Abstract

G. Vassal et al., 'Creating a unique, multi-stakeholder Paediatric Oncology Platform to improve drug development for children and adolescents with cancer', European Journal of Cancer , Volume 51 , Issue 2 , 218 – 224

Seven years after the launch of the European Paediatric Medicine Regulation, limited progress in paediatric oncology drug development remains a major concern amongst stakeholders – academics, industry, regulatory authorities, parents, patients and caregivers. Restricted increases in early phase paediatric oncology trials, legal requirements and regulatory pressure to propose early Paediatric Investigation Plans (PIPs), missed opportunities to explore new drugs potentially relevant for paediatric malignancies, lack of innovative trial designs and no new incentives to develop drugs against specific paediatric targets are some unmet needs. Better access to new anti-cancer drugs for paediatric clinical studies and improved collaboration between stakeholders are essential. The Cancer Drug Development Forum (CDDF), previously Biotherapy Development Association (BDA), with Innovative Therapy for Children with Cancer Consortium (ITCC), European Society for Paediatric Oncology (SIOPE) and European Network for Cancer Research in Children and Adolescents (ENCCA) has created a unique Paediatric Oncology Platform, involving multiple stakeholders and the European Union (EU) Commission, with an urgent remit to improve paediatric oncology drug development. The Paediatric Oncology Platform proposes to recommend immediate changes in the implementation of the Regulation and set the framework for its 2017 revision; initiatives to incentivise drug development against specific paediatric oncology targets, and repositioning of drugs not developed in adults. Underpinning these changes is a strategy for mechanism of action and biology driven selection and prioritisation of potential paediatric indications rather than the current process based on adult cancer indications. Pre-competitive research and drug prioritisation, early portfolio evaluation, cross-industry cooperation and multi-compound/sponsor trials are being explored, from which guidance for innovative trial designs will be provided.

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