The EU Paediatric Medicines Regulation came into force on 26th January 2007, aiming to provide better medicines for children. This Regulation is based on rewards, incentives and obligations for pharmaceutical companies; its intention was to accelerate the development of drugs for paediatric diseases, such as malignancies, with no expected direct return on investment for pharmaceutical companies. Warmly welcomed by the paediatric community, the Regulation was expected to facilitate access to anticancer drugs, which are in development in adults and to significantly increase the number of those drugs in clinical development for children and adolescents in Europe.

However, the number of new oncology drugs in paediatric development remains low in Europe. There is still a 10-fold difference between Europe and the US in the number of new anticancer drugs available for clinical research. **SIOP Europe, the European Society for Paediatric Oncology (SIOPE), considers new therapies for our patients, to be a priority.**

- Read an article by SIOPE President, Gilles Vassal, on why innovative therapies for childhood cancer therapies should be prioritised.
- SIOPE and other relevant stakeholders responded to a Public Consultation on the progress of the Regulation, after five years. View our response.
- The European Commission published a report on the Consultation in June 2013.

Now, SIOPE is joining BDA- the Biotherapy Development Association and other stakeholders in Paris in November, to discuss how to tackle current hurdles and explore potential solutions together with experts from academia, regulatory authorities, patient advocates, policymakers and industry.

We invite you to join us in Paris for this very important meeting.

More information

To register, go to the BDA website and read the announcement below.

Save the date:

Workshop: "Improving oncology drug development for children and adolescents"

18 -19 November 2013

Paris, France

*A **UNIQUE** opportunity to address hurdles and explore potential solutions together with experts from **ACADEMIA**, **REGULATORY AUTHORITIES, PATIENT ADVOCATES, POLICYMAKERS and INDUSTRY.***

PROGRAMME OVERVIEW

In June 2013, the European Commission published the interim report on the first 5 years of the implementation of the EU's Pediatric Regulation (link to the report) . This report and additional publications showed positive changes in the field of pediatric drug development and identified hurdles and bottlenecks in pediatric oncology drug development.

The goal of the meeting is to state where we are, to identify how the strategy for pediatric oncology drug development should be further defined and to propose solutions that may improve the implementation of the regulation in order to better meet the needs of children and adolescents with cancer.

This is a meeting where all stakeholders, namely academia, parents and patients, industry, regulators policymakers and others will share their views and challenges, will interact and propose solutions and actions for the future. This meeting is not aimed to be a consensus meeting.

The meeting will first address where we are at year 5 of the European Pediatric Regulation in the field of oncology and will follow on the actions proposed during the first BDA meeting in December 2011.

Discussions will be focused on three topics of major importance for the future:

§ Mechanism-of-action and biology driven development of oncology drugs for children and adolescents

§ New and innovative partnering for improving cooperation between stakeholders

§ Novel designs and development plans to improve feasibility and speed up introduction of new drugs in standard care.

WHO SHOULD ATTEND?

§ Representatives from Academia (scientists, clinicians)

§ Representatives from the Pharmaceutical Industry (senior decision makers from pediatric oncology, regulatory affairs, public affairs).

§ Representatives of European regulatory bodies

§ Policymakers

§ Parents and Patient Advocates

VENUE

Hotel Novotel Charenton

3-5 Place des Marseillais

94227 Charenton le pont

France

Venue Website

∅ **For more information, visit BDA website or contact the organising secretariat at marjorie.recorbet@ecco-org.eu**

∅ **Register here**