WRITTEN QUESTION P-1061/06
by Dagmar Roth-Behrendt (PSE)
to the Commission

Subject: Phthalates in medicinal products for human use

1. Does the Commission have any information to suggest that certain phthalates (plasticisers) in medicinal products authorised for human use in the European Union can, when used normally, have side effects that are toxic for reproduction or embryos?

2. Has the Commission discussed the occurrence of side effects harmful to embryos of certain phthalates in medicinal products, despite their authorised use, with the European Medicines Agency and the national medicines agencies of the Member States? If not, does the Commission intend to raise the matter with these agencies?

3. Does the Commission have access to information from comparative studies on whether alternative plasticisers can be used in the production of medicinal products? Furthermore, does the Commission see any scope for making it easier to change authorisations of pharmaceutical products exclusively for the purposes of avoiding the use of phthalates in production?

4. Has the Commission given consideration to whether, for example, a counterindication for pregnant women should be displayed on the packaging of pharmaceutical products made using phthalates toxic for reproduction or embryos?