



## MAC–CRUK–SIOPE Joint Press Release

Brussels, 8<sup>th</sup> September 2016

As the European Commission prepares to launch a consultation on the social and economic impact of the EU Paediatric Regulation 1901/2006, the European paediatric cancer community rings the alarm: less than 1 in 10 children with a terminal cancer have access to potentially life-saving innovative medicines for their disease.



The conference ['Review of the EU Paediatric Medicines Regulation – Let's do more for children with cancer'](#) (7<sup>th</sup> September 2016, European Parliament, Brussels) – hosted by Member of the European Parliament Elena Gentile and co-organised by European Parliament Against Cancer (MAC) Group, Cancer Research UK (CRUK) and the European Society for Paediatric Oncology (SIOPE) – sets out to address this urgent issue.

***“Ten years after the entry into force of the Paediatric Regulation, childhood cancer remains a great threat to children’s lives as innovation in the field is not sufficient at all. We cannot wait any longer to act”*** says Patricia Blanc of the [Unite2Cure](#) parent coalition. Blanc delivered a strong message communicating the sense of urgency to introduce the best treatments into standard care as ***“too few drugs are specifically developed for paediatric cancers”***.

Cancer remains the first cause of children’s death by disease in Europe, but too few drugs targeting paediatric oncology are currently under development. To make up for this situation, multiple stakeholders from academia, parents, regulatory agencies and industry worked together at length as part of the [ACCELERATE platform](#).

***“We, partners of ACCELERATE, look at the facts and want to concretely improve the situation. The Paediatric Regulation did change the landscape of drug development from 10 years ago, but it presents a loophole for paediatric cancers: the waivers. Drug development for children should be driven by science, not by the adult indication. It is also key to start paediatric investigation plans as the Regulation mandates, but in reality this is done too late”***, said SIOPE Past President and Board Member Gilles Vassal.

Speakers from prominent pan-European academia and parent organisations presented the jointly agreed proposals of the paediatric cancer community:

- 1) Ensure that the obligation to undertake a Paediatric Investigation Plan is based on how a drug works and its capacity to address an unmet medical need in children – rather than the type of disease in adults for which it is first introduced;
- 2) Set up a mechanism to choose the best potential drugs and prioritise, among drugs developed by different companies, in relation to the real needs of children affected by rare cancers;
- 3) Reduce delays in paediatric medicines reaching children by enabling Paediatric Investigation Plans (PIPs) to be submitted not later than the start of pivotal trials in adults, if paediatric biological, preclinical and preliminary clinical data are available to better evaluate the potential therapeutic benefit in the paediatric population;
- 4) Add provisions for more effective and flexible rewards for companies undertaking early and timely Paediatric Investigation Plans and those researching therapies specifically for cancers which only occur in children.

Clinical Advisor to CRUK and SIOPE Board Member Pamela Kearns commented: ***“academia has a crucial role in the progresses made by paediatric oncology research over the past fifty years. However, there is now an urgent need for more public-private partnerships with industry in order to go one step forward.”***

Policy makers and stakeholders including host MEP Elena Gentile, MEP Françoise Grossetête and MEP Caterina Chinnici showed their support to the proposals. ***“Often politics and institutions neglect the importance of time, but when time means the life of a patient everyone should act to make change possible”*** observed MEP Gentile. Cancer leagues can be instrumental in making change happen at national level as highlighted by Wendy Yared, Director of the Association of European Cancer Leagues (ECL).

Heightening the public’s awareness of the urgent need to provide more and better options for children with cancer, this event took place in September, International Childhood Cancer Awareness Month. Participants committed to further work on how to

implement the solutions suggested during this conference, which was attended by over 60 participants. Speakers urged the Commission to act now to improve the lives of children with cancer through looking again at the Regulation during its upcoming review. In the months to come, the issue is set to remain high on the EU political agenda with the intention to save children's lives and let survivors live to the fullest.

<b>EVENT INFORMATION:</b>	<a href="#">Conference 'Review of the EU Paediatric Medicines Regulation – Let's do more for children with cancer'</a> Hosted by Elena Gentile MEP (S&D, IT) Wednesday 7 <sup>th</sup> September 2016 European Parliament (Room ASP A1E-1), Brussels, Belgium
<b>PROGRAMME:</b>	Available <a href="#">here</a> (presentations, video and pictures soon downloadable on the same page)
<b>CONTACTS:</b>	Prof Martin Schrappe, SIOPE President (c/o Ms Samira Essiaf, <a href="mailto:office@siope.eu">office@siope.eu</a> , +32 2 775 02 12)
<b>TWITTER:</b>	@SIOPEurope #ChildhoodCancerAwarenessMonth #GoGold #ForTheKids
<b>USEFUL LINKS:</b>	<a href="#">Proposal by Stakeholders - International Childhood Cancer Awareness Day 2016</a> <a href="#">The SIOPE European Cancer Plan for Children and Adolescents</a> <a href="#">Cancer Research UK Kids and Teens</a>

### **About SIOPE**

The European Society for Paediatric Oncology represents more than 1,500 professional members across 31 European countries. SIOPE is the leading organisation in Europe fighting to ensure that children with cancer receive the best possible treatment and go on to live full and meaningful lives. Learn more: [www.siope.eu](http://www.siope.eu).



### **About Cancer Research UK**

- Cancer Research UK is the world's leading cancer charity dedicated to saving lives through research.
- Cancer Research UK's pioneering work into the prevention, diagnosis and treatment of cancer has helped save millions of lives.
- Cancer Research UK receives no government funding for its life-saving research. Every step it makes towards beating cancer relies on every pound donated.
- Cancer Research UK has been at the heart of the progress that has already seen survival in the UK double in the last forty years.
- Today, 2 in 4 people survive their cancer for at least 10 years. Cancer Research UK's ambition is to accelerate progress so that by 2034, 3 in 4 people will survive their cancer for at least 10 years.
- Cancer Research UK supports research into all aspects of cancer through the work of over 4,000 scientists, doctors and nurses.
- Together with its partners and supporters, Cancer Research UK's vision is to bring forward the day when all cancers are cured.



For further information about Cancer Research UK's work or to find out how to support the charity, please call 0300 123 1022 or visit [www.cancerresearchuk.org](http://www.cancerresearchuk.org). Follow us on [Twitter](#) and [Facebook](#).

### **About MAC**

The MEPs Against Cancer (MAC) group is an informal group of [Members of the European Parliament \(MEPs\)](#) at the European Parliament committed to actions against cancer. The MEPs Against Cancer work together in order to improve cancer prevention and control in Europe, in the belief that European cooperation adds value to member state actions. In order to address the challenges faced by the EU, MAC works together with the European Commission and Council and collaborate with relevant organisations to reduce cancer incidence by 15% by the year 2020.

In the 2014 to 2019 legislature the strategic goal of the MEPs Against Cancer (MAC) group is to reduce cancer incidence by:

- promoting prevention,
- reducing mortality by ensuring equitable access to high quality treatment and care, and
- ensuring a good quality of life for cancer patients and survivors.

For more information on the working of the MAC group, please consult our [strategic roadmap 2014-2019](#). ECL is proud to provide the Secretariat for MAC. For more information or to become a MAC member, please contact us at [mac\(at\)europeanleague.org](mailto:mac(at)europeanleague.org)



### **About ECL**

Association of European Cancer Leagues (ECL) is a pan-European umbrella organisation of national and regional cancer leagues. Since 1980, we have been providing a unique and important platform for cancer societies.

From Iceland to Turkey, ECL is represented by leagues in the extended Europe. ECL's member leagues provide advice, support and other services in cancer control in 23 countries (as of 2016), to a total of 489 million European citizens.

The role of ECL is to facilitate the collaboration between cancer leagues throughout Europe and to influence EU and pan-European policies. The mission of the Association of European Cancer Leagues is to influence and improve cancer control and cancer care in Europe through collaboration between its members in their fight against cancer, and to influence EU and pan-European policies. Together, we are "making a Difference in Cancer Prevention and Control!"

