EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Brief update:
Reform of the EU pharmaceutical legislation

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Background

Directive 2001/83/EC

Regulation (EC) 726/2004

Regulation (EC) No 1901/2006 on Med. Products for paediatric use

Regulation (EC) No 141/2000 on Orphan medicinal products

Revised into

- New Regulation
- New Directive

Objectives:

1- Improve access to medicines
2- Avoid shortages
3- Increase affordability
4- Create competitive regulatory framework
5- Ensure environmental sustainability

Revision of the Paediatric Provisions

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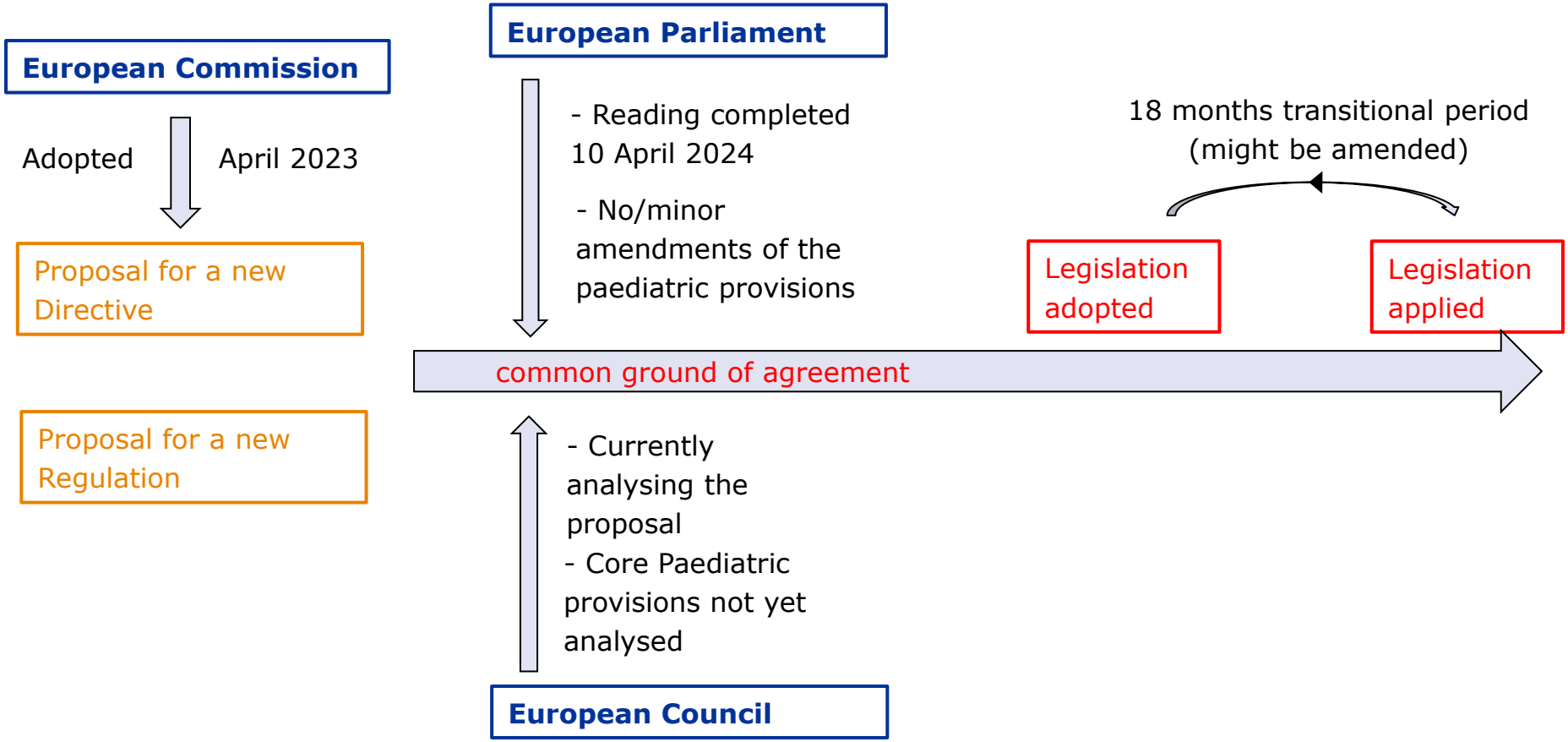
- Maintained structure of **obligations and rewards**
- **Objectives**
  - Facilitate PIP application process
  - Decrease delays in the development of paediatric medicines
  - Increase the development for unmet medical need areas
- **Changes**
  - Step-wise PIP
  - Mandatory PIP on the basis of MoA
  - Cap of 5 years for deferrals
  - Repurposing of medicines
- **EMA structural changes** → paediatric expertise to be present across committees and working parties
- **Enpr-EMA network role extended** → discussions on unmet medical needs and prioritisation of paediatric research

Timelines and Procedural steps



Thank you!