

Brussels, 03 November 2017

Press Release

Children with cancer still left behind!

Childhood Cancer professionals and parents say urgent action is vital following release of the European Commission report on 10 years of the EU Paediatric Regulation

[SIOPE – the European Society for Paediatric Oncology](#) and the [Unite2Cure](#) network of parents of children with cancer welcome the recognition of unmet needs in paediatric oncology in the European Commission's 10 years Report on the Paediatric Regulation but strongly regret the lack of urgency and concrete proposals on how the Regulation will be amended to improve the cure for children and adolescents with cancer.

Some of the important concerns voiced by the paediatric cancer community and its supporters are acknowledged in the report. These are:

- For cancer drugs at least, the driving force for the pharmaceutical industry remains the drug's market potential in an adult cancer rather than the needs of childhood cancer;
- Wide-spread use of the Regulation's 'deferral' system, which leads to delays in paediatric drug development, often until their market of an adult cancer indication is secured;
- Shortcomings of the Regulation's waiver system, giving companies a route to avoid the obligation for paediatric development for a drug even when the way the drug works might be effective in treating certain paediatric cancers.

Crucially, the Commission confirms the possibility of an amendment of the Regulation, which SIOPE and Unite2Cure have been calling for. Nevertheless, we are disappointed by the lack of urgency for change, with more debate planned and no definite proposals expected until the end of 2019.

Cancer remains the leading cause of children's mortality by disease in Europe with 6,000 young patients dying each year. Lack of access to innovative medicines is a principal problem behind stagnating survival rates and adverse long-term side-effects in survivors.

Introduced in 2007, the Paediatric Regulation intended to meet the therapeutic needs of children through better-evaluated and authorised medicines. However, progress for paediatric cancer has been insufficient, with only two new medicines authorised for cancer affecting children since the Regulation's entry into force.

Working with multi-stakeholder experts, SIOPE and Unite2Cure identified the weaknesses in the Regulation and ways to improve it. The European Parliament also called for revisiting the regulatory framework and implementation in its Resolution of December 2016.

A targeted revision of the Paediatric Regulation remains a much needed and urgent step to advance more and better cures for children and adolescents with cancer across Europe.

This is all the more urgent since it is clear that children with cancer do not benefit from the Orphan Drug Regulation. By contrast, the RACE for Children Act was recently passed in the United States which requires that new cancer drugs be studied in any paediatric cancers for which the molecular target of the cancer drug is relevant.

In passing the RACE for Children Act in August 2017, the FDA has made the law catch up with the science, which is unfortunately not yet the case for children in Europe.

SIOPE and Unite2Cure remain committed to advancing the necessary changes in cooperation with all stakeholders and call for the set-up of working groups that would work on the improvement of the Regulation.

Every day, every minute matters to patients – the time to take concrete measures for a brighter future for children and adolescents with cancer is now

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Link to the European Commission's 2017 Paediatric Report: https://ec.europa.eu/health/human-use/paediatric-medicines_en

Link to position statement 'Paediatric Cancer Medicines - Urgent need to speed up life-saving innovation': https://www.siope.eu/wp-content/uploads/2013/06/1.-Paediatric_Reg_Position_paper.pdf

Link to paper 'Orphan Drug Regulation: A missed opportunity for children and adolescents with cancer'. Vassal, Gilles et al. European Journal of Cancer , Volume 84 , 149 – 158: <https://www.ncbi.nlm.nih.gov/pubmed/28818704>

Link to the 6th ACCELERATE Paediatric Oncology Conference: <http://www.accelerate-platform.eu/annual-conferences-2/>

Unite2Cure

Unite2Cure (www.unite2cure.org) is a network of parents, parent organisations and patient advocates from across Europe, which is calling for better treatment and better access to treatment for children and young people with cancer.

Unite2Cure works in partnership with Childhood Cancer International (www.childhoodcancerinternational.org) which is the largest patient support organisation for childhood cancer in the world, and represents 181 parent organizations, childhood cancer survivor associations, childhood cancer support groups, and cancer societies, in 90 countries, across 5 continents.

SIOPE

SIOPE, the [European Society for Paediatric Oncology](http://www.siope.eu) (www.siope.eu), is the only pan-European organisation representing all professionals working in the field of childhood cancers in close cooperation with parents, patients and survivors. With more than 1,600 members across 35 European countries, SIOPE is leading the way to ensure the best possible care and outcomes for all children and adolescents with cancer across Europe.

The [SIOPE Strategic Plan](#) - endorsed by all partners in the field - aims to a future where no child dies of cancer and survivors live to the fullest. As the 'European Childhood Cancer Plan', it is based on seven key objectives and will inspire all future initiatives in this field.

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