FORUM

EU Pharmaceutical Legislation

The most important changes at a glance

Dr Alexander Natz, LL.M.

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About the author

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Dr Alexander Natz advises clients in the area of European and German health law with a focus on medicinal products, medical devices, food and cosmetics. Dr Natz has particular experience with the European legal framework with regard to Good Manufacturing Practice (GMP), lifecycle management, distribution as well as marketing authorisation and clinical trials of medicinal products. Since 2009, he has also been the Managing Director of EUCOPE - European Confederation of Pharmaceutical Entrepreneurs AISBL.

EU Pharma Package

EUCOPE
European Confederation of Pharmaceutical Entrepreneurs AISBL

EU plans changes to pharmaceuticals law to avoid medicine shortages

By Maggie Fick

EUROPEAN COMMISSION

Brussels, XXX
PLAN/2021/10601
[…](2023) XXX draft

SENSITIVE*

Pharmaceutical package

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006

(Text with EEA relevance)

The revision of the EU pharmaceutical framework

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Current framework

General Pharmaceutical Legislation (GPL)

Medicinal Products Directive (2001/83/EC)

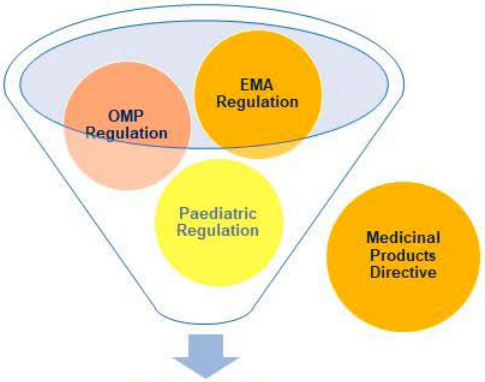
Dual legal path approval

EMA Regulation (no. 726/2004)

OMP Regulation (no. 141/2000)

Paediatric Regulation (no. 1901/2006)

EU Pharm Package 26 April



Merged into a 'Master Regulation'

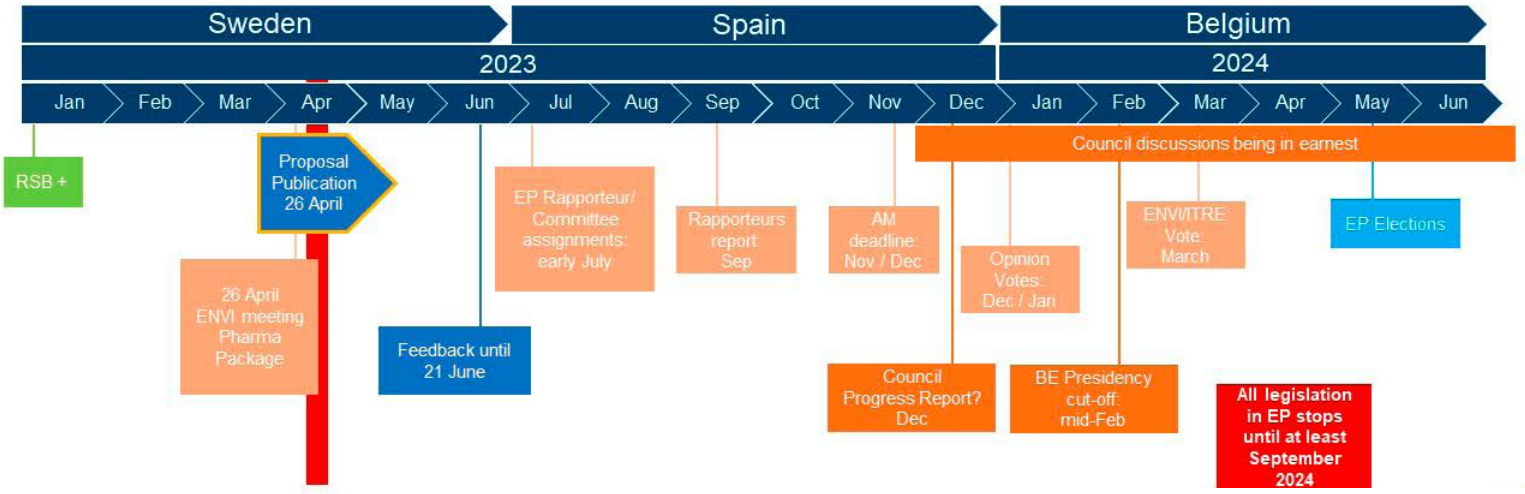
Context of proposed changes

General objectives

- Promoting innovation and novel technologies in areas of unmet medical need
- Access to affordable medicines
- Simplify regulatory framework, reduce the regulatory burden and provide a flexible regulatory framework, streamlining and acceleration of procedures
- Enhanced coordination of the European medicines regulatory network
- Enhanced digitisation (re-use of data, eSubmissions, ePI, etc.)
- Enhancing security of supply of medicinal products
- Reducing the environmental impact of the pharmaceutical product

Legislative process overview

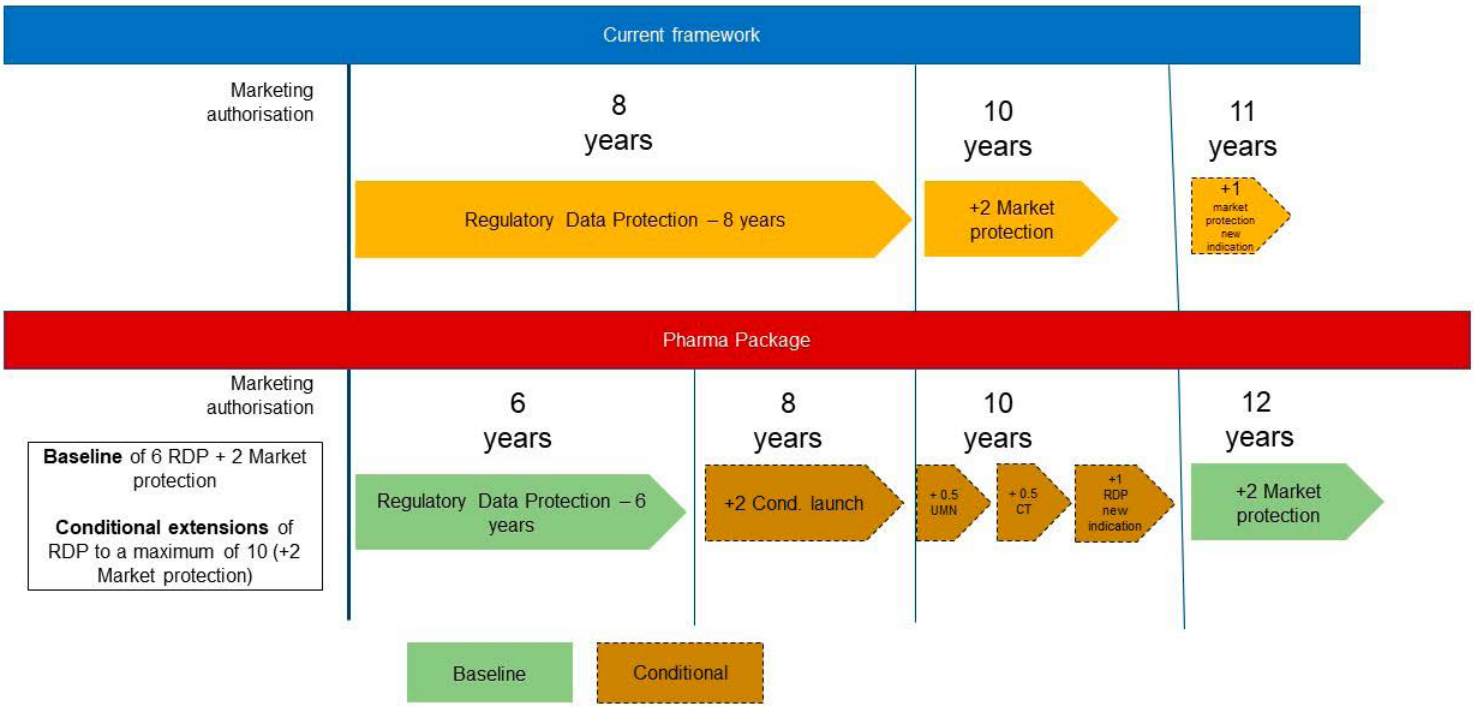
European Parliament will have **less than 11 months** to effectively discuss the proposal



NB: These timings are indicative and rough estimates, not official – it assumes a 'fast' process

Unmet medical need

Regulatory Data Protection (RDP)



Orphan Market Exclusivity (OME) Modulation *(Art. 71 Regulation)*

- Three 'classifications' of product are created:
  - 10-year OME, for OMPs addressing **high unmet medical needs** (HUMN)
  - 5-year OME, for well-established used OMPs
  - 9-year OME, for all remaining OMPs
- Exclusivity for products with 9/10 years OME can be extended (up to 12/13-year OME) if:
  - Expand into a new orphan indication (+1-year OME, max. twice)
  - Launch in all Member States (+1-year OME)
- Orphan Paediatric incentive is removed

(H)UMN

Unmet Medical Needs (UMN)
– art. 83 Directive

- A medicinal product is designated as UMN if:
  - At least one of its indications relates to a life-threatening or **severely** debilitating condition and;
  - no medicinal product is authorized in the EU, or where despite medical products being authorized for such disease in the Union, the disease is associated with a **remaining high morbidity or mortality**;
  - The use of the medical product results in a **meaningful reduction in disease morbidity or mortality** for the relevant patient population.
- All OMPs are designated as UMN

High UMN (HUMN)
– art. 70 Regulation

- An orphan medicinal product shall be considered as addressing a HUMN if it fulfills the following requirements:
  - There is no medical product authorized in the Union for such condition;
  - or despite medical products being authorized for such conditions, the applicant demonstrates the OMP, in addition to having a significant benefit, will bring **exceptional therapeutic advancement**;
  - The product must **meaningfully reduce** disease morbidity or mortality for the **relevant part of the population**
- The EMA will develop additional scientific guidelines to define HUMN

Definitions are strict and vague, especially related to wording such as 'severely', 'meaningful reduction', 'exceptional therapeutic advancement', 'relevant part of the population'

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