

## EAP position statement on the Paediatric Regulation and Rare diseases

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Rare diseases should not be overlooked in discussion on how to improve impact of Paediatric Regulation.

Developers of medicines for rare paediatric diseases need to comply with both the Orphan and Paediatric Regulation. Decisions of the Orphan and Paediatric Committees should be aligned.

To improve the availability of high quality medicines for use in children, transparency on development costs and agreement on maximum price, is warranted. The price should match a considerable and measurable clinical benefit.

Brussels, December 2th, 2017