EUROPEAN PARLIAMENT

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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.