

- There are likely to be competitive advantages for manufacturers in many central and eastern European countries over EU manufacturers, as a result of failure to comply with international quality standards, which push up costs, and government failure to enforce them?

Answer given by Mr Verheugen on behalf of the Commission

(30 June 2000)

The Commission considers that the large majority of the Central and Eastern European candidate countries have made substantive progress in harmonising domestic legislation with the *acquis* in the pharmaceutical sector. However, certain shortcomings still exist.

In the context of the accession negotiations, the Community has recalled the importance it attaches to the existence of an equal level of protection of industrial property rights within the enlarged Union.

The Community has therefore suggested that a specific mechanism be provided in the accession treaty in order to prevent distortions on the market for pharmaceutical products following enlargement. According to this mechanism the holder of a patent or supplementary protection certificate (SPC) for a pharmaceutical product filed in a Member State at a time when a product patent or SPC could not be obtained in a candidate country for that product, would be able to rely on the rights granted by that patent or SPC in order to prevent the import from that candidate country (following accession) and marketing of that product in the Member State or States where the product in question enjoys patent protection or SPC protection, even if this product was put on the market in the candidate country for the first time by the SPC or patent holder himself or with his consent.

In addition, as regards the introduction of a supplementary protection certificate, the Community stressed in the context of the accession negotiations that this Regulation is an essential part of the patent legislation in the pharmaceutical sector and that it should be applied in the candidate countries as early as possible and upon accession at the latest so that all patented pharmaceutical products with market authorisation should be eligible for a SPC even if the date of the first market authorisation has already expired.

As regards the protection of supporting clinical trial data submitted for the authorisation of pharmaceuticals, the candidate countries will have to take over the relevant '*acquis*' by the time of accession. Existing obligations under the Trade-related intellectual property right agreement (TRIPs) are also relevant in this context.

As part of the accession process, the candidate countries will also have to apply the manufacturing practices and quality standards applied in the present Member States and comply with them fully at the latest by the time of accession. In fact, many candidate countries have already made good progress in this respect.

The Commission will continue to give special attention to legislative approximation as well as to the reinforcement of candidate countries administrative capacity.

(2001/C 72 E/161)

WRITTEN QUESTION P-1835/00

by Gorka Knörr Borràs (Verts/ALE) to the Commission

(31 May 2000)

Subject: Trans-Pyrenean highway Navarre-Aquitaine

The Government of Navarre is studying the possibility of building a highway across the Pyrenees linking Pamplona/Iruña and Bayonne.

Does the Commission support this project, as is claimed by representatives of said regional government?

In view of the Navarre Government's failure to provide information, is the Commission aware of, or has it assessed, the enormous environmental impact of said project?

Does the Commission not consider that there is a far greater need to improve the national highway N-121 and the railway connections?

Answer given by Mrs de Palacio on behalf of the Commission

(11 July 2000)

According to the information in the Commission's possession there is indeed a projected new highway linking Pamplona with Bayonne. However, this project does not form part of the trans-European transport network as defined in Decision No 1692/96 on Community guidelines for the development of the trans-European transport network. So far the Spanish and French Governments have not asked the Commission to alter the definition of network in order to add this project, which thus remains within the purview of the national authorities.

In accordance with the declaration made in 1996 the Commission is, at this stage, also analysing projected Pyrenean crossings using a central route and by reopening the Pau-Canfranc line with a view to including these in the trans-European network maps. The projected improvements to highway N-121 is a common-interest project within the trans-European network. That network must consist of high-quality roads. The Commission thus supports any project enabling that aim to be achieved.

(2001/C 72 E/162)

WRITTEN QUESTION E-1845/00

by Christopher Huhne (ELDR) to the Commission

(9 June 2000)

Subject: Free movement of capital

Can the Commission confirm that certain Member States — notably Spain — set limits on the amount of cash that may be taken out of the country and, if so, state whether it regards these provisions as compatible with the obligations of the Member States under the Treaties?

If not, what action is the Commission taking to remedy this matter, and what courses of action are open to anyone who has suffered losses on account of these provisions?

Answer given by Mr Solbes Mira on behalf of the Commission

(7 July 2000)

Member States cannot under the obligations of Article 56 (ex Article 73b) of the EC Treaty set limits on the amount of cash that may be taken out of the country. Spain, in compliance with the EC Treaty's obligations, does not set limits to the export of capital.

However, under Spanish law the import or the export of currency in excess of a given amount has to be declared to the customs administration. The law establishing such a 'declaration system' is not in breach of Community law. In fact, under Article 58 (ex Article 73d) of the EC Treaty, it is set out that the provisions of Article 56 shall be without prejudice to the right of the Member States to 'lay down procedures for the declaration of capital movements for purposes of administrative or statistical information', provided the measures and procedures applied 'shall not constitute a means of arbitrary discrimination or a disguised restriction on the free movements of capital'. Moreover, Member States using such a 'declaration system' have also the right to define amounts of fines in case of infringements of the regulation.

Questions concerning damages for the loss suffered on capital (exchange rate differentials) and interest (interest on the sums withheld in excess of the fine) can only be determined by the Spanish courts.