European Parliament
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Committee on Petitions

2.5.2017

NOTICE TO MEMBERS

Subject: Petition No 0705/2016 by Jan Timmer (Dutch) on the replacement of a generic drug with the original and the subsequent increased cost thereof in the Netherlands

1. Summary of petition

The petitioner suffers from attention deficit hyperactivity disorder. Until recently he received a generic drug with a specific substance, which was prepared by his pharmacist, was low cost and was covered by his health insurance fund. A German company released a drug with this substance onto the market, meaning that under the European legislation its preparation by the pharmacist is no longer permitted. As a result, the cost has tripled and is no longer covered by the health insurance fund. He considers that the European legislation is not aimed at the commercialisation of the drug and stresses that in the Netherlands there is a large number of patients, who, like himself, were assisted greatly in their health by the drug, as well as that he cannot cope with the current cost of the drug.

2. Admissibility

Declared admissible on 1 December 2016. Information requested from Commission under Rule 216(6).

3. **Commission reply**, received on 2 May 2017

The petition

The petitioner, a Dutch citizen, explains that he no longer has access to a medicine called Dexamfetamine, which used to be prepared by pharmacists in the Netherlands to treat children and adults suffering from attention deficit hyperactivity disorder (ADD/ADHD). Since the medicinal product Amfexa has been placed on the market by a German company, pharmacists in the Netherlands are no longer permitted to make the medicine themselves under Directive 2001/83/EC. As a result, the cost of treatment has tripled and is no longer

covered by the health insurance fund and a large number of patients cannot afford the current cost of the drug.

The Commission's observations

One of the primary objectives of the EU legislation for medicinal products for human use is to ensure high standards of quality, safety and efficacy of medicinal products. It is based on the principle that medicinal products shall be granted a marketing authorisation by the competent authorities, in order to define the terms under which the product should be sold and used, following a critical assessment of the quality, safety and efficacy of the product by the competent authorities based on a dossier submitted by an applicant.

Article 3 (1) and (2) of Directive 2001/83/EC foresees a derogation to this general rule for medicinal products prepared in pharmacies (magistral formula and officinal formula), meaning that national conditions apply for pharmacists to prepare ad hoc preparations for individual patients on the basis of a specific prescription of a medical doctor. The European Court of Justice stressed in Joined Cases C-544/13 and C-545/13 that preparations cannot be prepared in advance, but just ad hoc for an individual patient based on a specific prescription by a doctor. It is not clear from the case described by the petitioner to what extent a prescription was required.

The Commission understands that a treatment exists on the Dutch market for adults and children suffering from ADD/ADHD, but that it is not accessible to all patients who need this treatment due to its high price and the fact that it is not reimbursed by the health insurance fund. On this particular aspect, it should be stressed that measures regulating the prices and reimbursement of medicines, the organisation of the health systems and the delivery of care are Member States' responsibility. The Commission promotes improved exchange of information among Member States on their pricing policies to minimise negative effects on the accessibility of medicines and strengthening their cooperation on a voluntary basis[1].

Conclusion

The Commission is of the opinion that the existing EU legal framework for medicinal products for human use is appropriate to guarantee a high level of protection of public health and stresses that the question of pricing and reimbursement falls within the competence of Member States.

[1] In particular through existing tools such as a European medicine price data base (such as Euripid).