EUROPEAN PARLIAMENT

2004 *2009*

Committee on Petitions

20.02.2009

NOTICE TO MEMBERS

Subject: Petition 1086/2003, by Sabine Hancl, (German), on diabetes patients and their need for animal insulin

1. Summary of petition

The petitioner, a diabetes sufferer, indicates that, over the last 20 years, genetically-engineered insulin has largely replaced animal insulin on the market. However, many diabetes patients require animal insulin because of the possibly serious side effects of genetically-engineered insulin. Animal insulin is produced in the United Kingdom and Switzerland, a fact of which many doctors are unaware. A German firm has sought authorisation to resume production thereof. The petitioner calls for action to be taken to ensure that animal insulin is available throughout Europe.

2. Admissibility

Declared admissible on 30 April 2004. Information requested from Commission under Rule 192(4).

3. **Commission reply**, received on 10 February 2005

Due to subsidiarity restrictions under Article 152 of the Treaty the petitioners request on the Commission to take action in insuring that insulin formulations from animal origin remain available in the European Union for the treatment of insulin dependent diabetes mellitus can not be served. Under Article 152 of the Treaty any form of health care delivery is the remit of the Member States. This includes also the national provisions for the availability of insulin formulations from animal origin in addition to the dominating genetically-engineered formulations of human insulin for individual treatment.

The possible side effects of genetically engineered insulin as described in the petition are not unique to the present genetically engineered insulin formulations and have become well known since insulin of animal origin has been introduced into the treatment of diabetes mellitus in the past. These side effects are considered in the central European authorisation of any proprietary insulin formulation, which is presently on the market.

The essential aim of the European legislation governing the production, distribution and use of medicinal products is to safeguard public health. In this respect, the scientific evaluation and marketing authorisation of insulin developed by means of recombinant DNA technology have to be in compliance with the same standards as for other types of medicinal products. More specifically, the particulars and documents which accompany an application for marketing authorisation must demonstrate that potential risks are outweighed by the therapeutic efficacy of the referred product.

In the Community, no medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State (in accordance with the provisions of Directive 2001/83/EC), or an authorisation has been granted by the Commission in accordance with Regulation (EEC) No 2309/93 . Therefore, the granting of new marketing authorisations for animal-derived insulins whose applications are submitted in Member States are under the remit of the concerned Member States' competent authorities.

4. Further Commission reply received on 20 February 2009

The Petition was first sent in 2003. The petitioner, a diabetes sufferer, claims that, in the last 20 years, genetically-engineered insulin has largely replaced animal insulin on the market. However, many diabetes patients require animal-origin insulin because of the possibility of serious side effects of genetically-engineered insulin. The petitioner asks for action to be taken to ensure that animal insulin is available in Europe.
In 2006, the EP Committee on Petitions re-opened the petition, because new information was provided. In the supplementary information on side effects of genetically-produced insulin, submitted by the petitioner on 29 February 2006, she re-iterates her original request, set out in the above-mentioned petition 1086/2003, requesting access to animal-derived insulin in the European Union.

Observations by the Commission

As already set out in the original Commission's answer (2004), no medicinal product may be placed on the market in any Member State unless a marketing authorisation has been issued by the competent authorities of that Member State (in accordance with the provisions of Directive 2001/83/EC), or an authorisation has been granted by the Commission in accordance with Regulation (EC) No 726/2004 (previously Regulation (EEC) No 2309/93).

The Member States (or, in the interest of patients, according to Article 3(2)(b) of Regulation (EC) No 726/2004, also the European Commission) can issue a marketing authorisation for animal-derived insulin – however only provided that an application for such marketing authorisation is submitted by an applicant.

However, to allow addressing the need for suitable medicines, there are several provisions in Community pharmaceutical legislation, allowing Member States to make products available even in the absence of a marketing authorisation.

Member States can allow access of patients to a medicinal product not authorised in their territory in a "compassionate use" situation (Article 5(1) of Directive 2001/83/EC). Member State may also, for a medicinal product authorised in another Member State and for justified public health reasons, authorise the placing of the said medicinal product on the market (Article 126a of Directive 2001/83/EC).

According to the Commission's information, animal-based insulin is currently authorised in the EU only in the UK (producer Wockhardt UK Limited) and in Poland (Polfa Tarchomin).

Conclusion

Animal-derived insulin is currently authorised in two Member States according to the information available to the Commission. If this product is needed to treat patients in other Member States, national authorities may rely on the mechanisms foreseen in the legislation to make them available.