"Role of licencing bodies to increase access to treatment" in the 68th WHA side event on
"Childhood cancer: the importance of universal access to treatment, care and support" 18 May 2015

Honourable ministers, Ladies and Gentlemen,

The *European Medicines Agency* is one of the regulatory authorities for medicines. Tonight I have the honour to speak for the Agency and on behalf of *Dr Gregory Reaman, associate director of the Office of Hematology and Oncology Products* of the *Food and Drug Administration* of the *United States of America*.

For any patient to have access to medicines, a regulatory approval is a necessary step. Our both Agencies' main role is to evaluate a medicine and to ensure it has more benefits than risks for the patients who will receive it.

For children of all ages, our experience is that it is necessary to attract the interest of pharmaceutical companies. Some of them do develop medicines to treat children with cancer. Incentive-programs aimed at children's medicines - first introduced in the U.S. and then in the EU - have attracted the interest of pharmaceutical companies. This model has shown that incentives can work. We have witnessed companies developing medicines for children with cancer and increasingly benefiting from incentives. Incentives to companies translate into benefits for patients, in particular children.

In *Low and Middle Income Countries*, children represent up to 50% of the population, and childhood cancer is not rare. The possible gains of curing children with cancer are enormous. We are indeed talking about cure because we know that cancer in children can very often be cured with medicines, much more often than in adults. For this reason, we welcome the updated *Essential medicines list for children:* It includes an increased number of cancer medicines, and this will lead to curing more children's cancers.

At this time, the reality of childhood cancer specialists in Low and Middle Income Countries is sobering. A curable lymph node cancer that goes by the name of Burkitt lymphoma is a frequent cancer in these countries: Only half of the children on treatment will be able to get the full amount of treatment. We have effective cures, but health professionals are powerless and half of the patients untreated.

What is unique to cancer is its diversity. Surprisingly most cancers affecting children have no equivalent in adults. However, this must not be a barrier because research has demonstrated that many medicines work well against both, cancers in adults and in children. Children and adults can share many cancer medicines, even if their cancers' names are different. The same medicine can be re-used - what we call "re-purposed" - for children despite the fact that it was developed for adult cancer. In the past, even though medicines did have regulatory approval, it unfortunately took many years of delay until innovative medicines came to children. However, children with cancer cannot wait.

Another important step is therefore to study medicines specifically in children. Cancers and body functions are different in children; they are not small adults. Medical research and medicines trials with children hence are necessary. Such research with children is increasing in *Low and Middle Income Countries*. This is a welcome global effort. In fact, there is a need for these countries to be involved in studies that are specifically relevant for their health care system.

Here, our role as regulators is to ensure that cancer research with children is of high ethical and scientific quality, when we evaluate the research proposals. In addition, we are taking an active role to safeguard patients' interests with the International Society of Paediatric Oncology and with the Paediatric Medicines Regulators' Network of the World Health Organization.

I would like to conclude by stating that medicine regulatory authorities today are committed to addressing the priority health needs of children, including all children with cancer.

In doing so,

We regulators are only effective for patients if we are part of chain, in which all are proactive:

- Governments because they can create incentives
- and because they can ensure that research and care of children with cancer is integrated with their health system
- Companies because they can conduct the research and development of new medicines
- and because they can manufacture and distribute generic medicines to make them accessible worldwide.

This will be in the best interest of our children.

Thank you.