

**Answer given by Mr Liikanen on behalf of the Commission**

(11 July 2002)

The advertising of medicinal products for human use is regulated primarily by Articles 86 to 100 of Directive 2001/83/EC of the Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use<sup>(1)</sup>.

Regarding advertising of medicinal products to the general public, Article 88, paragraph 1 of Directive 2001/83/EC provides that Member States shall prohibit the advertising to the general public of medicinal products, which are available on medical prescription only. The only exception to this strict ban is laid down in Article 88, paragraph 4 of the same Directive. This provision exempts vaccination campaigns carried out by the industry and approved by the authorities of the Member States from the general prohibition of advertising. Outside this exception, all kind of advertising of prescription-only medicines to the general public is strictly forbidden.

Regarding advertising of medicinal products to persons qualified to prescribe or supply such products, specific provisions are contained in Articles 91 to 96 of Directive 2001/83/EC. These provisions do not generally prohibit the advertising of medicinal products available on medical prescription only. Accordingly, pharmaceutical companies may advertise even prescription-only medicines to this category of persons.

In the specific context of television advertising, the particular ban of Article 14 of 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<sup>(2)</sup> has to be respected. It sets out that television advertising for medicinal products and medical treatment available only on prescription in the Member State within whose jurisdiction the broadcaster falls shall be prohibited.

At present, certain parts of the pharmaceutical legislation are under revision. The Commission's proposal<sup>(3)</sup> contains certain modifications of Article 88 of Directive 2001/83/EC in order to allow better information on certain prescription-only medicines. The strict ban of any kind of advertising for these products, however, is fully maintained.

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<sup>(1)</sup> OJ L 311, 28.11.2001.

<sup>(2)</sup> OJ L 298, 17.10.1989.

<sup>(3)</sup> COM(2001) 404 final.

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(2002/C 301 E/230)

**WRITTEN QUESTION E-1734/02****by Cristiana Muscardini (UEN) to the Commission**

(17 June 2002)

*Subject:* Recognition of naturopathy

In the last ten years a number of techniques have developed and become widespread, the aim of which is to prevent disease, promote well-being and in general improve the quality of life. They are often associated with forms of 'alternative medicine' (acupuncture, homeopathy, phytotherapy, etc) in order to distinguish them from generally recognised treatments practised in national health services. These forms of treatment are now universally recognised as safe aids to health and well-being and are particularly useful in preventive medicine, provided that the practitioners, i.e. naturopaths, are professionally qualified. They are also called 'health and fitness practitioners', and include professional nurses, physiotherapists, beauticians, naturopaths, shiatsu masseurs, reflexologists, herbalists, therapeutic gym instructors, personal trainers, etc, who (at least in Italy) have completed a practical training course of around 1 000/1 200 hours, over a period of 3/4 years. These training courses and the practice of naturopathy are becoming increasingly widespread, stimulating the body's capacity to heal itself and using natural substances for treatments (herbs, essential oils, Bach flowers, etc).

Can the Commission say whether this relatively new phenomenon has developed in the countries of the Union and, if so in which?

Is it aware of any scientific studies on the validity of this discipline?

In which countries is the profession of naturopath legally recognised?

Is there a European form of recognition?

If not, would it consider it useful and appropriate to take steps to promote the recognition of this form of preventive treatment which safeguards physical well-being?

### **Answer given by Mr Bolkestein on behalf of the Commission**

(24 July 2002)

The Honourable Member refers to non-conventional types of medicine and to professions which exist in this area. Such professions have in general developed in the Community in recent decades, although, on the basis of the information available to the Commission, no widespread consensus exists concerning the independent scientific and therapeutic value of at least some of the activities concerned.

As a general rule it is up to each Member State to determine if a professional activity is to be regulated or not. Furthermore, as regards the professions identified in the question from the Honourable Member, no coordination of the conditions of education and training exists at Community level. Therefore no 'European recognition' of those professions exists as such, in the sense that the names of the professional diplomas/titles relating to those professions have not been adopted in any legally binding act of Community legislation.

Professions can exist in Member States without being regulated. Member States continue to exercise a large measure of discretion whether to regulate any particular area of activity and, if so, in what form. The Commission is not necessarily aware of whether a profession is regulated or not in the different Member States. However, the Commission does have information to the effect that the profession of physiotherapist is regulated under 22 different titles in all Member States plus Iceland, Liechtenstein and Norway. Likewise, the profession of occupational therapist is regulated in 13 Member States (all except Austria and Sweden) plus Iceland, Liechtenstein and Norway. The profession of 'naturopath' (natural health practitioner) is regulated only by Norway, within the Union/European Economic Area (EU/EEA).

A profession is said to be regulated when there is an administrative, regulatory or other legal requirement to hold a diploma or other occupational qualification in order to pursue the profession in question. If someone is seeking recognition of a diploma in order to pursue a regulated profession in a field of non-conventional medicine in a Member State other than that in which the individual has obtained a professional qualification, one of two Directives may apply, depending on the level of studies recognised by the diploma: Council Directive 89/48/EEC of 21 December 1988 on a general system for the recognition of higher-education diplomas awarded on completion of professional education and training of at least three years' duration<sup>(1)</sup> (A-levels or equivalent + three years); or Council Directive 92/51/EEC of 18 June 1992 on a second general system for the recognition of professional education and training<sup>(2)</sup> which covers diplomas, certificates and other vocational training titles at a lower level than those covered by Directive 89/48/EEC.

The recognition provided for in these Directives constitutes the right to pursue a specific regulated profession under the same conditions as the holders of national diplomas. However, in the case of the existence of substantial differences between the applicant's qualifications and experience and the requirements of the host State, the host State may require a compensation measure from the applicant in the form of a period of relevant professional experience, an aptitude test or a period of supervised practice.

An impediment to the right to recognition can arise if a Member State reserves some or all of the activities in question to another profession, such as that of doctor. In that case, the same profession does not exist in the two Member States concerned and the professional who wishes to migrate will have to re-qualify for the different profession which exists in the host Member State in order to be able to practise the activities reserved to that profession. The Court of Justice has confirmed the right of Member States to reserve specific activities to certain professions in the absence of Community legislation providing otherwise<sup>(3)</sup>.

The Commission at present has no plans to promote the recognition of specific forms of preventive treatment, given the fact the primary interest and responsibility in this area lies with the Member States which decide on what action to take in accordance with their specific public health and other policies.

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(<sup>1</sup>) OJ L 19, 24.1.1979.

(<sup>2</sup>) OJ L 209, 24.7.1992.

(<sup>3</sup>) Court of Justice, judgement of 1/1/2001 in case C-108/96 'McQuen'.

(2002/C 301 E/231)

**WRITTEN QUESTION E-1737/02**

**by Jens-Peter Bonde (EDD) to the Commission**

(17 June 2002)

*Subject:* Rules on tendering

What is the Commission's response to the criticism of the EU's rules on tendering made by Jesper Fabricius and Rene Offersen of Lett & Co., reported in Børsen on 31 May 2002?

**Reply by Mr Bolkestein on behalf of the Commission**

(26 July 2002)

The Commission obviously does not agree with Mr Fabricius and Mr Offersen's generalisation according to which the provisions of the Directives on public contracts are 'incredibly rigid and formalistic ... and constitute the greatest obstacle to an effective policy on public contracts'. Nor, incidentally, is this extremely negative view shared by Mr Treumer and Mr Vesterdorff (<sup>1</sup>), who, among other things, stress the role of the Directives in preventing discrimination between economic operators — which is why Mr Vesterdorff is in favour of lowering the thresholds in order to 'increase transparency and equality in competition'.

It should also be borne in mind that a study carried out in 2000 by two French financial inspectors, Mr Bayle and Mr Jochum, in, inter alia, eight Member States has shown that correct application of the rules on tendering permits savings of between 5% and 30%, depending on the Member States and the type of goods purchased.

Apart from making this generalisation, the article stresses the need for dialogue with the economic operators, especially where particularly complex contracts were concerned — such as contracts for computer equipment — and for flexibility as regards technical specifications. The Commission realises that, in certain cases, it would be desirable to introduce scope for dialogue — in an appropriate context in order to safeguard the principles of equal treatment and transparency — in connection with the award of particularly complex contracts. This is why, as part of the reform of the rules on public contracts currently under way, it has proposed a new 'competitive dialogue' procedure that could be used for the award of such contracts.

The policy agreement reached on 21 May 2002 also confirms the Commission's intention to place technical specifications based on specific standards and those defined in terms of performance on an equal footing, while guaranteeing that the basic principles of Community law on public contracts are respected in both cases.

The Commission can therefore, only endorse Mr Fabricius' wish that the future Danish Presidency will give high priority to this matter and also hopes that this matter will soon receive a second reading.

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(<sup>1</sup>) Mr Treumer, Associate Professor at the Copenhagen Business School [Handelshøjskole], and Mr Vesterdorff of the Danish Federation of Crafts and Small Industries [Håndværksrådet] are both also quoted in the article.