Question for written answer E-001277/2011
to the Commission
Rule 117
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Subject: Suspension of financial support for research projects to develop medicines for children

Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use aims to facilitate future research and investigation so that new, effective medicines can be made available to children more rapidly. This Regulation also attempts to correct a shortcoming that has been identified, which is a lack of well-conducted paediatric studies and scientifically valid data for existing medicines which are intended for adults and regularly prescribed 'off label' for children, despite the uncertainties that use of these medicines exposes them to.

To remedy this situation, a specific provision of the Regulation (Article 40) provides for funding from the Community budget for research into 'medicinal products for the paediatric population …. not covered by a patent ….' and for this funding to 'be delivered through the Community Framework Programmes for Research, Technological Development and Demonstration Activities …'. It is therefore up to DG Research to put calls for tender in place and to fund projects that would make it possible to obtain valid and precise information on effectiveness and risks and formulations that are genuinely suitable for children.

To date, it seems that the Commission has launched three calls for tender and supported a dozen projects submitted under the Seventh Framework Programme. It has been brought to our attention, however, that this funding which has recently come on stream has now already been suspended, although the academic teams and SMEs involved are fully mobilised. This decision does not seem to have taken account of the continuing public health dangers resulting from irregular prescribing and use of these medicines on children.

Can the Commission say why the funding has been suspended?

Does it have any concerns in connection with an ongoing situation of 'off label' prescribing which is slow to change?

What action does the Commission intend to take to remedy this unfortunate situation and fulfil the wishes of Parliament, in accordance with the provisions of what is known as the Paediatric Regulation?