



SEPTEMBER
CHILDHOOD CANCER
AWARENESS MONTH

GOLD *for* **HOPE:**
**CURE MORE AND
CURE BETTER**



MEPs
AGAINST CANCER



ECL
Association of European
Cancer Leagues



SIOP Europe
the European Society for Paediatric Oncology



Childhood
Cancer
International
EUROPE

‘Championing the Paediatric Regulation in the future revision of the EU pharmaceutical legislation’

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MAC-SIOPE Webinar for Gold September
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A UNIQUE OPPORTUNITY FOR LIFE-SAVING CHANGE



❑ Important unmet needs of children and adolescents with cancer

- Access to **therapeutic innovation** in an area of relative market failure

❑ EU Paediatric Regulation

- European Parliament resolution from 2016 **called for targeted revision**
- European Commission recognised **the unmet needs in paediatric cancer** in the 2020 evaluation of the Regulation
- The **Pharmaceutical Strategy for Europe** also recognised in 2020 the need to revise the Paediatric Regulation

**The upcoming revision of the EU Paediatric Regulation
is a unique opportunity to accelerate innovation for children with cancer**



6 RECOMMENDATIONS

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European Childhood Cancer Organisations' **Recommendations**

following the European Commission's Evaluation of the Legislation for Medicines for Rare Diseases and Children and the launch of the Pharmaceutical Strategy for Europe.

1. **Align the Regulations** with Science and **Unmet Needs** of Children
2. Ensure Child-Specific and **First-In-Child Innovation**
3. Implement **Multi-Stakeholder Cooperation** and Prioritisation as a Standard
4. Allocate **Public Investment** in Medicine Development for Children
5. **Align Global** Regulatory Environment
6. Ensure **Equal Access** to Essential & Novel Anticancer Medicines & to Supportive Care Medicines



TANGIBLE ACTIONS



Align the Regulations with Science and **Unmet Needs** of Children

- ❖ **Focus on the targeting the right drug to the right disease (mechanism of action approach)**

Ensure Child-Specific and **First-In-Child Innovation**

- ❖ **Appropriate incentives balanced with obligations**

Implement **Multi-Stakeholder Cooperation** and Prioritisation as a Standard

- ❖ **ACCELERATE Paediatric Strategy Fora** as exemplars

Align Global Regulatory Environment

- ❖ **EMA-FDA aligned decision-making on paediatric cancer drug development plans**



Thank you very much for your valued
attention and instrumental support!

