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Commission proposes regulation aimed at promoting medicines for children

Today, the Commission has adopted a proposal for a regulation on medicines for children that aims to improve the health of the children of Europe by ensuring the authorisation of medicines, specifically researched and developed to meet their therapeutic needs. The proposal follows extensive consultation and a detailed assessment of the impact of the proposed measures on all stakeholders. It is a balanced package of measures that will ensure medicines are developed for children through the stimulation of innovation by the European pharmaceutical industry.

Commissioner Olli Rehn said: "Today's proposal is a good example of the Commission actively working to improve life for European citizens. In this case, by promoting the availability of new and better medicines specifically designed for our children. I believe that our proposal achieves the right balance between these objectives and the need to strengthen the competitiveness of the pharmaceutical industry."

More than 50% of the medicines used to treat children have not been tested and authorised for use in children. The health of the children may suffer as, when a doctor writes a prescription for a child for an untested, unauthorised product, that doctor can not be sure the medicine will be truly effective, what dose is appropriate or exactly what the side effects may be. Market forces have failed to stimulate the pharmaceutical industry to adequately development of medicines for children

The key objectives of the proposed regulation are to increase the development and authorisation of medicines for use in children while ensuring that children's medicines are subject to high quality research and children are not subjected to unnecessary clinical trials. The proposal also aims to improve the information available on medicines for children.

Key elements in the proposal:

- a new expert committee, within the European Medicines Agency to assess and agree companies' testing plans;
- a requirement at the time of marketing authorisation applications for data on the use of the medicine in children (plus a system of waivers from this requirement for medicines unlikely to benefit children and a system of deferrals to ensure medicines are tested in children only when it is safe to do so and to ensure the requirements do not delay the authorisation of medicines for adults);
- a reward for studying medicines for children of 6-months extension to the supplementary protection certificate - in effect, six-month patent extension;
- for off-patent medicines, ten-years of data protection for new studies awarded via a Paediatric Use Marketing Authorisation (P.U.M.A);
- increased safety monitoring for children's medicines and compulsory submission by industry of existing studies in children;

- an EU inventory of the therapeutic needs of children and an EU network of investigators and trial centres to conduct the studies required;
- a system of free scientific advice for the industry, provided by the European Medicines Agency.

The full text of today's proposal is available at:

http://pharmacos.eudra.org/F2/home.html

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