

**Copenhagen Centre for Regulatory Science (CORS)**

*Medical Product Innovation - Research & Education*



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**PhD project: The Impact of Paediatric Regulations on Drug Development in a Trans-Atlantic Perspective**

***Paediatric regulation and the accountable regulatory system for medicines***

In EU and US paediatric regulations has been set up to facilitate paediatric drug development, with the objective of improving the health of children. The regulations provide incentives and impose requirements (the ‘carrot and the stick’) on sponsors for the development of medicinal products for the paediatric population. Both EU and US paediatric legislations have generally been found to be successful, but the analyses are based on straightforward descriptive reports measuring regulatory processes and output of the regulations.

The regulatory system is provided by the means of public resources to regulate private sector activities, which creates a need for accountability and reversibility. It is therefore important to evaluate the paediatric regulation continuously against its objectives to assess if it is achieving its aims, and in the best way. If not, the regulatory instrument should either be revised, or replaced by an improved regulation, or removed altogether.

***Exploring access of medicines for the paediatric population in EU and US***

Currently, a mere measurement of compliance with the legislation and the number of developed medicine under the paediatric regulations has been assessed. However, an assessment should ideally also include an evaluation of the acquired knowledge about medication use in the paediatric population, how that knowledge is translated into action and how it facilitates access to treatments and how it impacts children’s health positively. We wish to provide insights into the effectiveness of the EU and US paediatric regulations to promote access to medicines for children.

***Barriers caused by the paediatric regulation***

The regulatory systems for medicines enable and support development in a global context, to avoid conflict with other regulatory and societal interests, such as increased costs of development, delayed timelines, and barriers to innovative drug development. This could lead to lack or delays in new treatments for adults, as well as for children, reaching the market. We aim to identify potential barriers to innovation caused by the introduction of the paediatric regulations in EU and US. Ultimately, the analyses from the PhD project should serve to provide recommendations for improvements to the global regulatory frameworks for paediatric medicines development with a focus on the US and the EU.

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