



Paediatric medicines development:
fostering more and better cure
through joint efforts



State of Paediatric Medicines in the EU

10 years of the EU Paediatric Regulation

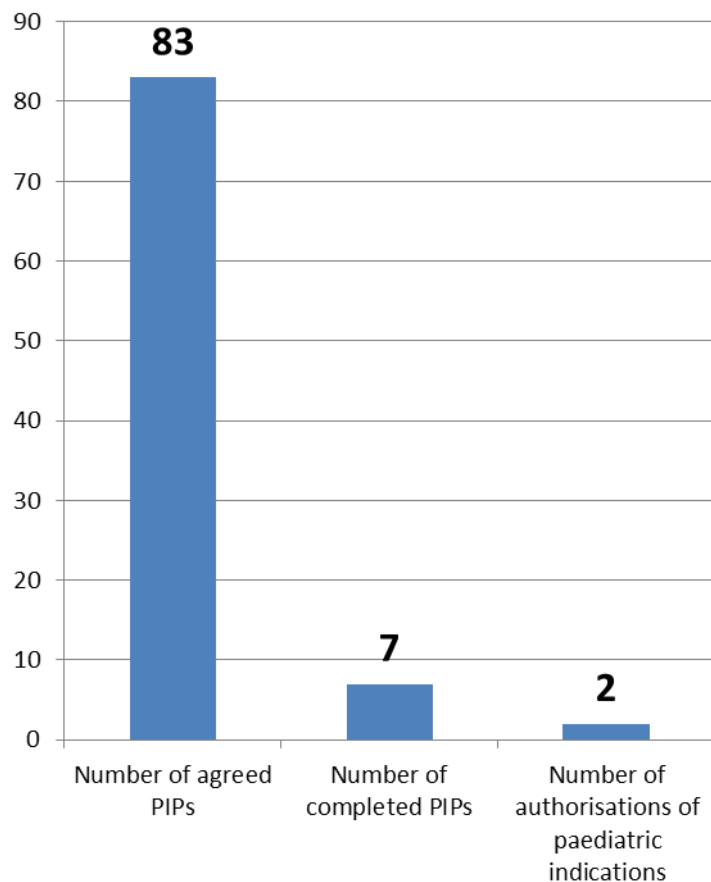
Report from the Commission to the European Parliament and the Council

COM (2017) 626

“paediatric oncology is often used as a case study for insufficient advances in an area of high unmet paediatric need”

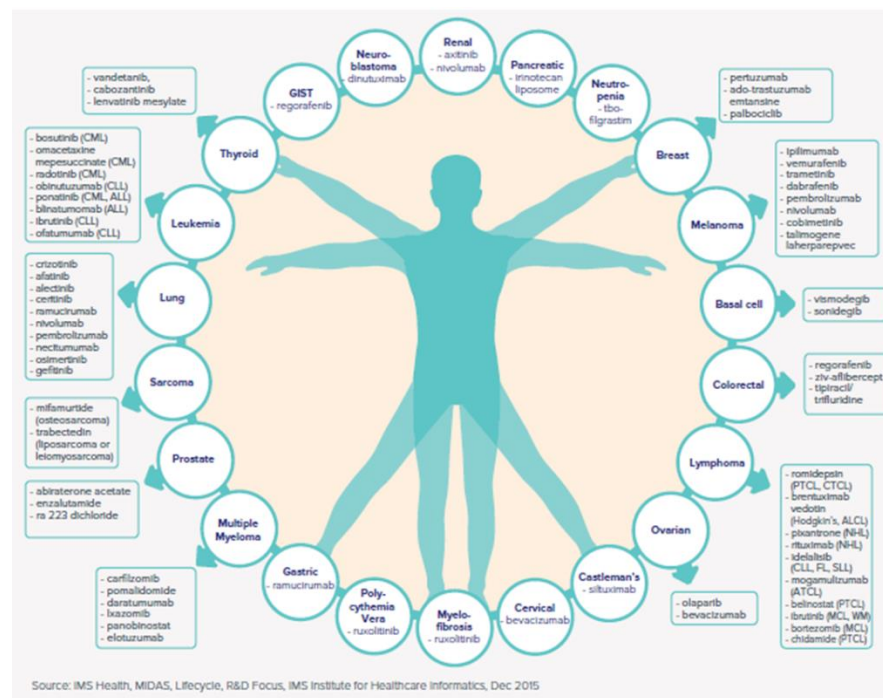
Oncology: the issue

PIP Oncology – 2007 - 2015



source: 10yr EMA report
EMA/231225/2015 21 october 2016

70 new approved oncology products
2011-2015



Source: IMS Health, MIDAS, Lifecycle, R&D Focus,
IMS Institute for Healthcare Informatics, Dec 2015

Newly approved medicines for childhood cancers

- **CAR T cells for ALL**
- **Blinatumomab for ALL**
- **Dinutuximab for neuroblastoma**

The oncology paradoxe in 2018

Many drugs in adults

Disease – based development



**Poor access
to pediatric patients**



**Poor access
to innovation**



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“the Regulation works best in areas where the needs of adult and paediatric patients overlap”



FDA REAUTHORIZATION OF 2017

RACE for Children ACT

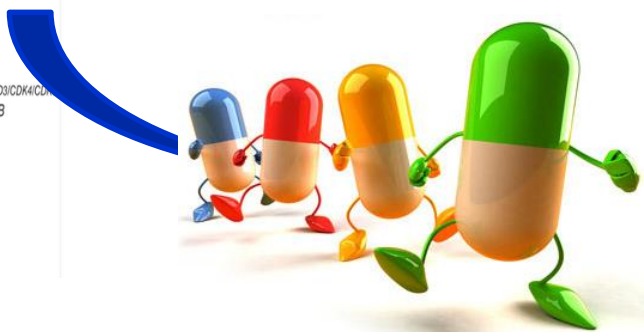
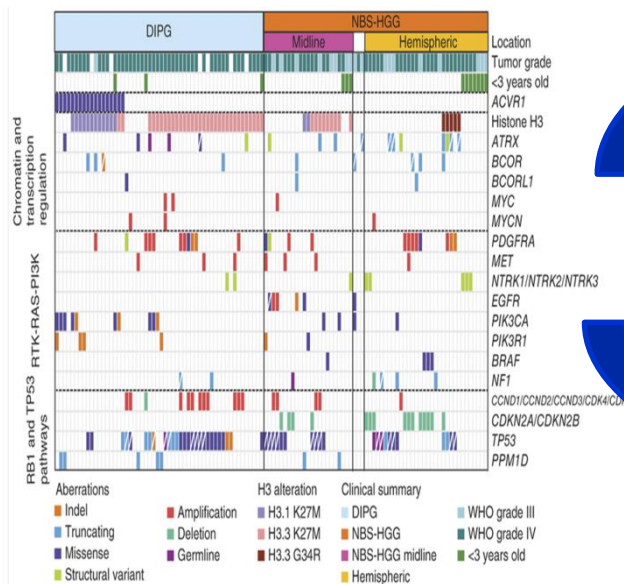
**Research to Accelerate Cures
and Equity for Children**

New oncology drug development for children : the goal

MOA* – based development and prioritisation

SCIENCE

NEEDS



Improve access

Specific pediatric drugs

*Mechanism of action



ACCELERATE

INNOVATION FOR CHILDREN AND ADOLESCENTS WITH CANCER

NEEDS

- **More investment in science**
- **A better incentivizing EU regulatory environment**
- **International cooperation**
- **Work together**