

# EUROPEAN PARLIAMENT

2004



2009

---

4.9.2006

0061/2006

## WRITTEN DECLARATION

pursuant to Rule 116 of the Rules of Procedure

by Amalia Sartori, John Bowis, Françoise Grossetête, Cristina Gutiérrez-Cortines and Thomas Ulmer

on pharmaceutical active principles

Lapse date: 4.12.2006

0061/2006

**Written declaration on pharmaceutical active principles**

*The European Parliament,*

- having regard to Rule 116 of its Rules of Procedure,
- A. whereas the high quality of pharmaceutical active principles is guaranteed by certification of conformity with good manufacturing practice (GMP),
- B. whereas some Community producers grant 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 them via self-certification (see resolution AP-CSP (99) 4) with no inspections being needed,
- C. whereas the marketing of non-Community active principles is a matter of concern for the scientific community in the EU, given the failure to meet safety standards,
- D. whereas consumers are ensured higher safety standards if they know the origin of an active principle,
- E. whereas the provisions concerning manufacturers of medicines and active principles (Article 111 of Directive 2001/83/EC) are also directly applicable to importers,
  1. Believes that both producers and importers of active principles should submit a certificate of good manufacturing practice delivered by the European authorities following mandatory inspection at the site of production;
  2. Proposes introducing traceability of the active principle, with indication of its origin (country, company, site of production), as a means of discouraging the relabelling or repackaging of non-Community products in the interests of public health;
  3. Instructs its President to forward this declaration, together with the names of the signatories, to the Council, the Commission and the Parliaments of the Member States.