A new pharmaceutical framework for Europe

European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties meeting

20 October 2026

DG SANTE



European Commission

#HealthUnion

GENERAL DISCLAIMER

This presentation is meant to give a general overview of the agreement reached between the co-legislators.

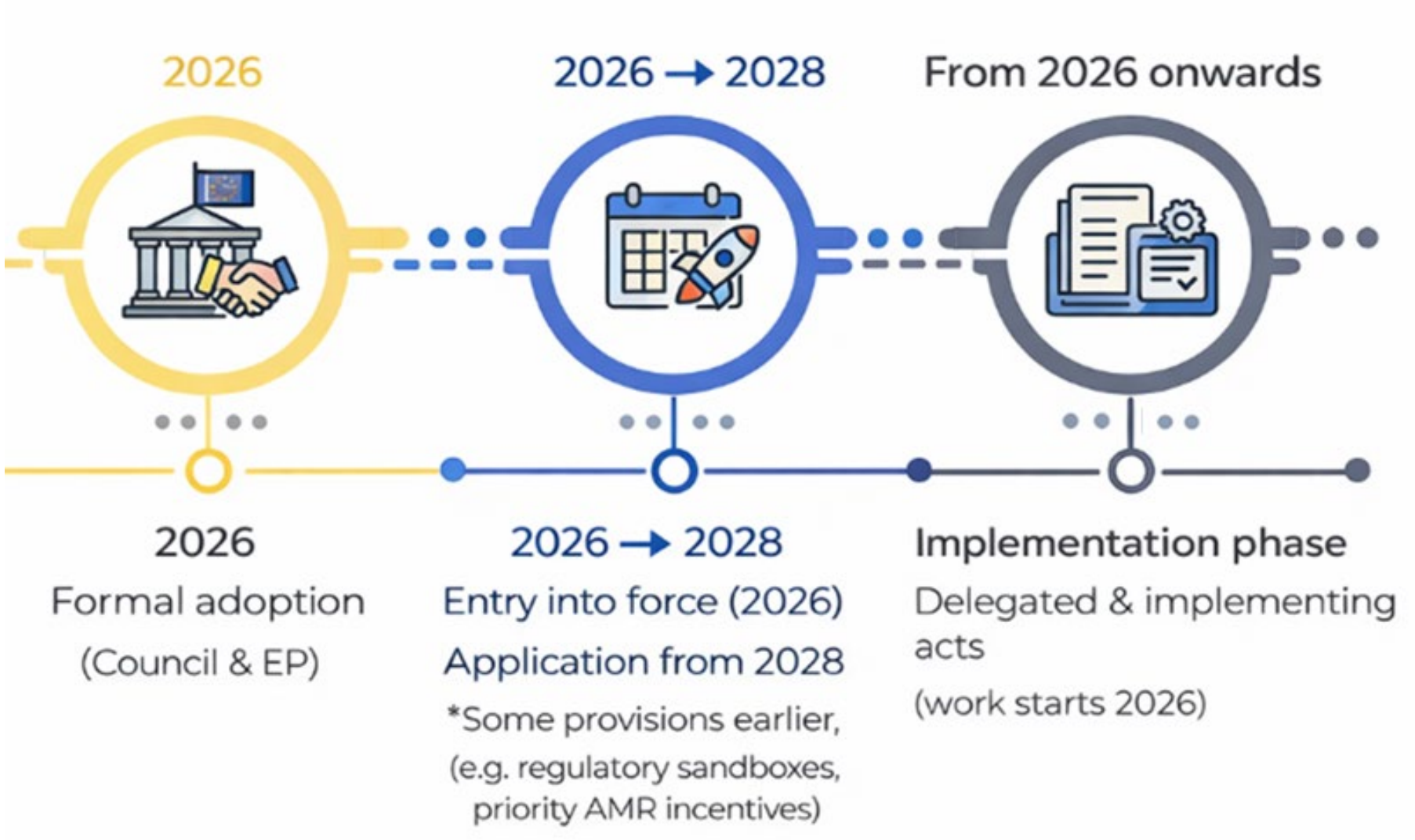
While the content is final, certain details, such as legal references cited in this document, may still change after the linguistic check of the file and therefore may differ slightly from the official versions of the two acts which will be published in the EU Official Journal.

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Implementation

European Commission

Next steps



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Implementation considerations: Application of key provisions

DATE OF ENTRY INTO FORCE (EiF)

- AMR Voucher, Antimicrobial Subscription model
- Regulatory sandboxes
- MS exemptions from Security of supply Chapter for security/defence
- Security of supply provisions
- EMA international regulatory cooperation
- EMA award of grants

6 months after date of EiF

Monitoring and shortage management provisions

12 months after EiF

Access provision for new medicines

24 months after EiF

ENTRY INTO APPLICATION / TRANSPOSITION

General date of entry into application DIR and REG

6 months after entry into application

Register of designated orphan medicines

Prioritisation programme for the ERA for legacy products (authorised before 2005 and identified as potentially harmful to the environment)

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List of implementing, delegated acts and other actions*

**Some elements of the list will be based on existing tertiary legislation and guidelines*

Acts to be adopted ASAP after entry into force (Q4 2026):

- Implementing Act on list of critical medicines (Article 133 Regulation)
- Implementing act to adopt and update the list of critical medicinal products identified by the competent authorities of the Member States ('Union long list') (Article 127 Regulation)
- Implementing act setting modalities and the conditions of the operation of the regulatory sandboxes (Article 115 Regulation)
- Guidelines to identify the relevant components for a subscription model system (Article 43a Regulation)

Acts to be adopted by 6 months before the date of application (Q2 2028)

- Implementing act to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling (Article 63 Directive).
- Implementing act laying down the principles and format for the information to be reported on public financing for development of medicines (Article 57(6) Directive).

Acts to be adopted by the date of application (by Q4 2028):

- Delegated act to update Annex II, which is replacing the existing Annex I of the Directive, on dossier requirements (Article 213 Directive)
- Delegated act on cooperation principles for decentralised manufacturing and change notifications by the qualified person (Article 190.1 (e) and 153(4)(c) Directive)
- Delegated act on active substance master file (Article 25 Directive)
- Implementing act on principles for approving decentralised manufacturing in marketing authorisation and clinical trial applications (Article 26b (8) Directive, Article 177 (1a) i Regulation))
- Delegated Act on principles applicable to the system of supervision, information exchange and cooperation for inspections (Article 190 (1) Directive)

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List of implementing, delegated acts and other actions

- Delegated Act for the submission and the harmonised assessment of the ERA for investigational medicinal products containing or consisting of GMOs (Art. 177 of Clinical trials Regulation)
- Implementing act on conditions/details for hospital exemption (Article 2 Directive)
- Delegated act on conditional marketing authorisation, including indication (CMA). (Article 19 Regulation)
- Implementing act on procedure for orphan designation (Article 63 Regulation)
- Delegated act on criteria for orphan designation (Article 63 Regulation)
- Delegated act on the principles of GDP for medicines and for active substances (Article160 Directive)
- Guidance to define potential serious risk to public health in context of divergent positions of Member States in decentralised or mutual recognition procedure – (Art. 38(2) Directive)
- Delegated act for authorisation and registration processes for decentralised manufacturing sites of IMPs. (Article 177(7b) Regulation)

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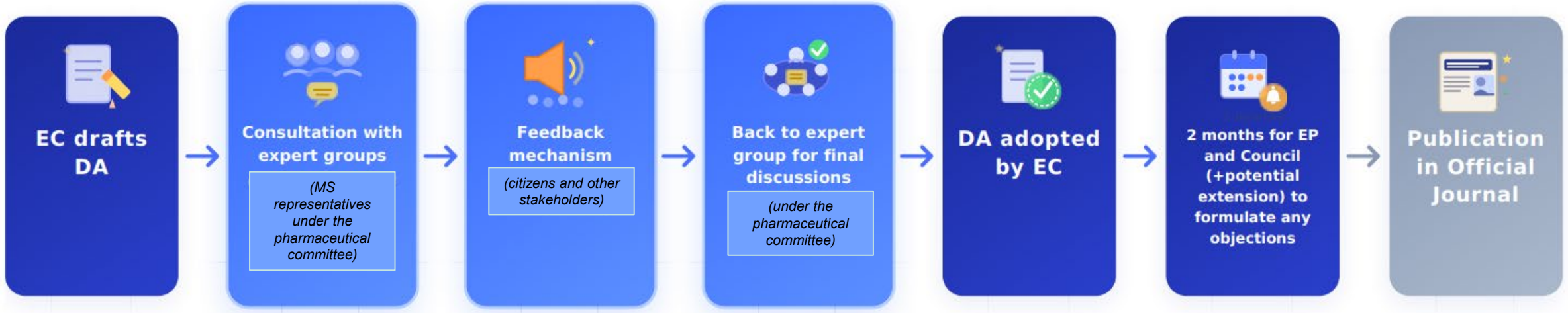
List of implementing, delegated acts and other actions

Other

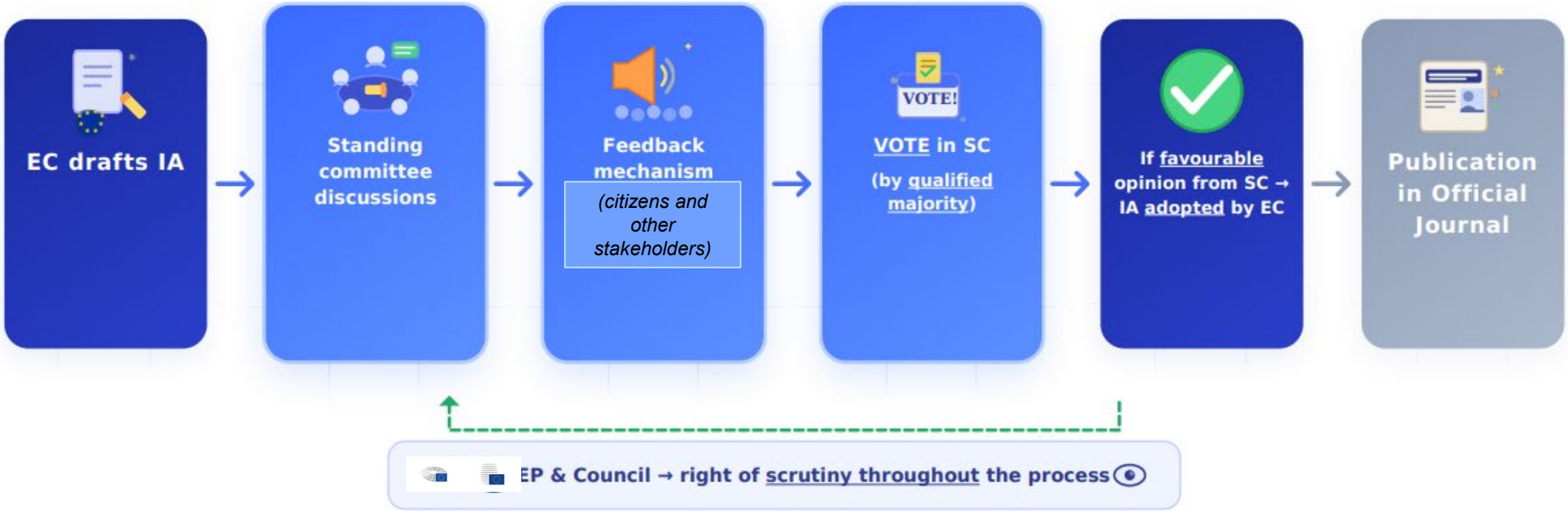
- Delegated act on variations for MA (Art. 92 Directive and Art. 47 Regulation)
- Delegated act on Additional Quality Master File (Article 26 Directive)
- Delegated act on adaptative frameworks (1st one on bacteriophages) (Article 28 Directive)
- Delegated act on penalties (Article 172 Regulation)
- Delegated act supplementing Annex IV regarding list of labelling particulars for multi-country language (article 65 Directive)
- Guidance on labelling particulars – (Article 77 Directive)
- Delegated acts to supplement this Regulation to identify additional medicinal products that require a shortage prevention plan (Article 126 Regulation)

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Delegated act



Implementing act



Update on the implementation of some selected actions

European Commission

Regulatory sandboxes

Scope

COM/EMA cooperation on the design and regulatory aspects

- Horizon scanning, screening phase
- Sandbox governance and end-to-end process
  - Assessment and eligibility
  - Sandbox plan recommendation to the Commission
  - Sandbox execution and oversight
  - Sandbox exit and outcome

- Commission implementing act(s): modalities and conditions of the operation of the regulatory sandboxes, including the eligibility criteria and the procedure for the application, selection, participation and exiting from the sandbox, and the rights and obligations of the participants

State of play

- Consultation of stakeholders: Innovative Health Initiative (IHI) bridge consortium and workshop on 21/09/2026
- Member States (Committees)
- Next steps: drafting of the implementing act(s)

Goal

- Implementing act(s) after the entry into force of the Regulation

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Guidelines for voluntary subscription model for the joint procurement of antimicrobials



Scope

- Any antimicrobial
- The contract to be awarded shall take the form of a multi-year subscription and include at least the following conditions:
  - De-linkage or partial de-linkage of funding from the volume of sales of the antimicrobial;
  - continuous and sufficient supply in pre-agreed quantities;
  - including, length of the subscription contract and the possibility of parallel procurement
- Guidelines, including the methodology for valuing and remunerating products to ensure economic viability of their supply



State-of-play

- Consultation activities:
  - with Member States
  - with industry and research organisations (study with external contractor)
- Next steps: finalisation of draft guidelines and start of consultation procedure



Goal

- Guidelines available after the entry into force of the Regulation

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AMR voucher guidelines



Scope

- Priority antimicrobials
- The eligibility requirements for "priority antimicrobial" status, are assessed by EMA
- Scientific guidance to govern the criteria set in the legislation (to address a multi drug-resistant organism, to have at least a new MoA or a new active substance that when used either alone or in combination with other active substances, addresses a serious or life-threatening infection.
- Guidance or templates for conditions (demonstrate capacity to supply and transparency on all direct financial support received for the development of the priority antimicrobial) are also under discussion.



State-of-play

- scientific guidelines under drafting process to define the scientific eligibility criteria
- Study on the capacity to supply and transparency conditions
- Analysis of stakeholder policy papers
- Next steps: consultation process (under consideration)

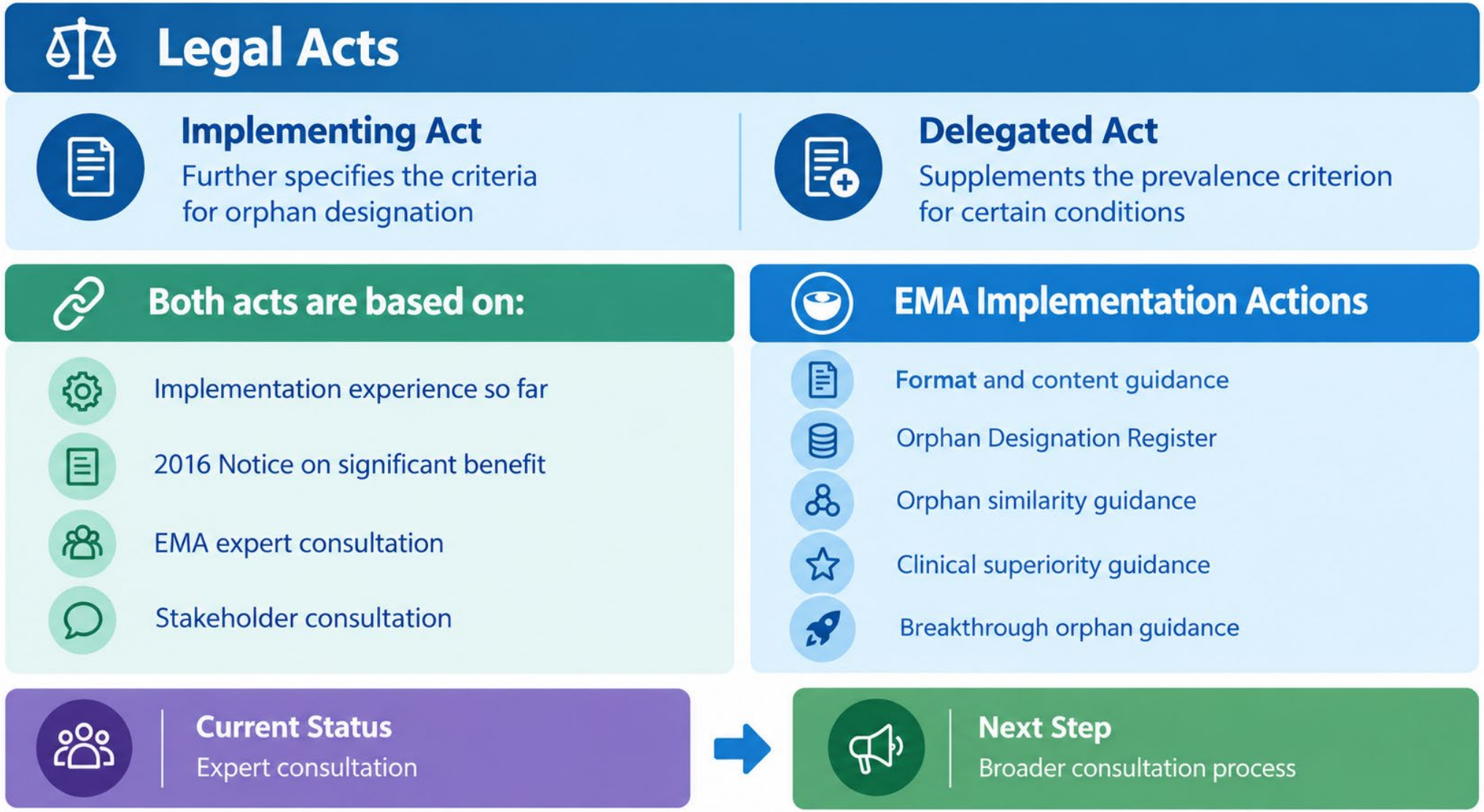


Goal

- Guidelines available for the application of the Regulation

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Orphan Implementing and Delegated Acts



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Security of supply

- **Section II of Chapter X** (Security of supply) will enter into application **immediately**
- Among the priority actions, the Commission is required to adopt:

Union list of critical medicines (ULCM)	• The ULCM is **urgently** needed as it defines the **scope of critical medicines act (CMA)** (expected to become applicable by end-2026) • These critical medicines will be subject to the vulnerability evaluation and, where relevant, MSSG recommendations
List of medicines identified as critical at national level (**Union long list**)	• The Union long list defines the scope of the obligation for companies to offer the marketing authorisation for transfer or the letter of access (Section I of Chapter X)

- To meet the deadlines, comitology procedures need to be launched as soon as possible.

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Implementing electronic package leaflets (ePL)



ePL required together with paper package leaflet
Marketing Authorisation Holder → responsible for making paper PL and ePL available to patients

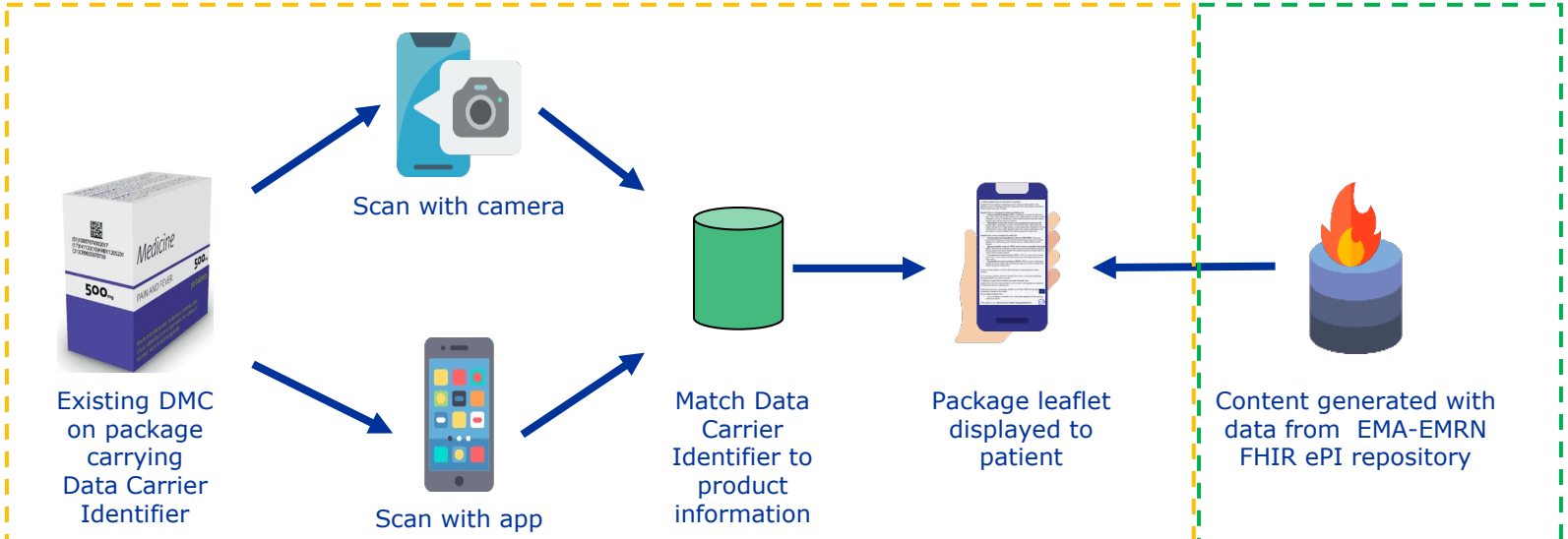
Commission implementing act
(DDL 18 months after entry into force)

- Common ***standards and formats***
- ***Criteria*** for the provision of information through secure digital platforms
- ***Processes*** to validate ePL and make it available to patients
- ***Packaging***
- ***Antimicrobial resistance (AMR) symbol***

EMA to make available a **system** to accommodate ePL

Green box covers the operational system already developed in the ePI pilot

Yellow box represents the operational system that still needs to be developed



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Adapted framework on bacteriophages



Scope

- Bacteriophages
- The current standard clinical development and manufacturing framework are not completely suitable for bacteriophages
- The delegated act will:
  - establish the technical documentation that applicants must submit when applying for marketing authorisation.
  - entail specific requirements and targeted technical adaptations proportionate to the risk and impact involved.



State-of-play

- Work with EMA on Annex II and to outline the delegated act
- Consultation with key stakeholders
- Next steps: drafting of the delegated act and start of consultation procedure



Goal

- Delegated act available after the entry into application of the Directive

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Annex II to the new Directive



Scope

- Delegated Act corresponding to Annex I of Directive 2001/83/EC;
- Build on and future-proof current requirements:
  - general requirements for Common Technical Document modules, specific requirements per legal basis and particular medicinal products;
  - Digitalisation/Data/AI;
  - Balancing granularity and flexibility while ensuring harmonisation;
- New elements reflecting novelties of the new Directive:
  - Example: applications under regulatory sandboxes, biohybrids, platform marketing authorisations, combination products;
- Interdependencies with other Delegated/Implementing Acts.



State-of-play

- EMA tasked with providing fully developed input :
  - Involvement of HMA experts, EMA Working Parties and Scientific Committees;

Stakeholders consultation



Goal

Commission adoption before date of application of new Directive.

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Joint EC/EMA/HMA Questions & Answers for the pharma reform

- The joint European Commission (EC)/ EMA (European Medicines Agency)/Heads of Medicines Agency (HMA) Questions & Answers (Q&A) for the pharma reform;
- This Q&A document addresses questions needed for implementation and frequently asked questions received from stakeholders;
- Intended to be a living document --> complemented and updated as implementation progresses & further questions are received from stakeholders;
- Additional queries not currently included in this Q&A can be submitted to: Send a question to the European Medicines Agency.

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Joint EC/EMA/HMA Questions & Answers for the pharma reform

- Publication of the official versions of the two acts in the EU Official Journal --> expected end 2026;
- First round of Q&A should come on time for the application time of the first applicable provisions (dates TBC);
- Next rounds will come depending on the following application dates/expected needs;
- Many details will be provided by the DA and IA acts or guidelines, which are also under preparation.

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Conference, 7 December

European Commission

Conference 7 December 2026 - New EU Pharmaceutical Legislation in Action
Innovating and Delivering for Competitiveness and Patients in Europe

Main theme
The new EU pharmaceutical legislation as a key building block for EU competitiveness, innovation, ensuring a modern stable and predictable environment for investment and improving patient access to medicines.

Keynote addresses by Commissioner Olivér Várhelyi and IE Jennifer Carroll MacNeill (Irish Minister for Health)

Main topics
- High level panel on the future of the new EU pharmaceutical legislation
- **Digital** by Default: The New Pharmaceutical Legislation as a launchpad for AI and data-driven medicines regulation in the EU (panel)
- Promoting **innovation** for the benefit of patients (participatory)
- Enhancing patient **access** to medicines (participatory)
- New **regulatory tools** enabling innovation (panel)
- A new EU toolbox against **AMR**: ensuring innovation, availability and prudent use of antimicrobials (participatory)
- **Shortages and security of supply** (participatory)



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