



Making Medicines Affordable

## EU PROPOSED REGULATION ON MEDICINES FOR CHILDREN Summary of Main issues

Market Sector	EU Draft Regulation
<b>ON-PATENT PRODUCTS</b>	<ul style="list-style-type: none"> <li>▪ For new medicines or for line extensions for older medicines still under patent</li> <li>▪ Paediatric studies will be <u>obligatory</u> unless a waiver or deferral is granted</li> </ul> <p><b>REWARD: SPC extension</b></p> <ul style="list-style-type: none"> <li>▪ 6-month extension, effectively of the patent, on the whole product in return for fulfilling paediatric investigation plan</li> </ul>
<b>OFF-PATENT GENERICS</b>	<ul style="list-style-type: none"> <li>▪ Off-patent sector has been identified as most in need of support for new investigations in children</li> <li>▪ If paediatric studies are fulfilled according to a Paediatric Investigation Plan: ‘Paediatric Use Marketing Authorisation’ (PUMA) granted</li> </ul> <p><b>REWARD: 10-years data exclusivity</b></p> <p><b>Research Funding: MICE Programme</b></p> <ul style="list-style-type: none"> <li>▪ ‘Medicines Investigation for the Children of Europe’ (MICE) will be introduced as a separate initiative at a later date.</li> </ul>
<b>GENERAL</b>	<ul style="list-style-type: none"> <li>▪ Expert <b>Paediatric Committee</b> established within EMEA as advisory board to examine and agree Paediatric Investigation Plans, waivers, deferrals</li> <li>▪ For <b>ORPHAN DRUGS</b> (for treating very rare diseases): companies would receive an additional 2 years of market exclusivity</li> </ul>