ensure that marketing authorisation holders, manufacturers and health professionals are not subject to civil or administrative liability for any consequences resulting from the use of a medicinal product otherwise than for the authorised indications or from the use of an unauthorised medicinal product, when such use is recommended or required by a competent authority in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm. Such provisions shall apply whether or not national or Community authorisation has been granted.

4. Liability for defective products, as provided for by Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States, concerning liability for defective products, shall not be affected by paragraph 3.]

(Articles 6-9 omitted.)

[Article 10 [7]

1. By way of derogation from Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community.

A generic medicinal product authorised pursuant to this provision shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product.

The first subparagraph shall also apply if the reference medicinal product was not authorised in the Member State in which the application for the generic medicinal product is submitted. In this case, the applicant shall indicate in the application form the name of the Member State in which the reference medicinal product is or has been

[6] substituted by Directive 2004/27/EC
[7] substituted by Directive 2004/27/EC

authorised. At the request of the competent authority of the Member State in which the application is submitted, the competent authority of the other Member State shall transmit within a period of one month, a confirmation that the reference medicinal product is or has been authorised together with the full composition of the reference product and if necessary other relevant documentation.

The ten-year period referred to in the second subparagraph shall be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies.

2. For the purposes of this Article:

(a) 'reference medicinal product' shall mean a medicinal product authorised under Article 6, in accordance with the provisions of Article 8;

(b) 'generic medicinal product' shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.

3. In cases where the medicinal product does not fall within the definition of a generic medicinal product as provided in paragraph 2(b) or where the bioequivalence cannot be demonstrated through bioavailability studies or in case of changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration, vis-à-vis the reference medicinal product, the results of the appropriate pre-clinical tests or clinical trials shall be provided.

4. Where a biological medicinal product which is similar to a reference biological product does not meet the conditions in the definition of generic medicinal products, owing to, in particular, differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference biological medicinal product, the results of appropriate pre-clinical tests or clinical trials relating to these conditions must be provided. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex I and the related detailed guidelines. The results of other tests and trials from the reference medicinal product's dossier shall not be provided.

5. In addition to the provisions laid down in paragraph 1, where an application is made for a new indication for a well-established substance, a non-cumulative period of one year of data exclusivity shall be granted, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication.

6. Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.]

(Articles 11-130 and Annexes omitted)

Done at Brussels, 6 November 2001.

For the European Parliament
The President
N. Fontaine

For the Council
The President
D. Reynders

Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 95 and 133 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee[8],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[9],

Whereas:

(1) On 14 November 2001 the Fourth Ministerial Conference of the World Trade Organisation (WTO) adopted the Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and Public Health. The Declaration recognises that each WTO Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted. It also recognises that WTO Members with insufficient or no manufacturing capacity in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing.

(2) On 30 August 2003 the WTO General Council, in the light of the statement read out by its Chairman, adopted the Decision on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (the Decision). Subject to certain conditions, the Decision waives certain obligations concerning the issue of compulsory licences set out in the TRIPS Agreement in order to address the needs of WTO Members with insufficient manufacturing capacity.

(3) Given the Community's active role in the adoption of the Decision, its commitment made to the WTO to fully contribute to the implementation of the Decision and its appeal to all WTO Members to ensure that the conditions are put in place which will allow the system set up by the Decision to operate efficiently, it is important for the Community to implement the Decision in its legal order.

(4) Uniform implementation of the Decision is needed to ensure that the conditions for the granting of compulsory licences for the manufacture and sale of pharmaceutical products, when such products are intended for export, are the same in all Member States and to avoid distortion of competition for operators in the single market. Uniform rules should also be applied to prevent re-importation into the territory of the Community of pharmaceutical products manufactured pursuant to the Decision.

(5) This Regulation is intended to be part of wider European and international action to address public health problems faced by least developed countries and other developing countries, and in particular to improve access to affordable medicines which are safe and effective, including fixed-dose combinations, and whose quality is guaranteed. In that connection, the procedures laid down in Community pharmaceutical legislation guaranteeing the scientific quality of such products will be available, in particular that provided for in Article 58 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[10].

(6) As the compulsory licensing system set up by this Regulation is intended to address public health problems, it should be used in good faith. This system should not be used by countries to pursue industrial or commercial policy objectives. This Regulation is designed to create a secure legal framework and to discourage litigation.

(7) As this Regulation is part of wider action to address the issue of access to affordable medicines for developing countries, complementary actions are set out in the Commission Programme for Action: Accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction and in the Commission Communication on a Coherent European Policy Framework for External Action to Confront HIV/AIDS, malaria and tuberculosis. Continued urgent progress is necessary, including actions to support research to combat these diseases and to enhance capacity in developing countries.

(8) It is imperative that products manufactured pursuant to this Regulation reach only those who need them and are not diverted from those for whom they were intended. The issuing of compulsory licences under this Regulation must therefore impose clear conditions upon the licensee as regards the acts covered by the licence, the identification of the pharmaceutical products manufactured under the licence and the countries to which the products will be exported.

(9) Provision should be made for customs action at external borders to deal with products manufactured and sold for export under a compulsory licence which a person attempts to reimport into the territory of the Community.

(10) Where pharmaceutical products produced under a compulsory licence have been seized under this Regulation, the competent authority may, in accordance with national legislation and with a view to ensuring that the intended use is made of the seized pharmaceutical products, decide to send the products to the relevant importing country according to the compulsory licence which has been granted.

(11) To avoid facilitating overproduction and possible diversion of products, the competent authorities should take into account existing compulsory licences for the same products and countries, as well as parallel applications indicated by the applicant.

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[8] OJ C 286, 17.11.2005, p. 4

[9] Opinion of the European Parliament of 1.12.2005, and Council Decision of 28 April 2006.

[10] OJ L 136, 30.4.2004, p. 1.

(12) Since the objectives of this Regulation, in particular the establishment of harmonised procedures for the granting of compulsory licences which contribute to the effective implementation of the system set up by the Decision, cannot be sufficiently achieved by the Member States because of the options available to exporting countries under the Decision and can therefore, by reason of the potential effects on operators in the internal market, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(13) The Community recognises the utmost desirability of promoting the transfer of technology and capacity-building to countries with insufficient or no manufacturing capacity in the pharmaceutical sector, in order to facilitate and increase the production of pharmaceutical products by those countries.

(14) In order to ensure the efficient processing of applications for compulsory licences under this Regulation, Member States should have the ability to prescribe purely formal or administrative requirements, such as rules on the language of the application, the form to be used, the identification of the patent(s) and/or supplementary protection certificate(s) in respect of which a compulsory licence is sought, and rules on applications made in electronic form.

(15) The simple formula for setting remuneration is intended to accelerate the process of granting a compulsory licence in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use under Article 31(b) of the TRIPS Agreement. The figure of 4 % could be used as a reference point for deliberations on adequate remuneration in circumstances other than those listed above,

HAVE ADOPTED THIS REGULATION:

Article 1
Scope

This Regulation establishes a procedure for the grant of compulsory licences in relation to patents and supplementary protection certificates concerning the manufacture and sale of pharmaceutical products, when such products are intended for export to eligible importing countries in need of such products in order to address public health problems.

Member States shall grant a compulsory licence to any person making an application in accordance with Article 6 and subject to the conditions set out in Articles 6 to 10.

Article 2
Definitions

For the purposes of this Regulation, the following definitions shall apply:

(1) "pharmaceutical product" means any product of the pharmaceutical sector, including medicinal products as defined in Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[11], active ingredients and diagnostic kits ex vivo;

(2) "rights-holder" means the holder of any patent or supplementary protection certificate in relation to which a compulsory licence has been applied for under this Regulation;

(3) "importing country" means the country to which the pharmaceutical product is to be exported;

(4) "competent authority" for the purposes of Articles 1 to 11, 16 and 17 means any national authority having competence to grant compulsory licences under this Regulation in a given Member State.

Article 3
Competent authority

The competent authority as defined in Article 2(4) shall be that which has competence for the granting of compulsory licences under national patent law, unless the Member State determines otherwise.

Member States shall notify the Commission of the designated competent authority as defined in Article 2(4).

Notifications shall be published in the Official Journal of the European Union.

Article 4
Eligible importing countries

The following are eligible importing countries:

[11] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

(a) any least-developed country appearing as such in the United Nations list;

(b) any member of the WTO, other than the least-developed country members referred to in point (a), that has made a notification to the Council for TRIPs of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way;

(c) any country that is not a member of the WTO, but is listed in the OECD Development Assistance Committee's list of low-income countries with a gross national product per capita of less than USD 745, and has made a notification to the Commission of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way.

However, any WTO member that has made a declaration to the WTO that it will not use the system as an importing WTO member is not an eligible importing country.

Article 5

Extension to least-developed and developing countries which are not members of the WTO

The following provisions shall apply to importing countries eligible under Article 4 which are not WTO members:

(a) the importing country shall make the notification referred to in Article 8(1) directly to the Commission;

(b) the importing country shall, in the notification referred to in Article 8(1), state that it will use the system to address public health problems and not as an instrument to pursue industrial or commercial policy objectives and that it will adopt the measures referred to in paragraph 4 of the Decision;

(c) the competent authority may, at the request of the rights-holder, or on its own initiative if national law allows the competent authority to act on its own initiative, terminate a compulsory licence granted pursuant to this Article if the importing country has failed to honour its obligations referred to in point (b). Before terminating a compulsory licence, the competent authority shall take into account any views expressed by the bodies referred to in Article 6(3)(f).

Article 6

Application for a compulsory licence

1. Any person may submit an application for a compulsory licence under this Regulation to a competent authority in the Member State or States where patents or supplementary protection certificates have effect and cover his intended activities of manufacture and sale for export.

2. If the person applying for a compulsory licence is submitting applications to authorities in more than one country for the same product, he shall indicate that fact in each application, together with details of the quantities and importing countries concerned.

3. The application pursuant to paragraph 1 shall set out the following:

(a) the name and contact details of the applicant and of any agent or representative whom the applicant has appointed to act for him before the competent authority;

(b) the non-proprietary name of the pharmaceutical product or products which the applicant intends to manufacture and sell for export under the compulsory licence;

(c) the amount of pharmaceutical product which the applicant seeks to produce under the compulsory licence;

(d) the importing country or countries;

(e) where applicable, evidence of prior negotiation with the rights-holder pursuant to Article 9;

(f) evidence of a specific request from:

  (i) authorised representatives of the importing country or countries; or

  (ii) a non-governmental organisation acting with the formal authorisation of one or more importing countries; or

  (iii) UN bodies or other international health organisations acting with the formal authorisation of one or more importing countries,

  indicating the quantity of product required.

4. Purely formal or administrative requirements necessary for the efficient processing of the application may be prescribed under national law. Such requirements shall not add unnecessarily to the costs or burdens placed upon the applicant and, in any event, shall not render the procedure for granting compulsory licences under this Regulation more burdensome than the procedure for the granting of other compulsory licences under national law.

Article 7

Rights of the rights-holder

The competent authority shall notify the rights-holder without delay of the application for a compulsory licence. Before the grant of the compulsory licence, the competent authority shall give the rights-holder an opportunity to comment on the application and to provide the competent authority with any relevant information regarding the application.

Article 8

Verification

1. The competent authority shall verify that:

(a) each importing country cited in the application which is a WTO member has made a notification to the WTO pursuant to the Decision,

or

(b) each importing country cited in the application which is not a WTO member has made a notification to the Commission pursuant to this Regulation in respect of each of the products covered by the application that:

(i) specifies the names and expected quantities of the product(s) needed;

(ii) unless the importing country is a least-developed country, confirms that the country has established that it had insufficient or no manufacturing capacity in the pharmaceutical sector in relation to a particular product or products in one of the ways set out in the Annex to the Decision;

(iii) confirms that where a pharmaceutical product is patented in the territory of the importing country, that importing country has granted or intends to grant a compulsory licence for import of the product concerned in accordance with Article 31 of the TRIPS Agreement and the provisions of the Decision.

This paragraph is without prejudice to the flexibility that least-developed countries have under the Decision of the Council for TRIPS of 27 June 2002.

2. The competent authority shall verify that the quantity of product cited in the application does not exceed that notified to the WTO by an importing country which is a WTO member, or to the Commission by an importing country which is not a WTO member, and that, taking into account other compulsory licences granted elsewhere, the total amount of product authorised to be produced for any importing country does not significantly exceed the amount notified by that country to the WTO, in the case of importing countries which are WTO members, or to the Commission, in the case of importing countries which are not WTO members.

Article 9

Prior negotiation

1. The applicant shall provide evidence to satisfy the competent authority that he has made efforts to obtain authorisation from the rights-holder and that such efforts have not been successful within a period of thirty days before submitting the application.

2. The requirement in paragraph 1 shall not apply in situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use under Article 31(b) of the TRIPS Agreement.

Article 10

Compulsory licence conditions

1. The licence granted shall be non-assignable, except with that part of the enterprise or goodwill which enjoys the licence, and non-exclusive. It shall contain the specific conditions set out in paragraphs 2 to 9 to be fulfilled by the licensee.

2. The amount of product(s) manufactured under the licence shall not exceed what is necessary to meet the needs of the importing country or countries cited in the application, taking into account the amount of product(s) manufactured under other compulsory licences granted elsewhere.

3. The duration of the licence shall be indicated.

4. The licence shall be strictly limited to all acts necessary for the purpose of manufacturing the product in question for export and distribution in the country or countries cited in the application. No product made or imported under the compulsory licence shall be offered for sale or put on the market in any country other than that cited in the application, except where an importing country avails itself of the possibilities under subparagraph 6(i) of the Decision to export to fellow members of a regional trade agreement that share the health problem in question.

5. Products made under the licence shall be clearly identified, through specific labelling or marking, as being produced pursuant to this Regulation. The products shall be distinguished from those made by the rights-holder through special packaging and/or special colouring/shaping, provided that such distinction is feasible and does not have a significant impact on price. The packaging and any associated literature shall bear an indication that the product is subject to a compulsory licence under this Regulation, giving the name of the competent authority and any identifying reference number, and specifying clearly that the product is exclusively for export to and distribution in the importing country or countries concerned. Details of the product characteristics shall be made available to the customs authorities of the Member States.

6. Before shipment to the importing country or countries cited in the application, the licensee shall post on a website the following information:

(a) the quantities being supplied under the licence and the importing countries to which they are supplied;

(b) the distinguishing features of the product or products concerned.

The website address shall be communicated to the competent authority.

7. If the product(s) covered by the compulsory licence are patented in the importing countries cited in the application, the product(s) shall only be exported if those countries have issued a compulsory licence for the import, sale and/or distribution of the products.

8. The competent authority may at the request of the rights-holder or on its own initiative, if national law allows the competent authority to act on its own initiative, request access to books and records kept by the licensee, for the sole purpose of checking whether the terms of the licence, and in particular those relating to the final destination of the products, have been met. The books and records shall include proof of exportation of the product, through a declaration of exportation certified by the customs authority concerned, and proof of importation from one of the bodies referred to in Article 6(3)(f).

9. The licensee shall be responsible for the payment of adequate remuneration to the rights-holder as determined by the competent authority as follows:

(a) in the cases referred to in Article 9(2), the remuneration shall be a maximum of 4 % of the total price to be paid by the importing country or on its behalf;

(b) in all other cases, the remuneration shall be determined taking into account the economic value of the use authorised under the licence to the importing country or countries concerned, as well as humanitarian or non-commercial circumstances relating to the issue of the licence.

10. The licence conditions are without prejudice to the method of distribution in the importing country. Distribution may be carried out for example by any of the bodies listed in Article 6(3)(f) and on commercial or non-commercial terms including completely without charge.

Article 11
Refusal of the application

The competent authority shall refuse an application if any of the conditions set out in Articles 6 to 9 are not met, or if the application does not contain the elements necessary to allow the competent authority to grant the licence in accordance with Article 10. Before refusing an application, the competent authority shall give the applicant an opportunity to rectify the situation and to be heard.

Article 12
Notification

When a compulsory licence has been granted, the Member State shall notify the Council for TRIPS through the intermediary of the Commission of the grant of the licence, and of the specific conditions attached to it.

The information provided shall include the following details of the licence:

(a) the name and address of the licensee;

(b) the product or products concerned;

(c) the quantity to be supplied;

(d) the country or countries to which the product or products are to be exported;

(e) the duration of the licence;

(f) the address of the website referred to in Article 10(6).

Article 13

Prohibition of importation

1. The import into the Community of products manufactured under a compulsory licence granted pursuant to the Decision and/or this Regulation for the purposes of release for free circulation, re-export, placing under suspensive procedures or placing in a free zone or free warehouse shall be prohibited.

2. Paragraph 1 shall not apply in the case of re-export to the importing country cited in the application and identified in the packaging and documentation associated with the product, or placing under a transit or customs warehouse procedure or in a free zone or free warehouse for the purpose of re-export to that importing country.

Article 14

Action by customs authorities

1. If there are sufficient grounds for suspecting that products manufactured under a compulsory licence granted pursuant to the Decision and/or this Regulation are being imported into the Community contrary to Article 13(1), customs authorities shall suspend the release of, or detain, the products concerned for the time necessary to obtain a decision of the competent authority on the character of the merchandise. Member States shall ensure that a body has the authority to review whether such importation is taking place. The period of suspension or detention shall not exceed 10 working days unless special circumstances apply, in which case the period may be extended by a maximum of 10 working days. Upon expiry of that period, the products shall be released, provided that all customs formalities have been complied with.

2. The competent authority, the rights-holder and the manufacturer or exporter of the products concerned shall be informed without delay of the suspended release or detention of the products and shall be given all information available with respect to the products concerned. Due account shall be taken of national provisions on the protection of personal data and commercial and industrial secrecy and professional and administrative confidentiality.

The importer, and where appropriate, the exporter shall be given ample opportunity to supply the competent authority with the information which it deems appropriate regarding the products.

3. If it is confirmed that products suspended for release or detained by customs authorities were intended for import into the Community contrary to the prohibition in Article 13(1), the competent authority shall ensure that the products are seized and disposed of in accordance with national legislation.

4. The procedure of suspension or detention or seizure of the goods shall be carried out at the expense of the importer. If it is not possible to recover those expenses from the importer, they may, in accordance with national legislation, be recovered from any other person responsible for the attempted illicit importation.

5. If the products suspended for release or detained by customs authorities are subsequently found not to violate the prohibition in Article 13(1), the customs authorities shall release the products to the consignee, provided that all customs formalities have been complied with.

6. The competent authority shall inform the Commission of any decisions on seizure or destruction adopted pursuant to this Regulation.

Article 15

Personal luggage exception

Articles 13 and 14 shall not apply to goods of a non-commercial nature contained in travellers' personal luggage for personal use within the limits laid down in respect of relief from customs duty.

Article 16

Termination or review of the licence

1. Subject to adequate protection of the legitimate interests of the licensee, a compulsory licence granted pursuant to this Regulation may be terminated by a decision of the competent authority or by one of the bodies referred to in Article 17 if the licence conditions are not respected by the licensee.

The competent authority shall have the authority to review, upon reasoned request by the rights-holder or the licensee, whether the licence conditions have been respected. This review shall be based on the assessment made in the importing country where appropriate.

2. Termination of a licence granted under this Regulation shall be notified to the Council for TRIPS through the intermediary of the Commission.

3. Following termination of the licence, the competent authority, or any other body appointed by the Member State, shall be entitled to establish a reasonable period of time within which the licensee shall arrange for any product in his possession, custody, power or control to be redirected at his expense to countries in need as referred

to in Article 4 or otherwise disposed of as prescribed by the competent authority, or by another body appointed by the Member State, in consultation with the rights-holder.

4. When notified by the importing country that the amount of pharmaceutical product has become insufficient to meet its needs, the competent authority may, following an application by the licensee, modify the conditions of the licence permitting the manufacture and export of additional quantities of the product to the extent necessary to meet the needs of the importing country concerned. In such cases the licensee's application shall be processed in accordance with a simplified and accelerated procedure, whereby the information set out in Article 6(3), points (a) and (b), shall not be required provided that the original compulsory licence is identified by the licensee. In situations where Article 9(1) applies but the derogation set out in Article 9(2) does not apply, no further evidence of negotiation with the rights-holder will be required, provided that the additional amount requested does not exceed 25 % of the amount granted under the original licence.

In situations where Article 9(2) applies, no evidence of negotiation with the rights-holder will be required.

Article 17
Appeals

1. Appeals against any decision of the competent authority, and disputes concerning compliance with the conditions of the licence, shall be heard by the appropriate body responsible under national law.

2. Member States shall ensure that the competent authority and/or the body referred to in paragraph 1 have the power to rule that an appeal against a decision granting a compulsory licence shall have suspensory effect.

Article 18
Safety and efficacy of medicinal products

1. Where the application for a compulsory licence concerns a medicinal product, the applicant may avail himself of:

(a) the scientific opinion procedure as provided for under Article 58 of Regulation (EC) No 726/2004, or

(b) any similar procedures under national law, such as scientific opinions or export certificates intended exclusively for markets outside the Community.

2. If a request for any of the above procedures concerns a product which is a generic of a reference medicinal product which is or has been authorised under Article 6 of Directive 2001/83/EC, the protection periods set out in Article 14(11) of Regulation (EC) No 726/2004 and in Articles 10(1) and 10(5) of Directive 2001/83/EC shall not apply.

(Articles 19 and 20 omitted)

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 17 May 2006.

For the European Parliament
The President
J. Borrell Fontelles

For the Council
The President
H. Winkler