

WRITTEN QUESTION E-1321/08
by Jules Maaten (ALDE)
to the Commission

Subject: Testing medicines for paediatric use

1. Is the Commission aware of the report published on 19 February 2008 by the Centre for Research on Multinational Corporations (SOMO), 'Ethics for Drug Testing in Low and Middle Income Countries – Considerations for European Market Authorisation' and the report 'A Bitter Pill' published in December 2007 by the Wemos Foundation?

2. The drug Olmetec is said to have been approved by the German medical authority in March 2003 after trialling on children from 1 to 16 years old in developing countries such as Kenya, Peru and Uganda. Is this in conflict with the guideline on medicinal products for paediatric use (Regulation (EC) No 1901/2006¹)?

¹ OJ L 378, 27.12.2006, p. 1.