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Regulatory situation 9 years after the implementation of the EU Paediatric Regulation

The *EU Regulation on Medicinal Products for Paediatric Use* came into force in 2007. Its objectives are to ensure high quality, ethical research into medicines for children, increase availability of authorized medicines for children, improve information available on medicines for children. The *Paediatric Regulation* consists of an obligation for pharmaceutical companies to perform *Paediatric Investigation Plans (PIP)* for all new drugs or on-patent drugs intended for label extension, rewards for paediatric development such as a patent extension, and a *Paediatric Committee* to guide this process. Moreover, a number of collateral measures are aimed to increase information, transparency, and stimulate research into paediatric medicines.

The Paediatric Regulation has changed the environment for paediatric medicine development in Europe. In the last 9 years, the Paediatric Committee has agreed more than 900 PIPs, most of which are still ongoing. All collateral measures have been implemented. The proportion of clinical trials in the EU involving children has substantially increased. As a result of the regulation, more than 250 drugs have received new paediatric authorizations, new age-appropriate formulations, or updates of product information with new paediatric data. However, there are ethical, methodological, and practical challenges to the successful and timely completion of PIPs. Moreover, the need for paediatric studies is not yet universally accepted among patients, parents, health professionals, and ethics committees. In summary, the Paediatric Regulation has implemented important measures to improve medicine development for children. To achieve broad availability of authorized medicines for children will require more time.