Influencing EU Pharmaceutical Legislation:

Increasing Impact of the Paediatric Regulation

Before 2007 there was no specific provision in EU pharmaceutical legislation to encourage the research and development of medicines for children. Doctors had to use information based on clinical studies in adults which lead to uncertainty in dosage, benefits and adverse events, and the majority of medicines that were used to treat children had not been tested on children. Companies had little financial incentive to conduct paediatric studies given the small patient numbers in most diseases and the complicated nature of conducting studies in children. Given the clear public health need to encourage greater knowledge of how to treat children appropriately, there was broad support to reform EU pharmaceutical legislation.

The European Commission's draft Paediatric Regulation proposed a six month Supplementary Protection Certificate (SPC) extension as a reward for completing a pre-agreed Paediatric Investigation Plan (PIP). This SPC extension however, would only apply and benefit those products that had at least two years left to run on their SPC. This meant that products nearing the end of their SPC life would be excluded from the provisions of the legislation. Although not a major issue for the industry as a whole, it did pose a significant challenge for certain products nearing SPC expiry. Amending the legislative proposal to ensure all products that could benefit children fell within scope was achieved by:

1. **Gathering Evidence:** Review of product portfolio identified a key cardiovascular medicine that would fall outside the scope of the paediatric regulation. To gather evidence on the public health impact, a paediatric cardiology group documented their need for greater knowledge on how this medicine could be used to benefit children. This report was used to demonstrate that critical information on medicines in children could be lost if the scope of the legislation was not broadened to include those products that were nearing the end of their SPC protection.
2. **Building Consensus:** The evidence was presented to key experts at the European Commission, EMA, MEPs leading the review in Parliament and the Council working group. This group of experts agreed that they would accept an amendment to the legislation, as long as it remained consistent with the overall objectives of the legislative proposal and the provision was temporary.
3. **Amending the legislation:** A proposal was developed to incorporate a transition period in the legislation whereby in the first 5 years following entry into force, rather than having to apply for an SPC extension two years prior to expiry, the deadline was 6 months. Extensive outreach with stakeholders was required to ensure this amendment achieved majority support in the Parliament and Council.

This amendment, which granted an additional 18 months for sponsors to complete their PIP, was accepted by the European Commission, adopted by the European Parliament and agreed by the European Council. By doing this, products that were nearing the end of their SPC fell into scope of the regulation. This broadened the public health benefit of the legislation, increasing the available knowledge to appropriately treat children and benefited the cardiovascular medicine identified in the portfolio review, which was subsequently granted a 6 month SPC extension as a reward for completing paediatric studies.

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