(98/C 45/17)

WRITTEN QUESTION E-1172/97

by Carmen Díez de Rivera Icaza (PSE) to the Commission

(3 April 1997)

Subject: Vaccines, medicines and BSE

In view of the most recent events in Italy, I would ask:

1. What is the Commission's position on vaccines made with bovine brain cells?
2. How widespread are vaccines of this type in the various Member States?
3. What products in the various risk categories are still in circulation within the Union?
4. Is there a European Register of Medicines which pose a risk of BSE?

Answer given by Mr Bangemann on behalf of the Commission

(6 June 1997)

1. - 3. The Commission is concerned about the use of bovine brain material in any pharmaceutical product, particularly those which are intended for injection. In December 1996, the Commission proposed a general ban on the use of certain tissues, including bovine brain. However, the proposal was rejected by a simple majority in the Council. The Commission is currently reflecting on follow-up action.

It should be borne in mind that, since the end of 1991, a set of provisions (directives and scientific guidelines, as described by the Commission in its answer to written question No 2335/96 from Ms Breyer ([1])) has been introduced with a view to minimizing the risk of transmitting the agent responsible for bovine spongiform encephalopathy (BSE) to man via medicines. The Commission is taking steps to ensure that this set of provisions is updated in the light of the latest scientific findings. Furthermore, by way of a precaution, the Commission intends to amend the Annex to Council Directive 75/318/EEC of 20 May 1975 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 proprietary medicinal products ([2]), so as to prohibit the manufacturers of such products from using substances derived from cattle, sheep or goats and which carry an infection risk associated with the agent responsible for BSE. This ban would apply to all such substances, whatever their place of origin. Exemptions would, however, be allowed in the case of medicinal products for which there is no therapeutic alternative, so that these products can temporarily be kept on the market.

2. A number of vaccines are manufactured from materials of bovine origin. Since most of these vaccines are authorized on a purely national basis by the Member States, the Commission has no precise data on them.

4. No medicinal product is classified as posing a known risk of contamination by the agent responsible for BSE. If there were such a risk, the medicinal product in question would have to be withdrawn from the market immediately.

([1]) OJ C 83, 14.3.1997.
([2]) OJ L 147, 9.6.1975, as last amended by Directive 93/39/EEC of 14 June 1993 (OJ L 214, 24.8.1993).

(98/C 45/18)

WRITTEN QUESTION E-1200/97

by Nikitas Kaklamanis (UPE) to the Commission

(3 April 1997)

Subject: Temporary number plates for cars intended for sale

In the EU there are cars which are bought in one Member State and taken to other Member States to be sold. The country in which they are bought issues temporary number plates for the journey (e.g. 'Zoll-Nummer' plates in Germany and 'plaque de transit' plates in Belgium).

The issuing of such plates entails a hefty charge of approximately DM 700, with insurance cover, which is added to the final cost of the vehicle and must be paid by the consumer.