Brussels, on 10th November 2015

Dear Commissioner,

September 2015 was the International Childhood Cancer Awareness Month. Today in Europe, children with cancer and other life-threatening diseases are being denied access to potentially life-saving treatments. This is a public health issue of prime importance.

Cancer is the leading cause of death by disease in children across Europe. Each year, 35,000 children and adolescents are diagnosed with leukaemia or malignant solid tumours and 6000 of them die. Of the survivors, 40% will be left with severe long term side-effects which impact their daily life.

For some conditions with a poor prognosis, only very limited improvements in treatments for children have been seen in recent decades. The problem is not only medical but economic. As childhood cancers are comparatively rare, they have been largely neglected as they do not represent a broad enough market for drug manufacturers, who still consider adults their main customer base.

The Paediatric Regulation adopted in 2007, and in which we have been greatly involved, has been a big step to push industry to consider research and development of paediatric drugs in Europe. But it has unfortunately not met all our expectations and has had very little impact on the availability of treatment for paediatric cancers, with only one oncology drug developed since the Regulation was put in place

Today, European children still have no access to evaluate safe and innovative medicines. We think the problem is threefold:

First, the system of Paediatric Investigation Plans (PIP) is currently too rigid and slow moving. The Paediatric Regulation stipulates that companies have to evaluate every new product they are developing for adults to determine whether it has potential for the treatment of children. To this aim, they have to submit a PIP to the European Medicine Agency in the first stage of research. However, research in children is currently difficult to conduct, due to very rigid rules, the ethical difficulty of submitting children to clinical trials, and the fact that children only constitute a very small population of those affected by rare illnesses.

If the industry is to be fully engaged, it must be given reasons to do so. Therefore, we propose that a more effective system of incentives and sanctions is put in place to encourage the industry to engage in paediatric research, and that clinical trial sponsors are encouraged to be more flexible about including paediatric patients in adult trials, where this would be beneficial to paediatric research.

Second, there are simply too many waivers. Specifically, when it is determined that the drug being researched is intended for the treatment of a disease that only occurs in adults, companies can apply to have the PIP waived. This possibility is largely abused, even taking into account the review of the class waiver list by EMA in July 2015. More than 60% of PIPs associated with waivers and all possible procedures are used to delay the paediatric development. For example, in the first five years of the Regulation, twenty six drugs with potential application to childhood cancers were approved for adult marketing, but over half of these received a paediatric waiver.

Third, the processing time of files is problematic, with many cases still awaiting evaluation. We must accelerate the process in the EMA as well as with national agencies.

We know that some drugs for adults can be active at a molecular level in certain childhood diseases. In cancer, for example, there are important biological connections between adult and childhood malignancies. Therefore, we propose replacing the current waiver system with one that instead examines the mechanism of action of the drug.

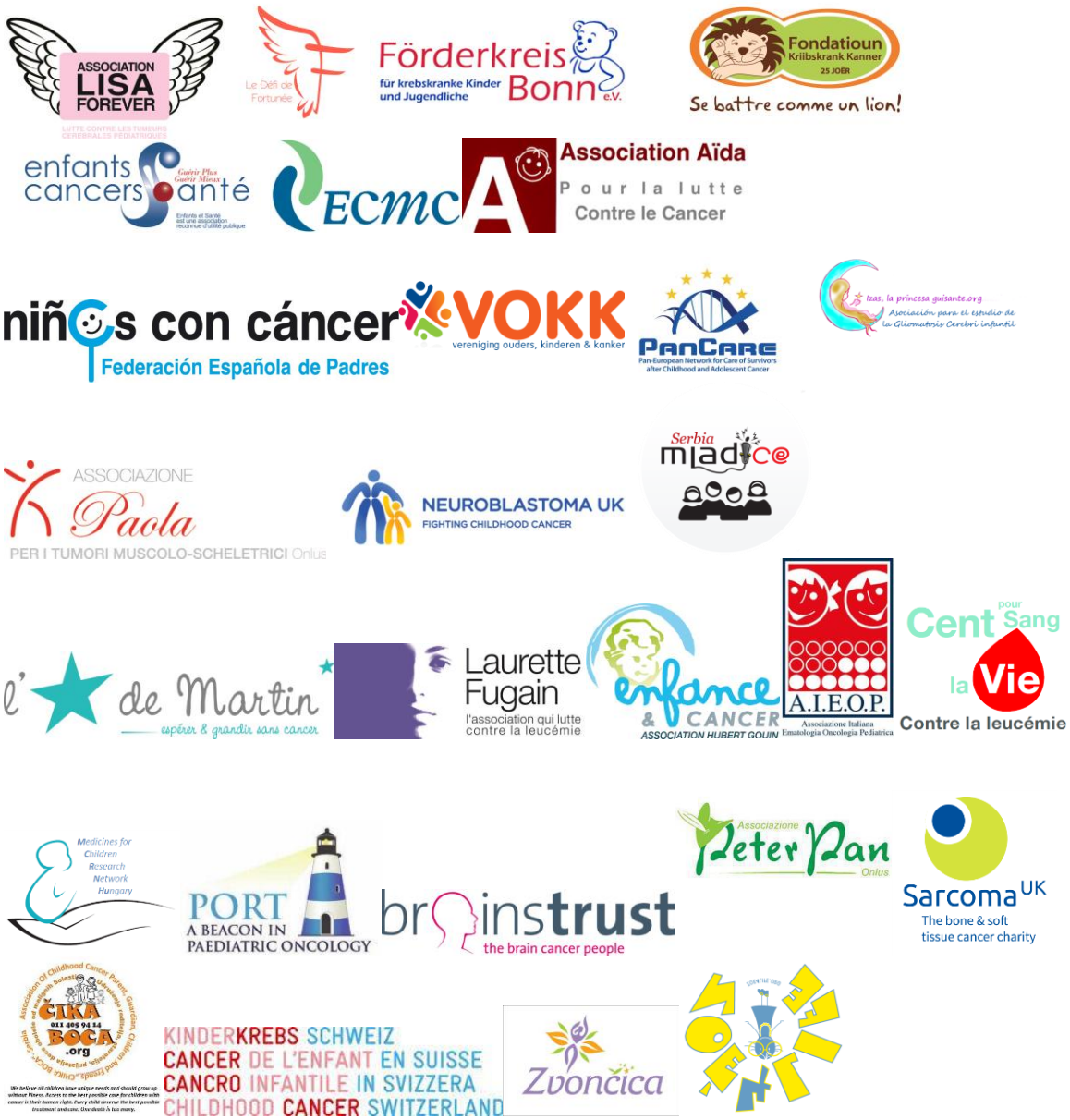
We cannot afford to wait 2017 for a potential review of the Paediatric Regulation, not when so many children are suffering because treatments either do not exist or those that do often have severe, long-lasting side-effects. We ask, at the very least, that the Commission immediately evaluate the situation and the application of the Paediatric Regulation, in order to be able to correct it as soon as possible.

As MEPs highly involved in the cause of children with cancer for many years, we have decided, together with the new European network “Unite2cure” which is supported by numerous parents' organizations, NGOs, doctors and researchers, to CALL FOR IMMEDIATE ACTION to give more children and adolescents the prospect of a better life.

The time for action is NOW.

Françoise GROSSETÊTE

Glenis WILLMOTT



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