Calls for policy changes as lives put at risk by bureaucracy

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A European Parliament event to discuss how EU legislation has negatively affected the treatment received by children and adolescents has marked International Childhood Cancer Day - 15th February.

The meeting was hosted in association with the European Society for Paediatric Oncology (SIOPE) to raise awareness of the many hurdles faced by patients and those who care for them as a result of the EU Clinical Trials Directive (CTD).

The Directive (2001/20/EC) has been one of the most controversial pieces of European legislation related to health since its introduction in 2004; seen by many to be having a detrimental effect on academic-led clinical research in Europe. Member of the European Parliament Glenis Willmott, who hosted the event in Brussels, Belgium, stated: "EU countries are still using different standards for clinical trials, which means researchers have to apply multiple times for a clinical trial, with different applications.

This makes the whole process time-consuming, expensive, and sometimes futile. That's why we want to make sure all EU countries are playing by the same rules. We need to do everything we can to encourage more research and more clinical trials, specifically designed for children and adolescents".

Although the objective of the Directive was to standardise the regulation and quality of trials, there has been a lack of coordination and huge

increases in bureaucracy and administration to meet EU CTD requirements, especially for non-commercial investigator-led, multinational trials.

The CTD is currently being revised by the European Commission, with a proposed revision expected to be published in September 2012 for legislative review by the European Parliament and Council.

While each major type of childhood cancer is individually rare, 1 in 500 will be affected by cancer during childhood- cancer remains the leading cause of death from disease in children and young adults. Clinical trials in this field have provided the evidence base on which current best practice is built and are complex treatments.

The international paediatric oncology community has successfully raised survival, from less than 20% of young people surviving cancer to about 80% over the last four decades. The principal reasons for this are the creation of international networks that have harmonised treatment protocols across geographical borders and delivered high-quality clinical trials.

Currently, over 80% of chemotherapy agents that form the backbone of treatments for children with cancer and standard practice for over 40 years are used 'off label', due to lack of economic interest from the pharmaceutical industry.

SIOPE President Dr Ruth Ladenstein commented: "While clinical research is a necessary tool to combat the burden of cancer the current bureaucratic workload of trial activation in Europe is much too high. Moreover, we are dependent on the pharmaceutical industry to apply for licensed indications and there currently is no economic interest, nor sufficient incentive for the industry to engage in this field of off- patent drug development, especially given the rarity of childhood cancers."

As the treatment provided to young people with cancer in Europe has been based upon years of experience and success, there is a need for an introduction of proportionate risk management to the EU Clinical Trials Directive. "It is paramount that the European Commission takes a reasonable approach when addressing the associated risk of standard care drugs in off-label use that have proven to be successful in orphan indications like paediatric cancer", Ladenstein pointed out.

In addition, the implementation of the EU CTD in individual Member States was accompanied by a variety of interpretations and diversity rather than harmonisation of the conduct of clinical trials. Some Member States consider all off-label drugs within a trial as IMPs whilst others restrict this definition to one drug only specifically under investigation within a randomised trial.

The current revision of the EU Clinical Trials Directive by the European Commission represents a major opportunity to simplify approval and monitoring requirements, provide greater clarity on the scope of the Directive, including the definition of an IMP and to simplify approval and monitoring requirements for low risk trials delivering standard care within a scientific setting.

Provided by The European Society for Paediatric Oncology