To the Members of the Employment, Social Policy, Health and Consumer Affairs (EPSCO) Council and to Vytenis Andriukaitis, Member of the European Commission for Health and Food Safety

Tuesday, the 6th of December 2017

Dear Ministers, dear Commissioner,

We, the European Academy of Paediatrics, the voice of children, families and paediatricians across 40 European countries, and whose primary objective is to promote the health of children and young people, congratulate the Estonian presidency and the European Commission on their promotion of e-health; on Anti-Microbial Resistance (and the concomitant Anti-Microbial Stewardship); and action to tackle vaccine hesitancy and to promote sustainable vaccine policies in the EU; as well as a review of incentives in the pharmaceutical industry, all of which have a critical impact on the health of Europe’s children.

The importance of these can be illustrated by reference to the risks associated with the spread of Multi-drug resistant TB (MDR-TB) in Europe. Indeed, TB remains a common disease and an important cause of child morbidity and mortality in Europe. It has the second highest burden of disease of all infectious diseases, with multidrug-resistant tuberculosis (MDR-TB) most prevalent in the Baltic states.

Children with TB have excellent outcomes if diagnosed and treated early. However, treatment of TB in children is hampered by limited data for safety, dosing and drug-drug interactions as well as the scarcity of child-friendly drug formulations. Moreover, treatment options for MDR-TB in children are lacking compared with those for adults. Children with MDR-TB have not benefited from therapeutic advances resulting from the use of new and repurposed drugs in adults with MDR-TB. Clinical guidance is lacking on the use of these drugs and regimens in children and adolescents, in part because of exclusion of children from most drug trials for TB. As a result, current recommendations are based on extrapolations from adult recommendations and expert opinion.

No child should die from TB. We therefore call on the forthcoming Council to:

- **Ensure that the review of the Paediatrics Regulation encourages the development of new child-friendly drug treatments;** and ensure that the rewards to the pharmaceutical companies are proportionate to the development costs and risks, with transparency on those, and commensurate with the therapeutic benefit.

- **Increase funding opportunities for research on antibiotics and children** Governments should cooperate to incentivise research by pharmaceutical companies into novel antibiotic and vaccine solutions.
• Foster “vaccine confidence” among parents and the general adult population, and support immunisation initiatives. Specifically, EU policy-makers can raise awareness about the positive effect of vaccinations to prevent serious illness and further development of AMR.

• Facilitate the access to eHealth tools and foster eHealth literacy
  Government’s health education programmes must prioritise public information about the need only to seek antibiotic treatment when necessary and use their media to promote awareness of a ‘one Health’ approach, limiting use of antibiotics in animal husbandry.

• Increase AMS training and knowledge-sharing opportunities for health professionals
  The European Commission intends to develop AMR training programmes for health professionals through the ECDC, and the EU health programme. Given that many factors related to paediatric AMS are unique to children, the EAP is ready to share its knowledge and experience.

At the Council meeting in Brussels on 8 December 2017, we seek an initiative from the Commission and Council to bring legislative and advisory responsibilities of the EU together in order to secure further coordinated action to combat TB in Europe.

We remain at your disposal should you wish to discuss any elements of this letter in further details.

With our best wishes for a successful meeting,

Tom Stiris
President
European Academy of Paediatrics