

How to initiate EU Paediatric Plans – Regulatory Strategy & Writing

Our experts at BlueReg are covering the different aspects of the Paediatric Plan, specific to the European Market.

The different subjects covered are :

1. Regulatory Strategy

- Why do we need an EU Paediatric Plan?
- Is a PIP required?
- Plan the PIP procedure
- Overview of the PIP procedure
- Which PIP condition?
- Should the PIP include a paediatric development, a waiver and/or a deferral?
- Content of the PIP Application

2. Writing the Paediatric Scientific Document

- Application Summary
- Overall Development
- Product-Specific Waiver(s)
- Paediatric Investigation Plan
- Deferral(s)

- References

3. Q&A's