



European Commission

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Medicines for children





Medicines for children

Why do we need a proposal for a regulation?

- > 50% of medicines used by children not tested or authorised: maybe given ineffective or harmful treatment.
- Market forces insufficient as market small and studies in children judged to be too complex
- December 2000 Council Resolution; European Parliament also calling for action
- 2000-2003 – Proposal researched and Extended Impact Assessment conducted
- 2004 – Consultation
- Today - proposal adopted by the Commission



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Objectives of the proposal

- To improve the health of the children of Europe, by:
 - increasing high quality research into medicines for them
 - promoting the development and authorisation of such medicines
 - improving the information on medicines designed for children
- While avoiding unnecessary studies in children and not delaying the authorisation of medicines for adults

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Key measures for patented medicines

Requirement at the time of applications for new medicines for:

- data in children (as agreed by paediatric committee), or
- a waiver from the requirement, or
- a deferral of the timing of the studies

Reward for studies conducted:

- 6-months extension of the supplementary protection certificate (in-effect, a patent extension)
- For orphan medicines, 2-years additional market exclusivity (10+2)

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Key measures for off-patent medicines

For new off-patent medicines specifically developed for children:

- new type of Marketing Authorisation, the Paediatric Use Marketing Authorisation (P.U.M.A.):
 - enabling 10-years data protection
 - use of existing brand name (brand recognition)
 - amended data requirements



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Horizontal key measures

- A new expert paediatric committee to scrutinise company testing plans
- European network of experts
- Free scientific advice from the EMA
- Information tools – inventory of therapeutic needs, new product labelling requirements, database of studies
- Enhanced safety monitoring for marketed products

Conclusions

- Better medicines for children
- Innovation stimulated

Now to the Council and Parliament