Declaration on pharmaceutical active substances

2006/2302(DCE) - 12/12/2006 - Written declaration

The European Parliament adopted a declaration on pharmaceutical active substances, and proposed the introduction of a system for the traceability of the active substance, with an indication of its origin i.e. country, company, site of production, as a means of discouraging the re-labelling or re-packaging of non-Community products in the interests of public health. Parliament considered that the marketing of non-Community active substances is a matter of concern for the scientific community in the EU, given the failure to meet safety standards. Consumers are ensured higher safety standards if they know the origin of an active substance.

Members pointed out that the high quality of pharmaceutical active substances is guaranteed by certification of conformity with good manufacturing practice (GMP). Some Community producers obtain such certificates under Article 111(5) of Directive 2001/83/EC following inspection at the site of production, while producers outside the Community may obtain certificates under Resolution AP-CSP(99) 4 of the Council of Europe via self-certification with no inspections being needed. The provisions concerning manufacturers of medicines and active substances in Article 111 of the above-mentioned Directive are also directly applicable to importers.

Parliament believed that both producers and importers of active substances should submit a GMP certificate delivered by the European authorities following mandatory inspection at the site of production.