A new pharmaceutical framework for Europe

16th Industry Standing Group (ISG) meeting

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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.

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
But also simplification and competitiveness; and improved **access, availability, affordability**

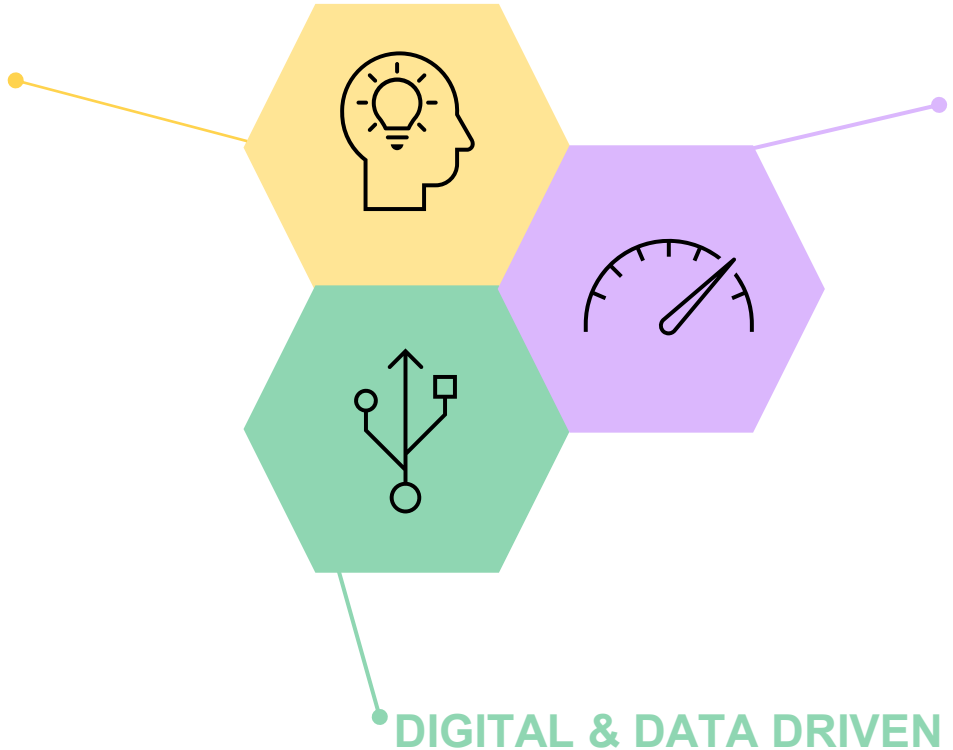
The reform is complemented by the proposed **Critical Medicines Act** and the **Biotech Act, new MDR etc.**

Regulatory excellence and simplification

Regulatory excellence and simplification

FORWARD - LOOKING

- Regulatory **sandboxes** for groundbreaking therapies
- A voucher for **Priority Antimicrobials**
- **Adapted frameworks** with tailored requirements for novel medicines
- Strengthened **early regulatory support** by EMA
- **Platform technologies**
- **Decentralised manufacturing**
- **Clarity** for products at the interphase of **multiple regulatory frameworks**



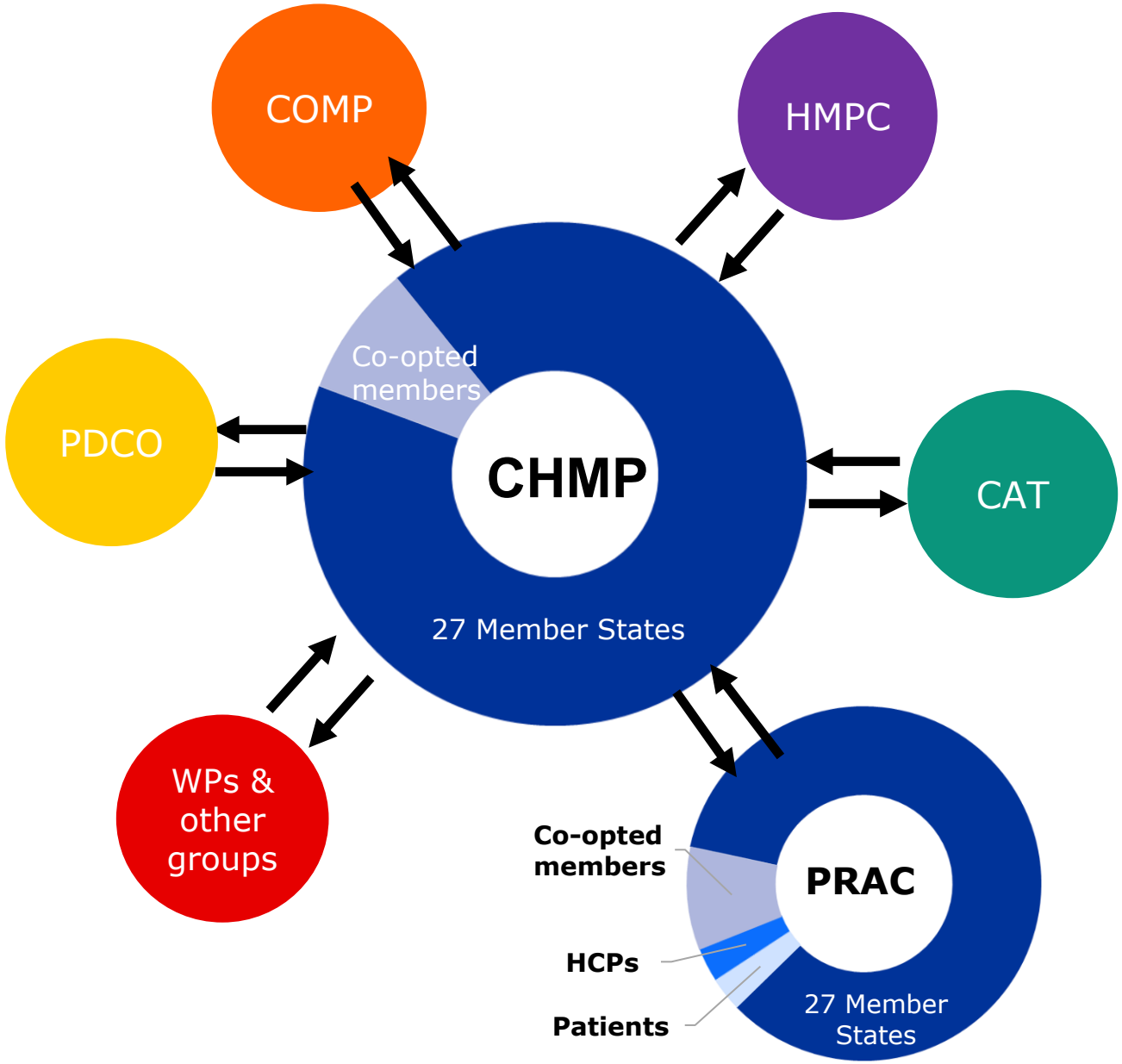
SIMPLIFICATION

- **Reform of EMA Committees**
- **Streamlining of regulatory procedures**
- **Phased review** of data for medicines of major interest for public health
- **Reduction of scientific assessment** from 210 to 180 days (150 for accelerated)

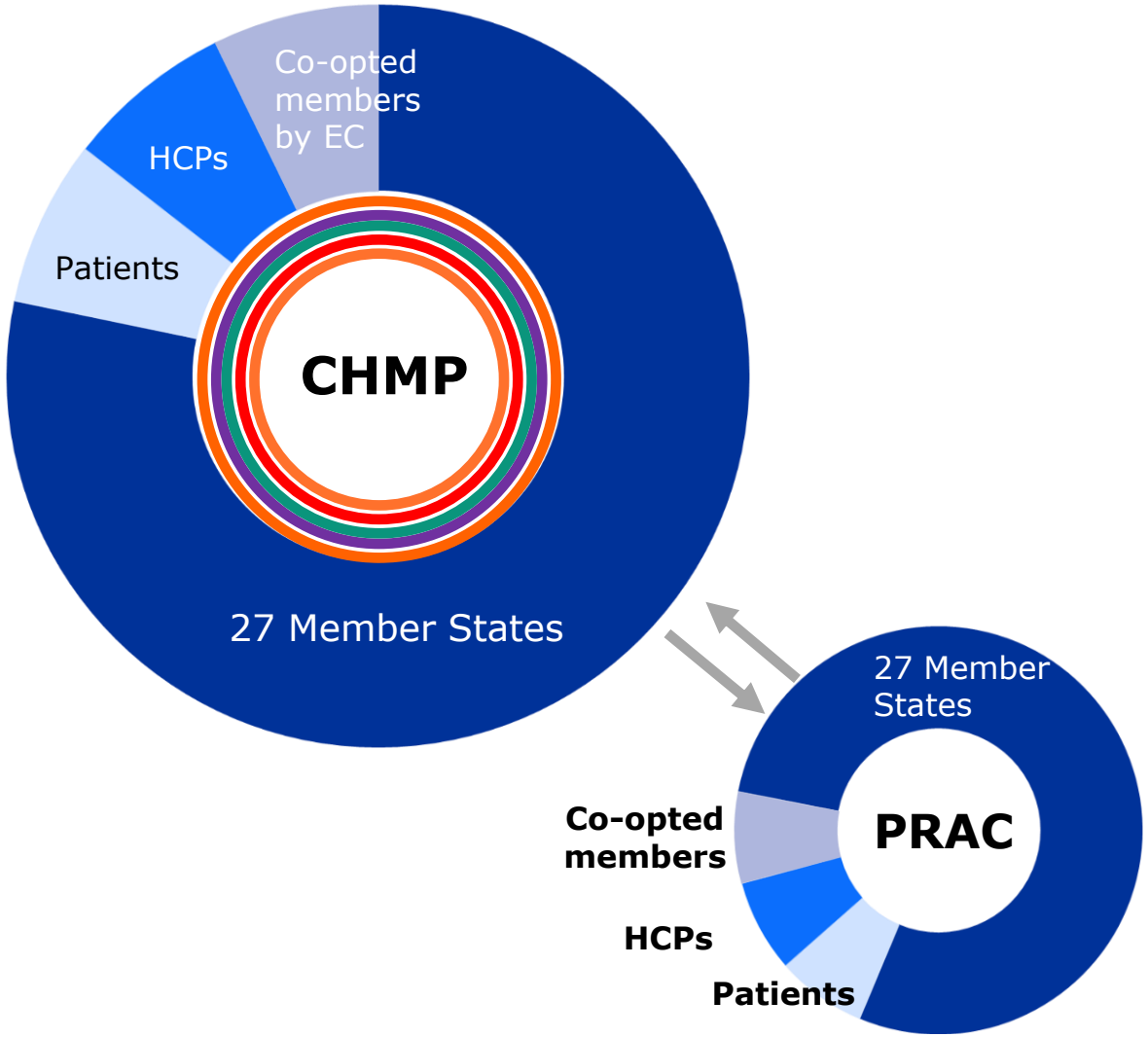
DIGITAL & DATA DRIVEN

- Use of **real-world evidence**, and of health data for regulatory purposes
- **Electronic submission** of applications
- **Electronic Product Information**

Current EMA committee structure



New EMA committee structure



Regulatory Sandboxes in pharma

The regulatory framework may not be fit for disruptive innovation, difficult to align speed of innovation with “speed” of legislative review cycles, while ensuring patients have breakthrough treatments

Future-Proofing Regulation

Prepares for the “unknown”, i.e for diseases, therapies and technologies that we cannot really imagine at the moment, but become a reality due to rapid technological and scientific progress which challenges the *status quo*

Mutual Learning

Creates valuable mutual learnings for regulators/developers

Regulatory Calibration

Informs adapted frameworks, future regulatory changes and avoids over- or under-regulation

Strictly controlled environment

Platform marketing authorisations/technology

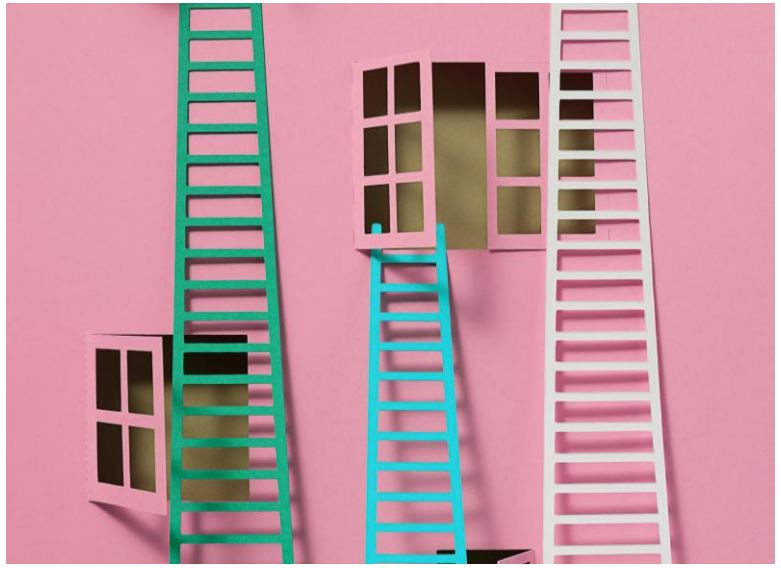
- New concepts recognised in the reform of the pharma legislation

Platform marketing authorisations – “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 to tailor the medicinal product to characteristics of an individual patient or a group of patients

Platform technology – multiple-use technology for MA

A technology or collection of technologies that is comprehensive, well-characterised, reproducible, and standardised and used to support the development, or the manufacturing process, or quality control, or testing of medicinal products or their components and rely on prior knowledge and the same scientific principles

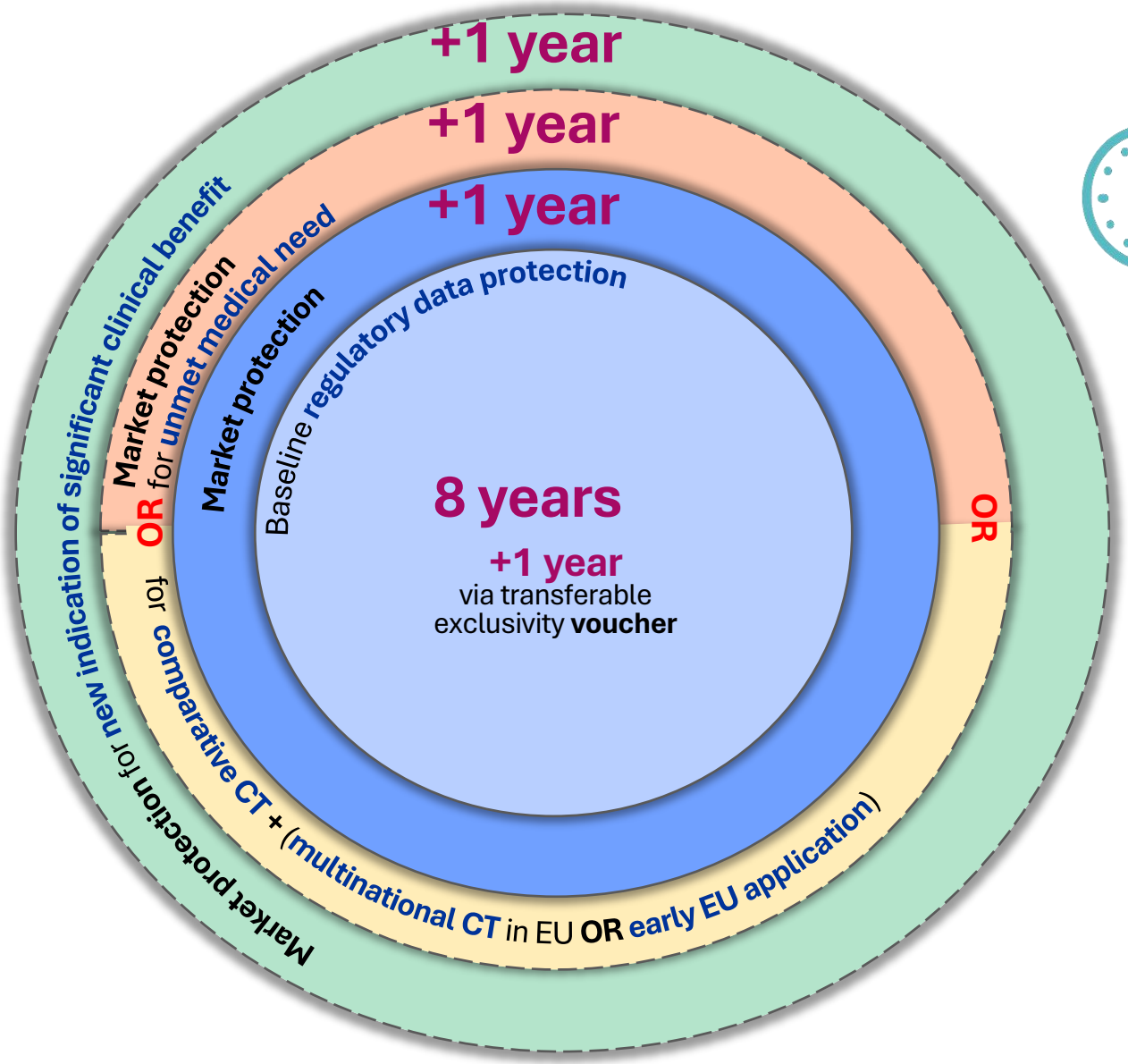


Regulatory simplification for DCP&MRP

- **Duration of assessment is 180 days** (105 days for the reference MS (RMS) to prepare an assessment report + 75 days for MS concerned (CMS) to agree) + 30 days to adopt the decision (DIR Art 30)
- Clear obligation to the applicant to provide high-quality **translations of the PI** within **7 days**
- Applicant shall inform **all** MSs of its application, MS that are not MS concerned, may request to enter ('opt-in') the procedure, **if necessary to meet the needs of patients in that** MS (DIR Art 34(3), 36(4))
- **Simplification** of repeat use procedure (RUP) → RMS shall provide the Assessment Report within **30 days**; only if CMS request the update of assessment report, the procedure may be extended to 90 days (DIR Art 36(5))
- If the application dossier is **not of sufficient quality or maturity** for the completion of the examination, it can be terminated within 90 days (DIR Art 34(4)).

Incentives

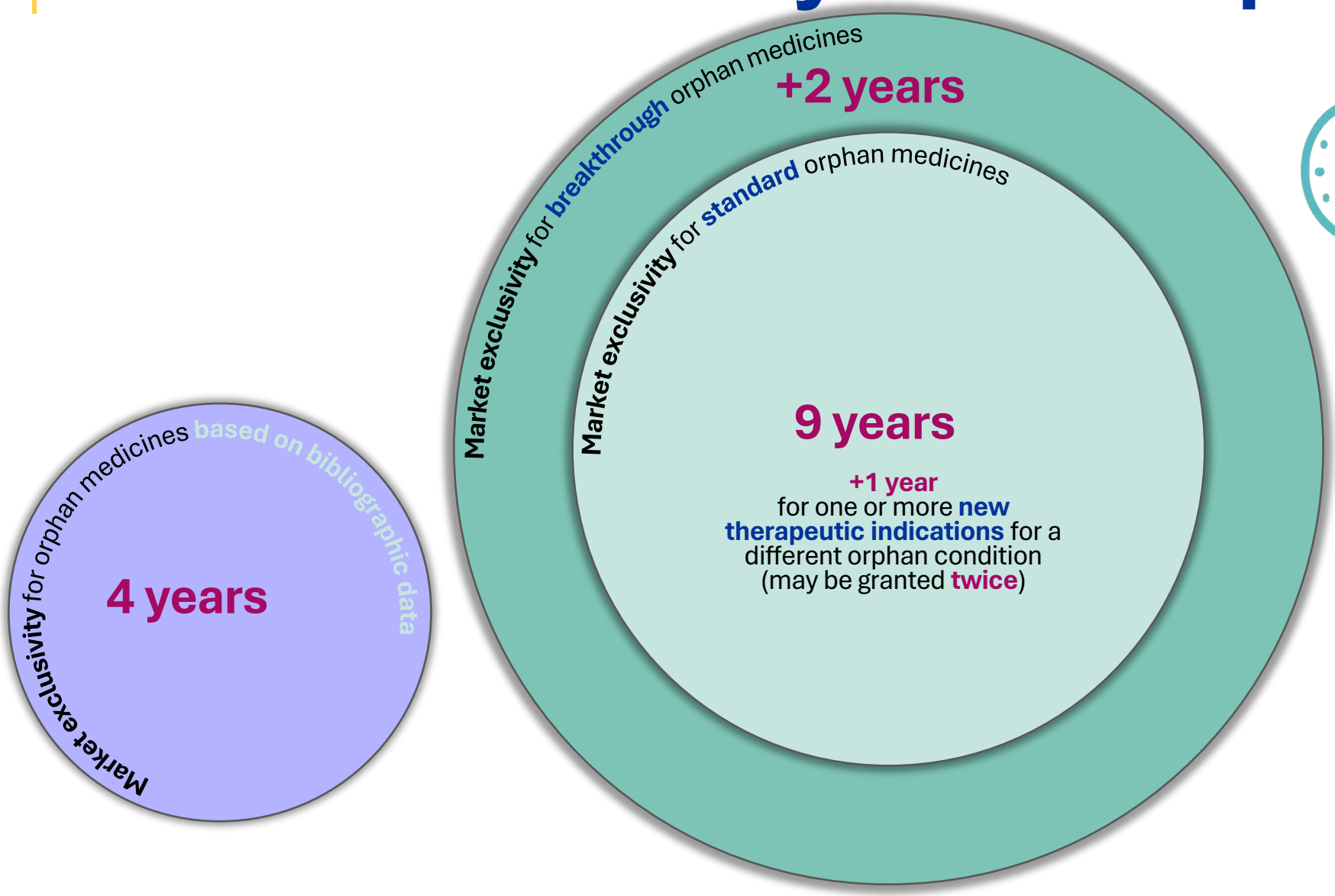
New incentives system



Maximum achievable market protection:

12 years

New incentives system - Orphans



Maximum achievable market protection:

13 years

Unmet medical needs

Medicinal product addressing an Unmet Medical Need
Article 83

(a) there is **no medicinal product authorised** in the Union for the **life threatening or severely debilitating disease**;

OR

(b) the use of the medicinal product for the **life threatening or severely debilitating disease** results in a **clinically relevant improvement in efficacy**, **or** in **safety** with at least comparable efficacy, in comparison with existing medicinal products or other methods of diagnosis, prevention or treatment authorised in the Union

clinical efficacy endpoints such as survival, symptoms and health-related quality of life, and clinical safety endpoints such as side effects

Breakthrough orphan medicines – Article 70

A medicinal product shall be considered as a breakthrough orphan medicinal product where it fulfils the following requirements:

(a) there is **no medicinal product authorised** in the Union for such *condition*;

AND

(b) the use of the medicinal product results in a *clinically relevant reduction* in disease morbidity or mortality for the relevant patient population

Orphan medicines authorised using bibliographic data (well established use) cannot be considered as ‘breakthrough’.

UMN-related incentives

PRIME

Increased regulatory support for developers of products likely to address UMN and of major interest from the point of view of public health, in particular as regards therapeutic innovation

Market protection

Additional 12 months for UMN medicines

Breakthrough orphan medicines

Additional 2 years of market exclusivity

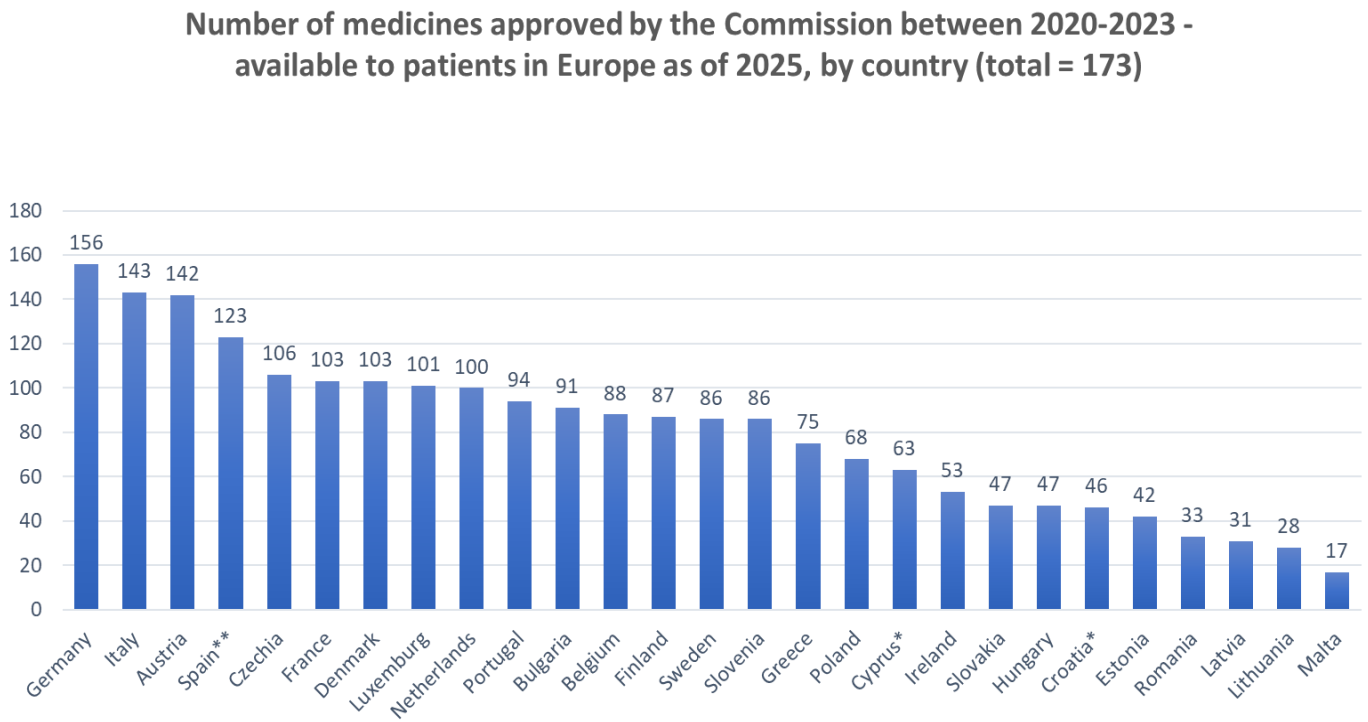
Implementation via EMA guidelines

- **EMA will develop detailed guidelines** for the application of the UMN criteria with the involvement of **HTA bodies, pricing & reimbursement authorities, patient organisations** and other relevant groups

- **Advantages of EMA guidelines** over prescriptive definition in the legislation:
  - Ensure that **all** relevant scientific/ technical considerations taken into account
  - **Can evolve with time**, to reflect the evolving scientific state of the art

Access to medicines

Access to medicines



*Country did not complete a full dataset and therefore availability may be unrepresentative. ** In Spain, the WAIT analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations.

Note(s): Number of new medicines approved by the EMA available to patients in Europe as of 2025, by country.

Source(s): IQVIA; EFPIA; ID 1011132

How the reform delivers

Regulatory tools:

- **Dir. Art 56a** → Access = for NAP/CAP – on MSs request -> MSs and companies agree on supply in quantities/ presentations required
- **Opt-in** of MS in MRP/DCP procedure
- Earlier **access to generic** medicines: Bolar, regulatory simplification
- Incentives for **earlier application in EU**, **multinational clinical trials in the EU**
- **Multicountry/multilanguage packages and electronic product information**

Member States' & companies' engagement for Access

Within 1 year: MS can REQUEST SUPPLY

MS may require one or more of the following:
a) P/R application (filing),
b) fulfil procurement procedures,
c) roll-out plan [what supply over what timeframe]

Within 3 years: SUPPLY TEST

Make the product available and supply continuously (within limits of responsibility)

If NO SUPPLY

- Non-application of market protection (all medicines)
- Non-application of right for extension of market exclusivity (orphans)

Measures on orphan and paediatric medicines

Orphan designation criteria

Chapter VI
Article 63

Rarity of the condition safeguarded by the possibility to use another criterion than prevalence (like incidence), case-by-case

No 'insufficient return criterion/ sufficient profitability ' neither as a criterion for designation nor as a reason for reducing the market exclusivity

Procedure for orphan designation criteria

Chapter VI
Article 64-68

Agency -> CHMP -> Scientific expertise involved through working parties

Validity: **7 years** (extendable)

Register: Agency

Market exclusivity concept

Chapter VI
Article 70-72

Market exclusivity: 4, 9 and 11 years!

Extension of indication in a new orphan condition: +1 year (prolongable twice) instead of a separate market exclusivity period

Global market exclusivity concept -> No evergreening!

Entry of generics at day-1 of the expiration of the market exclusivity

Paediatrics – main changes (1)

- Paediatric provisions **both in Regulation** “Chapter VII” and **in Directive** (Art 4, 6, 48, 49, 59, 60, 86, 94)
- Centralised MA procedure **compulsory for PUMA** medicines, optional for paediatric only MPs (REG Annex 1 & Art 3(2))
- Step-wise PIP, simplified PIP (REG Art 74(2), Art 85(2))
- **Mandatory PIP** on the base of the mechanism of action of a MP (same therapeutic area – REG 75(1))
- **Temporary waiver** from PIP obligation during public health emergencies for medicines relevant for the public health emergency (DIR Art 6(5)(e)& REG Art 83).

Paediatrics – main changes (2)

- Cap to the **length of deferrals** (extendible) (REG Art 81 (3), REG Art 82)
- EMA responsible for agreeing on PIP, when appropriate CHMP for PIP compliance (REG Art 77, 86 & DIR Art 48)
- **6 months SPC extension** following PIP completion **also for orphan medicines** (DIR Art 86)
- **Increased transparency** on PIP conducted for discontinued medicines - REG Art 88
- Multi-stakeholders discussions about **prioritisation of paediatric R&D** in a pre-competitive environment (REG Art 95)
- Amendment of **Clinical Trials Regulation** to reflect the current timing of publication of summary of results of paediatric CT (6 months after the end of the trial) (REG Art 177)

Security of supply

Availability – Chapter X Regulation

SECTION I - MONITORING AND MANAGEMENT OF SHORTAGES AND CRITICAL SHORTAGES

Apply 6m after entry into force

Earlier and harmonised notification
116R

Shortage Prevention Plans for prescription medicines
117R

EU coordination SPOC MSSG
118-126R

MSSG recommendations on critical shortages
123(4)R

Voluntary solidarity mechanism
125aR

European Shortages Monitoring Platform
122(4b)R

SECTION II - SECURITY OF SUPPLY (CRITICAL MEDICINES)

Apply immediately as of entry into force

Union List of critical medicines
127-131R

Analysis of supply chain vulnerabilities
130(1)(a)R

MSSG recommendations on critical medicines
132(1)R

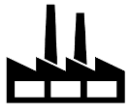
Commission guidelines/ recommendations on security of supply
134R

OBLIGATION TO SUPPLY (MAH & WHOLESALER) 56D, 167D

DECENTRALISED MANUFACTURING (DCM)

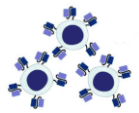
New manufacturing framework

Central manufacturing site
- supervision and control, coordination
- manufacturing authorisation,
- Qualified person



Decentralised manufacturing (DC) sites
- full or partial manufacturing performed in compliance with GMPs
- located in sufficient proximity to patients (e.g. hospital)
- can be located in different Member States
- registration process

Specific products (short shelf life, customisation for an individual patient…)
- ATMPs
- 3D printing...



Use of DCM justified and approved through the marketing authorisation or clinical trial authorisation

- Implementing Act on DCM principles
- Delegated act on exchange of information and cooperation between the competent authorities
- Delegated act on DCM for IMPs

Provisions related to inspections

- **System of supervision and inspections** more flexible and focused on risk (DIR article 188)
- **EMA inspectorate** supporting MS for inspections in 3rd countries (REG article 52)
- **Joint inspections** and delegation of inspections between EU competent authorities (DIR article 189)
- **Joint audit programme** between competent authorities (REG article 52)
- **International cooperation** in inspections (REG article 53)

Measures against Antimicrobial Resistance

Prudent use measures

- **Antimicrobial stewardship plan** (risk mitigation measures, monitor and report)
- Special information requirements for antimicrobials (**educational materials** to HCPs, **awareness card, AMR symbol**)
- **ERA for antimicrobials includes manufacturing**
- All antimicrobials are subjects to the **medical prescription (exception for topical use)**
- **Pack size** of the antimicrobial shall correspond to the usual posology and duration of treatment
- **Additional obligations** if the risk mitigation measures contained in the antimicrobial stewardship plan is unsatisfactory

AMR voucher

- Developer receives the voucher at the time of initial MA for a '**priority antimicrobial**'

- Sale of the voucher to another Marketing Authorisation Holder (once only, notification/publication of value of transaction)

- Buyer uses the voucher to extend RDP of a product in their portfolio by 1 year

- Use on same product or other product in the developer's portfolio
- Extends RDP of a product in their portfolio by 1 year

- Use
- Supply
- Transparency

Blockbuster clause: €490mn EU turnover

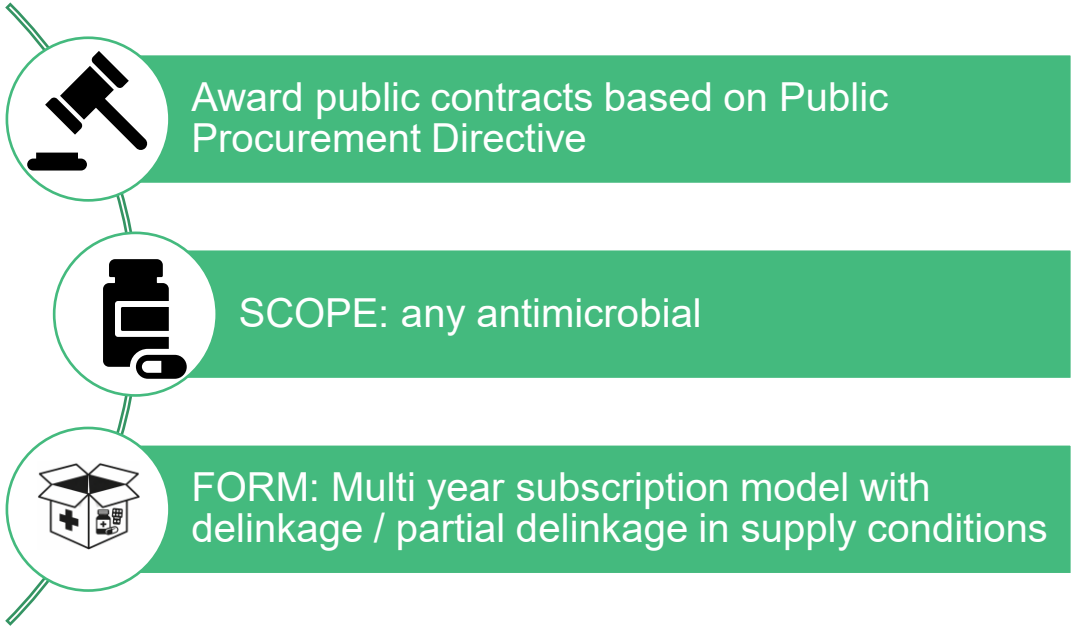
5 years validity if not used

Sunset clause of this measure: 5 vouchers or 15 years

Commission Reports: evaluation of effectiveness / appropriateness after 2 vouchers and every 5 years

Voluntary subscription model for antimicrobials

Voluntary joint MS initative



Commission Role

- **Guidelines** on components of subscription model to ensure economic viability and incentives to encourage investments
- MS may request EC for **ad hoc support** or to organise **joint meetings** with MS, EMA, P/R bodies etc. to discuss practical application

Environmental Risk Assessment (ERA)

Strengthening the ERA in the MA procedure

Ground of refusal if ERA is not sufficiently substantiated

(DIR Art 47)

For antimicrobials, added the risk for AMR selection in the environment due to the manufacturing, use and disposal of antimicrobials into the protection goals of ERA (DIR Art 4(33)

ERA for legacy products (authorised before 2005) carried out on a risk-based prioritisation approach

(DIR Art 23)

Update ERA in light of new information (DIR Art 22)

Obligation to conduct post-authorisation ERA studies / appropriate mitigation measures at the time of MA and after authorisation

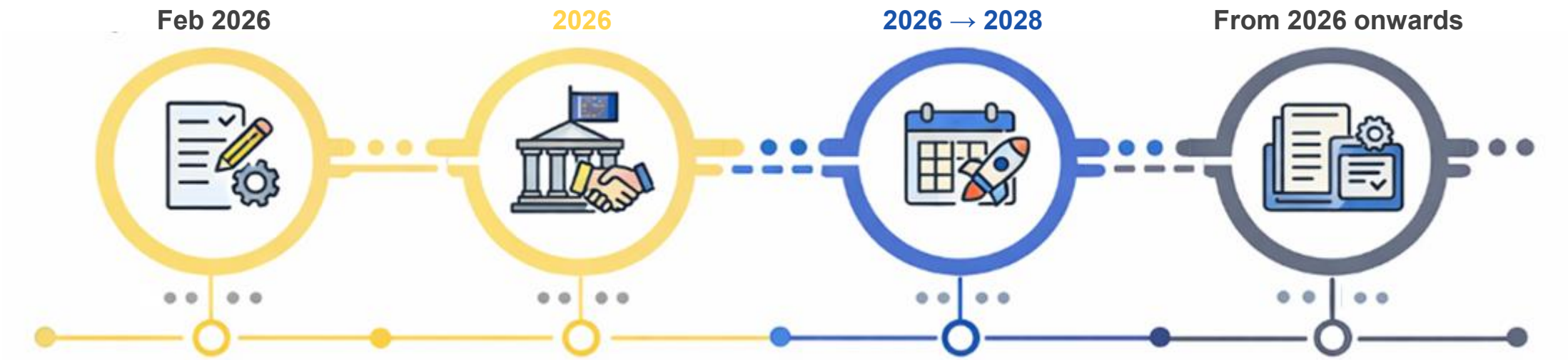
(DIR Art 44, 87, REG Art 20)

Grounds for suspension, variation, revocation of MA +prohibition of the supply of medicines in case of environmental concerns

(DIR Art 195, 196)

Next steps and implementation

Next steps



Technical text finalised

Formal adoption Q4 2026

2026 → 2028
Entry into force (Q4 2026)
Application from Q4 2028
* Some provisions earlier

Implementation phase
Delegated & implementing acts (work starts 2026)

Application of key provisions

DATE OF ENTRY INTO FORCE (EiF)

AMR **Voucher**, Antimicrobial **Subscription** model (Art. 40-43a REG)
Regulatory **sandboxes** (Art. 113-115 REG)
MS exemptions from Security of supply Chapter for **security/defence** (Art. 115a REG)
Security of supply provisions (Art. 127-134 REG)
EMA **international** regulatory cooperation (Art. 141 REG)
EMA award of **grants** (Art.154(5) REG)

6 months after date of EiF

Monitoring and **shortage** management provisions (Art. 116-126 REG)

12 months after EiF

Access provision (Art. 56a DIR) for new medicines

24 months after EiF

ENTRY INTO APPLICATION / TRANSPOSITION

General date of entry into application DIR and REG

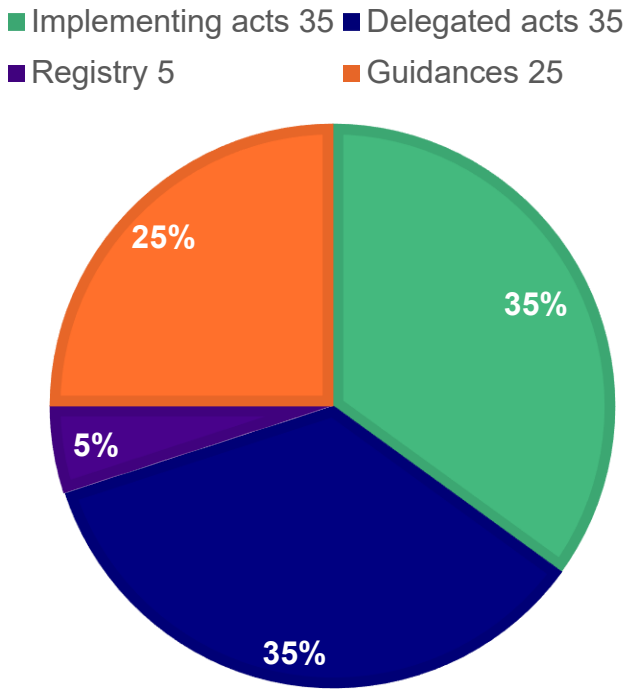
6 months after entry into application

Register of designated orphan medicines (Art. 67 REG)

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

Implementation phase

More than 100 actions for the COM, the EMA and the Network.



Legal priorities for the COM:

- Acts to be adopted by the date of entry into force (Q4 2026):
  - IA on list of critical medicines and IA to adopt and update the list of critical medicinal products identified by the competent authorities of the Member States
  - IA on regulatory sandboxes
  - Guidelines for a subscription model system

- Acts to be adopted by 6 months before the date of application (Q2 2028): IA on ePI

- Acts to be adopted by the date of application (Q4 2028): more than 30 IAs & DAs of which 20 are priority

List of priority 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 (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).

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 (we would aim to have it before the date of application). (Article 213 Directive)
- Delegated act on inspection (Article 190 Directive)
- Delegated act on active substance master file (Article 25 Directive)
- Implementing act on decentralised manufacturing (format and content) (Article 26b Directive)
- Implementing act on information to be reported on public financing for development of medicines (Article 57 Directive)
- 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)

List of priority implementing, delegated acts and other actions

- Delegated act on notification from qualified person to supervisory authority of decentralised site (Article 153 Directive)
- Delegated act on GMP and GDP for medicines and for active substances (Article160 Directive)
- Delegated act on criteria for orphan designation (Article 63 Regulation)
- Delegated act on prove of concept + System of ERA monographs of the ERA data of active substances (Article 24 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)
- The COM shall select representatives of patients and healthcare professionals to CHMP (Article 143 Regulation)

Acts under the clinical trials Directive

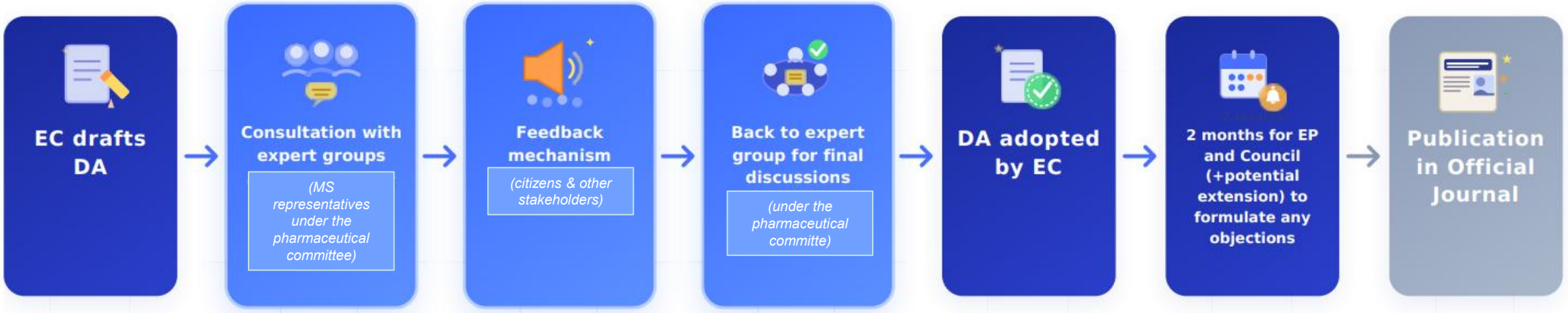
- Delegated act for decentralised manufacturing for investigational medicinal products (Article 177 Regulation)
- Delegated act for ERA of GMO-containing investigational medicinal products. (Article 177 Regulation)

List of priority implementing, delegated acts and other actions

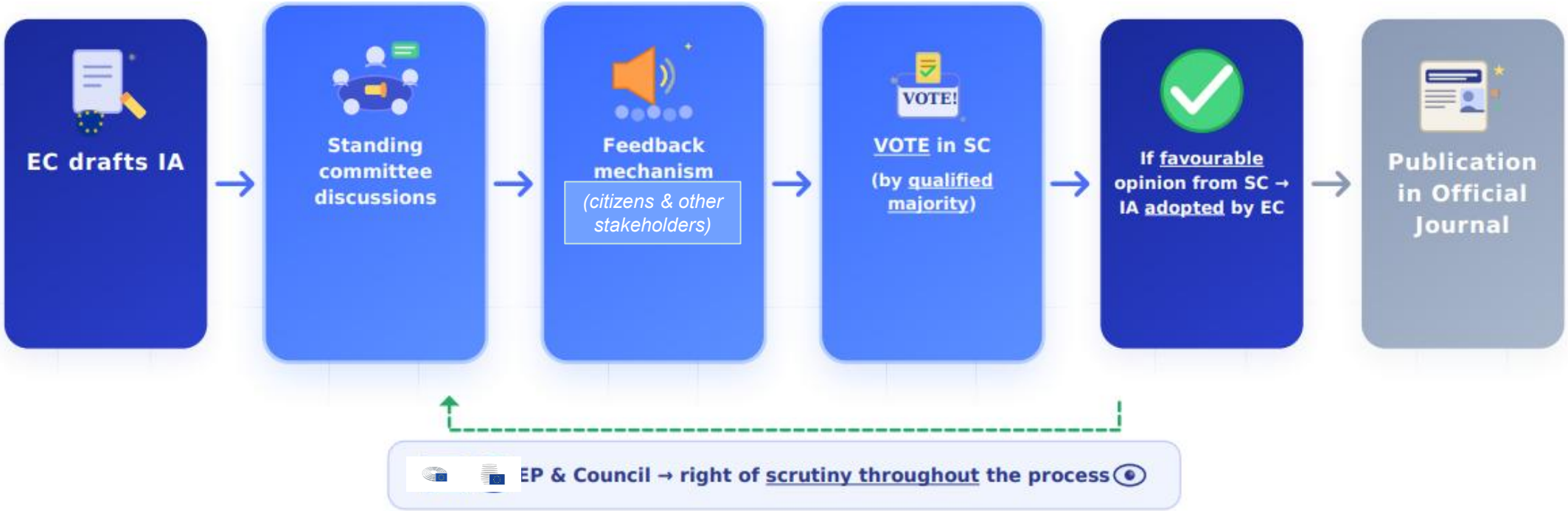
Other

- Delegated act on variations for MA (Art. 92 Directive and Art. 47 Regulation)
- Delegated act on Active 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 amending list of labelling particulars
- Implementing act to establish a list of herbal substances, preparations and combinations (Article 139 Directive).
- Delegated act on procedures for the examination of applications to the Agency for the transfer of marketing authorisations (Article 49 Regulation)
- Delegated act specifying the criteria to be considered and the verifications to be made when assessing the potential falsified medicines (Article 150 Directive)
- Delegated act to supplement on the formalised risk assessment for ascertaining the appropriate good manufacturing practice (Article 161 Directive)
- Delegated act to supplement Annex IV (labelling particulars) by laying down detailed rules for the safety features (Article 67 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)
- Implementing act to amend the details concerning clinical trials conducted in third countries to be submitted to the EU database of Art. 81 of Reg 536/2014 (Article 94 Regulation)
- Guidance on principles applicable to international inspection programmes (Art. 53)(2) Regulation

Delegated act



Implementing act



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