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From:	General Secretariat of the Council
To:	Council
Subject:	**Employment, Social Policy, Health and Consumer Affairs Council** meeting on 8 December 2016 Revision of the paediatric medicines Regulation – *Information from the Luxembourg delegation* (Any Other Business item)

Delegations will find attached an information note[1] from the Luxembourg delegation on the above mentioned subject.

[1] In this revised note, the heading on page 2 has been corrected. There are no other changes to the text in the annex.

ANNEX

Regulation 1901/2006 on medicinal products for paediatric use

Considerable progress concerning the development of paediatric medicines has been made since the entry into force of the paediatric medicines regulation. The number of paediatric research projects has increased, more high quality information is available, the relative number of paediatric clinical trials has been stepped up and multi-stakeholder dialogue enhanced.

These developments are, however, overshadowed by concrete numbers: fewer than 10% of children with non-curable conditions have access to innovative therapies, particularly in the field of oncology and neonatology. Since the paediatric medicines regulation came into force, only two innovative targeted cancer drugs have been authorised.

The efficient development of specific medicinal products for children is being impeded by several factors, amongst others:

- Drugs are usually developed for rare adult conditions or cancers, whereas many infantile pathologies do not occur in adults.
- There is a lack of financial incentives for the pharmaceutical industry to develop specific drugs for children, which leads to major delays, as only successful drugs for adults are being considered before starting clinical trials involving children.

Childhood cancer remains the first cause of death by disease in children aged one and above. 6.000 young people die of cancer each year in Europe.

It is therefore vital to put the necessary means in place to further enhance the access of children to innovative medicinal products as well as to ensure that children benefit from developments in personalised medicines.

As foreseen by the regulation, the European Commission tabled a first progress report in 2013. A second progress report, including an impact analysis in order to determine whether a revision of the regulation or of certain of its aspects is necessary for better results, is due in January 2017.

Given the interests at stake and in support of the call recently expressed by the European Parliament[2], Luxembourg welcomes the launch of the public consultation by the European Commission on 15 November 2016 and invites the Commission to table the second progress report within the timeframe foreseen by the regulation and to propose the necessary measures from its findings in due course.

Luxembourg is confident that these measures will significantly contribute to meeting the specific therapeutic needs of the paediatric population in the European Union and looks forward to a timely follow-up to the 2013 and upcoming progress reports.

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[2] European Parliament draft motion for a resolution on the Regulation on Paediatric Medicines, 10.10.2016, 2016/2902.