

Paediatric Regulation: Clinician's view

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Clinician's needs

- Drugs for children
 - National legislation vs. EMA
 - Off-label use
 - Funding
 - Deals with companies on a national basis
 - Reimbursement systems very variable
- Good quality data to tell us how to use them
 - Appropriate clinical trials
 - Research infrastructure
 - Research funding
 - Distribution of data
 - Company files

The past 12 years

- The Paediatric Regulation is only one factor
 - Its effect has not been as large as expected
 - Money talks!
- More emphasis on rare diseases, better incentives
 - Some new diseases have become treatable!
- New drugs are usually very expensive
 - Less drugs available
- Production and delivery problems have become common
 - Less drugs available
- Clinical work has become very demanding
 - Less time for research