WRITTEN QUESTION P-2317/99
by James Fitzsimons (UEN) to the Commission
(29 November 1999)

Subject: New controls on the sale of St. John’s Wort

The European Commission is currently considering what controls, if any, should be applied to health food products and natural medicines. The Irish Medicines Board recently decided that, from 1 January 2000, St. John’s Wort (a herb that has been in use for thousands of years) cannot be sold without a doctor’s prescription. That decision might also affect other herbs such as Ginko Bilba.

1. Will the Commission indicate when it is likely to reach a decision on whether controls should or should not be applied to health food products and natural medicines?

2. Can the Commission confirm that St. John’s Wort and Ginko Bilba are readily available over the counter in all other EU Member States?

3. Can it also confirm that these two herbs, which have been the subject of intensive research over a long period of time, have been shown to be extremely safe?

4. In the light of its own information, does the Commission consider that restricting the sale of these two herbal products is justified?

5. Will the Commission ensure that its decision on whether or not controls are needed is publicised and made known immediately?

Answer given by Mr Liikanen on behalf of the Commission
(16 December 1999)

According to Article 1 of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (1), any substance or combination of substances presented for treating or preventing disease in human beings or animals shall be regarded as medicinal product. Likewise, any substance or combination of substances which may be administered to human beings or animals with a view to making a medicinal diagnosis or to restoring, correcting or modifying physiological functions in human beings or animals, has to be considered a medicinal product. The decision whether a given product falls under the above definition of medicinal product and therefore needs to be authorised as medicinal product must be taken by the authorities on a case by case approach, taking into account both the ingredients and the presentation of a concrete product.

Community pharmaceutical legislation makes no distinction between ‘herbal’ or ‘non-herbal’ medicinal products. Therefore, in the absence of any specific legislation on ‘herbal medicinal products’, medicinal products containing St. John’s Wort or Gingko Biloba have to be assessed and authorised like other medicinal product.

Community legislation acknowledges, however, the fact that long term experience with well established substances may offer help in the assessment of the safety and efficacy of a given product. According to Article 4 paragraph 8 lit.a (ii) of Directive 65/65/EEC an applicant for a marketing authorisation for a medicinal product shall not be required to provide the results of pharmacological and toxicological tests or the results of clinical trials if he can demonstrate ‘by detailed references to published scientific literature presented in accordance with the second paragraph of Article 1 of Directive 75/318/EEC that the constituent or constituents of the medicinal product have a well established medicinal use, with recognized efficacy and an acceptable level of safety’. Commission Directive 1999/83/EC of 8 September 1999 amending the Annex to Council Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmaceutotoxicological and clinical standards and protocols in respect of the testing of medicinal products (2) has specified in detail the practical application of this provision and may be of particular help for the authorisation of well established herbal medicinal products.
It is up to the regulatory authorities in Member States to apply the principles of Community pharmaceutical legislation and to take concrete decisions on authorisations and restrictions (e.g. medical prescription) for specific products. The Commission is not contemplating any changes to that approach.

As the practical application of the above rules falls under the competence of Member States, the Commission is not in a position to give answers to the very detailed and product-specific questions raised by the Honourable Member. The attention of the Honourable Member is, however, drawn to the activities of the ‘working party on herbal medicinal products’ at the European agency for the evaluation of medicinal products (EMEA) in London, which was created with the aim of fostering the gradual harmonisation of the safety and efficacy evaluation of herbal medicinal products in the Community. Reports on the activities of this working group can be easily accessed through the EMEA’s website: http://www.eudra.org/emea.html.


WRITTEN QUESTION E-2320/99

by Freddy Blak (PSE) to the Commission

(13 December 1999)

Subject: Injuries caused by using a mouse

Injuries resulting from the use of a mouse look set to become a major occupational health hazard and have been proclaimed as the big new health and safety problem of the future. A Danish study of the problems caused by working at a VDU, commissioned by Århus district council, shows that just four hours a day is enough to cause damage to the wrists, elbows, neck and shoulders. However, it is not only those who use computers intensively that are at risk, for more than half of all the VDU users who took part in the survey had problems. Those who work at VDUs are just as badly affected physically as other groups who normally report most wrist, elbow neck and shoulder injuries.

Does the Commission know of similar research elsewhere in Europe into the extent of injuries caused by using a mouse?

The Danish study also shows that, unfortunately, there is a long way to go before the requirements of the European directive on working with display screen equipment are met. Only 36% of desks could be height-regulated, and only 30% of employees could rest their lower arm whilst using a keyboard or a mouse.

Does the Commission have an overview of how the directive is being implemented in other Member States?

Will it take steps to update the directive so that it takes account of any new findings concerning injuries caused by using a mouse at work.

Answer given by Mrs Diamantopoulou on behalf of the Commission

(17 January 2000)

Council Directive 90/270/EEC of 29 May 1990, which lays down minimum safety and health requirements for work with display screen equipment (1), has been transposed by all the Member States.

Pursuant to Article 11(3) of the Directive, Member States must report to the Commission every four years on the practical implementation of the provisions of the Directive, indicating the points of view of employers and workers. These reports have allowed the Commission to obtain an overall view of the practical enforcement of this Directive.