
New Pharmaceutical Legislation:

Platform Approaches

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Florian Schmidt, DG SANTE



#HealthUnion



A new pharmaceutical framework that builds on the EU's strengths



A reform package revising 20 years of EU rules for pharmaceuticals

A new **Directive and Regulation** updating current rules and simplifying the framework

Main objective: **guarantee safety, efficacy & quality** of medicines

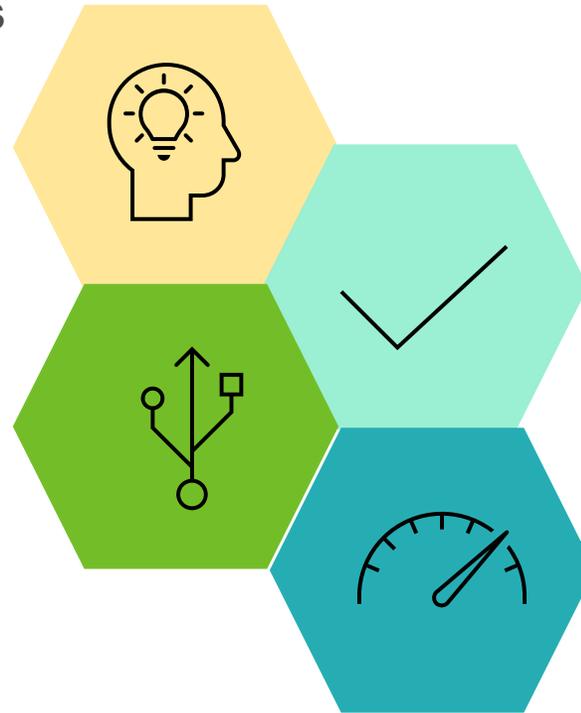


The reform is complemented by the proposed **Critical Medicines Act** and the **Biotech Act, new MDR etc.**

Regulatory excellence and simplification

- Interplay of pharma/other frameworks
- Regulatory sandboxes
- Adapted frameworks
- Early regulatory support by EMA, esp. SMEs
- Platform technologies
- Decentralised manufacturing

- Use real-world evidence,
- Electronic submission of applications
- Electronic Product Information



- Simplification of procedures
- Simplification of EMA structure
- Phased review
- Simplified rules for GM medicines
- Stronger interactions with downstream decision-makers (HTA, P&R)

- Reduction of assessment and approval time - --Reduction of clock stops
- Screening of immature applications

Platform marketing authorisation/technology

- New concepts recognised in the reform

Platform marketing authorisation – “we are family”

“Where justified for clinical purposes, a marketing authorisation may be granted for a medicinal product comprised of a fixed component and a variable component that is pre-defined in order to, where appropriate, target different variants of an infectious agent or, where necessary, to tailor the medicinal product to characteristics of an individual patient or a group of patients (‘platform marketing authorisation’)”

Platform technology – multiple-use technology for MA

‘platform technology’ means a technology or collection of technologies that has the potential to be incorporated in, or used by, more than one medicinal product and is comprehensive, well-characterised, reproducible, and standardised and used for the development, the manufacturing process or quality control of medicinal products that rely on prior knowledge and are established under the same underlying scientific principles, which have reasonable scientific certainty to remain unchanged across medicinal products



Platform marketing authorisation

- Fixed and variable component
- Variable component needs to be pre-defined in the marketing authorisation and serve clinical purposes
- Use of this option is subject to the pre-agreement by the competent authority
- Use cases: targeting different variants or tailoring the medicinal product to an individual patient

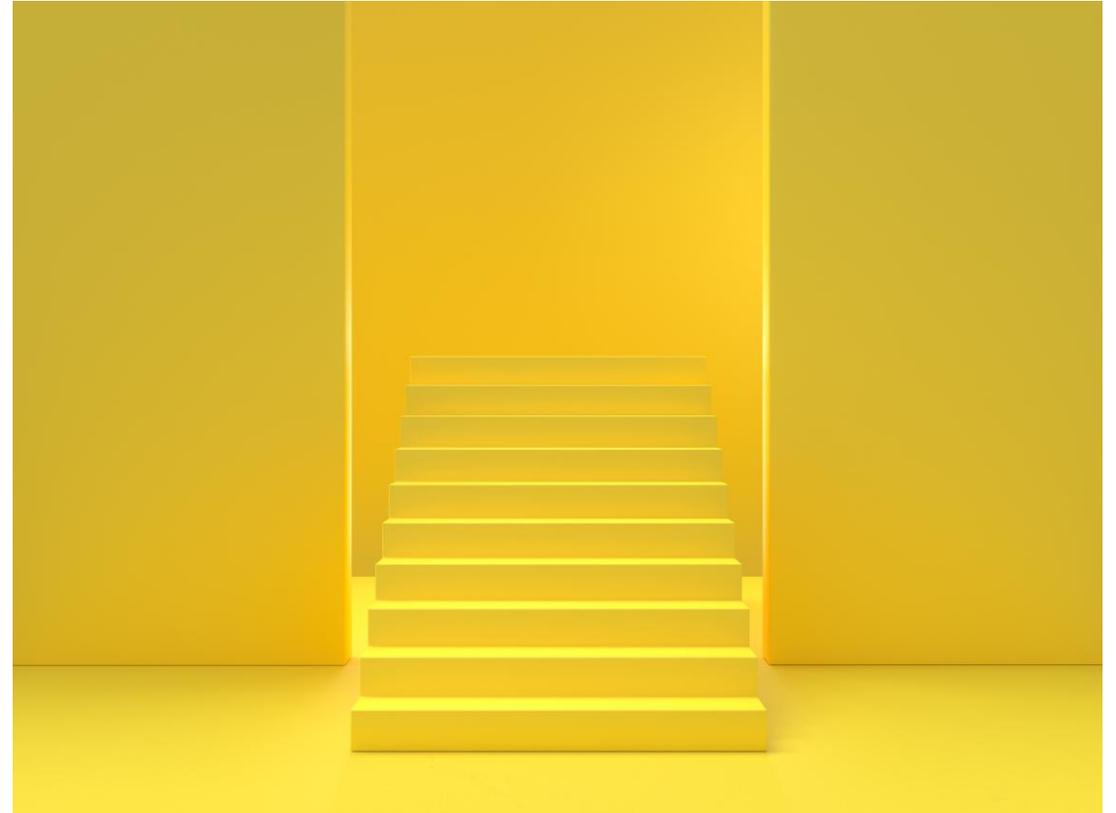


Platform technology

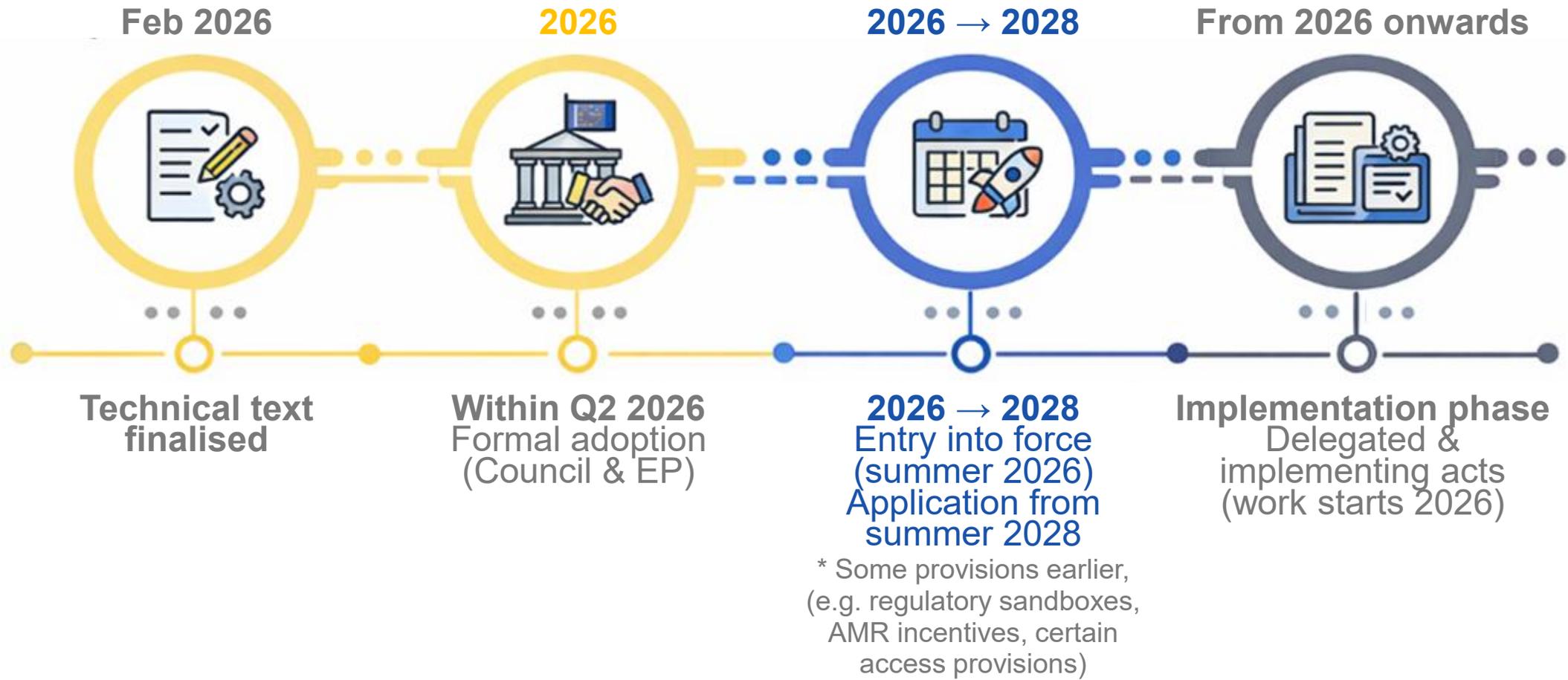
- **Advantages of platform technology master file:**
 - Recognising prior knowledge
 - Several use cases
 - Facilitating applications (master file concept)
 - Certification by EMA
 - Additional details in the new Annex II and scientific guidelines to be prepared by EMA
- **Process for obtaining platform technology master file**
 - Eligibility check by EMA
 - Submission as part of marketing authorisation or subsequently
 - Owner responsible for life-cycle management of certification
 - Responsibility for medicinal product remains with MAH

Platform technology – take away messages

- Platform technologies are a regulatory enabler to simplify and streamline applications and lifecycle management of medicines
- Platform technologies will become an integral part in future marketing authorisations, but they will never replace a marketing authorisation



Next steps



Thank you



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