EMA
EUROPEAN MEDICINES AGENCY

New EU pharmaceutical legislation

What it means for EMA's regulatory procedures

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A new framework that builds on the EU's strengths

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

New Directive

- Updating and repealing Directive 2001/83/EC on medicinal products for human use
- Incorporating and amending relevant parts of the **Paediatric Regulation** (EC) No 1901/2006

New Regulation

- Updating and repealing Regulation (EC) No 726/2004
- Incorporating the **Orphan Regulation** 141/2000/EC
- Incorporating relevant parts of the **Paediatric Regulation** (EC) No 1901/2006

The reform is complemented by the proposed Critical Medicines Act, the Biotech Act and the Medical Devices and In-Vitro Diagnostic Medical Devices Regulations

Also includes:

- Amendments to the **regulation on Advanced Therapy Medicinal Products (ATMPs)**
- Amendments to the **clinical trials regulation** for medicines containing genetically modified organisms (GMOs) and the de-centralised manufacturing for investigational medicinal products

Together with the legislative package, the EC published a Proposal for a Council Recommendation on stepping up EU actions to combat **antimicrobial resistance (AMR)** in a 'One Health' approach (adopted June 2023)

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Key goals of revision

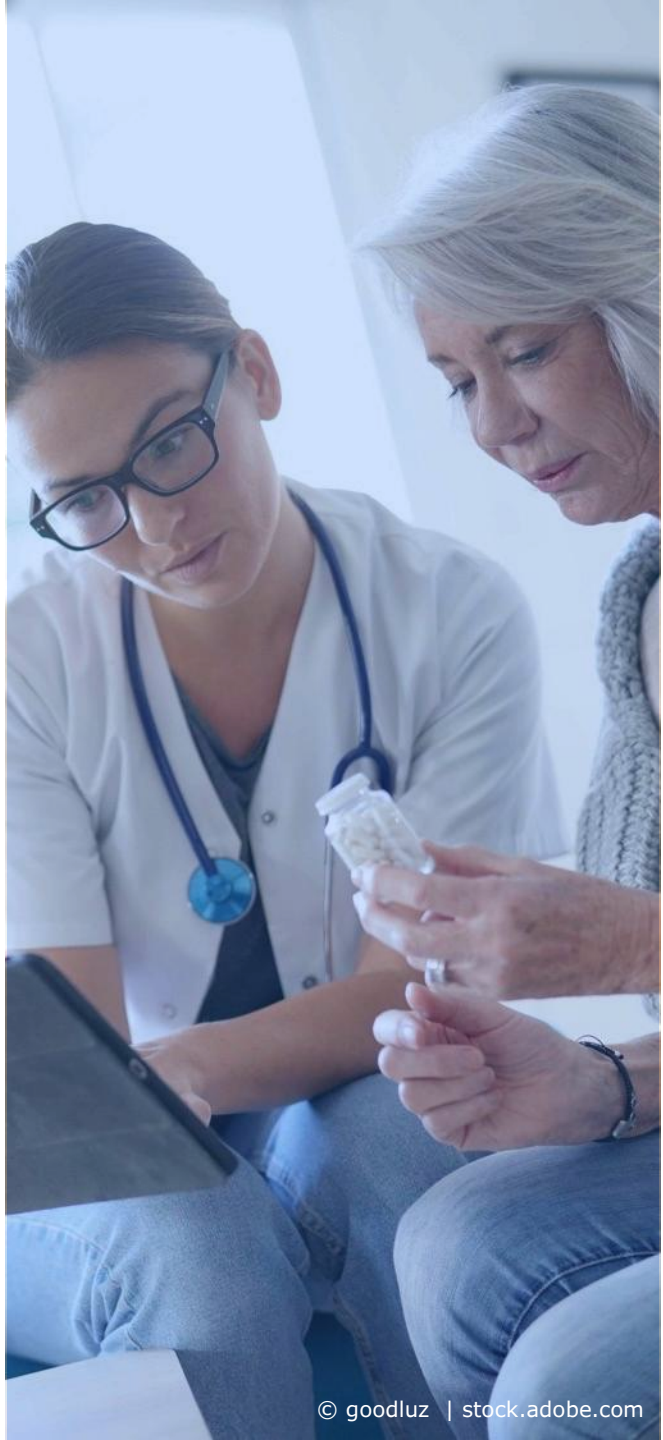
Opportunity to **reshape medicines regulation** in the European Union by:

- making the EU regulatory framework fit for new, innovative medicines
- supporting better access to medicines for patients
- addressing major public health challenges of the future, e.g., antimicrobial resistance
- supporting ongoing work linked to the **European Medicines Agencies Network Strategy to 2028** (e.g., digitalisation, sustainability of the network, support to innovation and availability, addressing environmental concerns)

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Key goals of revision: regulators' perspective

- Opportunity to simplify structures and procedures for a more integrated regulatory system - easier to navigate for **developers**; making Europe more attractive and competitive in global market
- Facilitating availability of medicines that can have an impact on **patients**
- Ensuring that the voice of **patients and healthcare professionals** continues to be heard in EMA's human medicines committee (CHMP) and safety committee (PRAC)
- Reducing administrative burden to help improve **network sustainability** and to help the network become more agile in assessing complex products



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Key changes for EMA and the centralised procedure

1. EMA scientific committees
2. Reduction in assessment times
3. Incentives to encourage innovation
4. Reinforcing existing tools for developers and new tools
5. Shortages - EMA’s extended role
6. Strengthening rules for Environmental Risk Assessment (ERA)
7. Inspections
8. Other changes

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EMA scientific committees

- **Reduced number of committees:** EMA's human medicines committee (CHMP), safety committee (PRAC) and committee for veterinary medicinal products (CVMP) remain
- **Extended expertise** in CHMP and PRAC core membership
- Complemented by **stronger scientific support** from network experts (pool of experts, working parties)
- CHMP shall, where necessary, establish an Environmental Risk Assessment working party and working parties with expertise on paediatric and orphan medicines
- **Strengthened voice** of patients and healthcare professionals in the CHMP and PRAC
- Possibility to have **public hearings in the CHMP**
- EMA to be responsible for **orphan designations** and **paediatric investigation plan** (PIP) applications/deferrals/waivers



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EMA’s human medicines committee (CHMP)

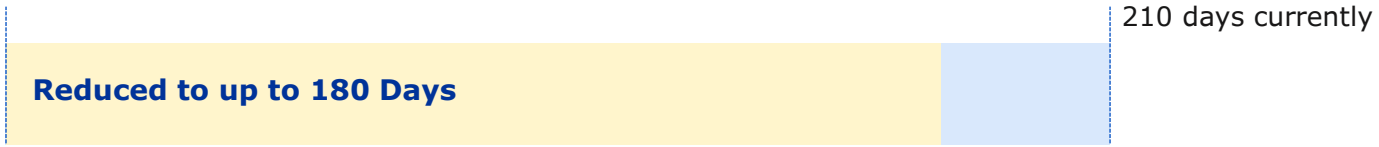
	Current composition	New composition **=>ATMP specific expertise contribution**
Member State representative	1 member per Member State + 1 alternate per Member State	1 member per Member State + 1 alternate per Member State
Co-opted members	Up to 5 co-opted members based on their specific scientific competence	**Up to 7 co-opted members based on their specific scientific competence**
Stakeholder representatives		
Healthcare professional representatives	no healthcare professional representatives	**2 members *** + **2 alternates**
Patient representatives	no patient representatives	**2 members *** + **2 alternates**

* entitled to one vote

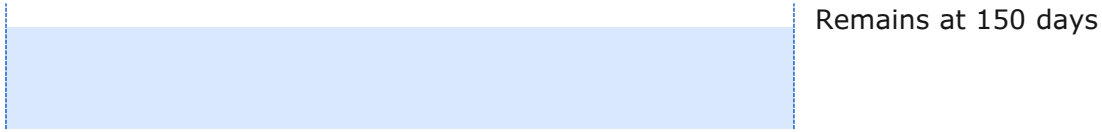
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Reduction in assessment times

Standard marketing authorisation application



Accelerated assessment

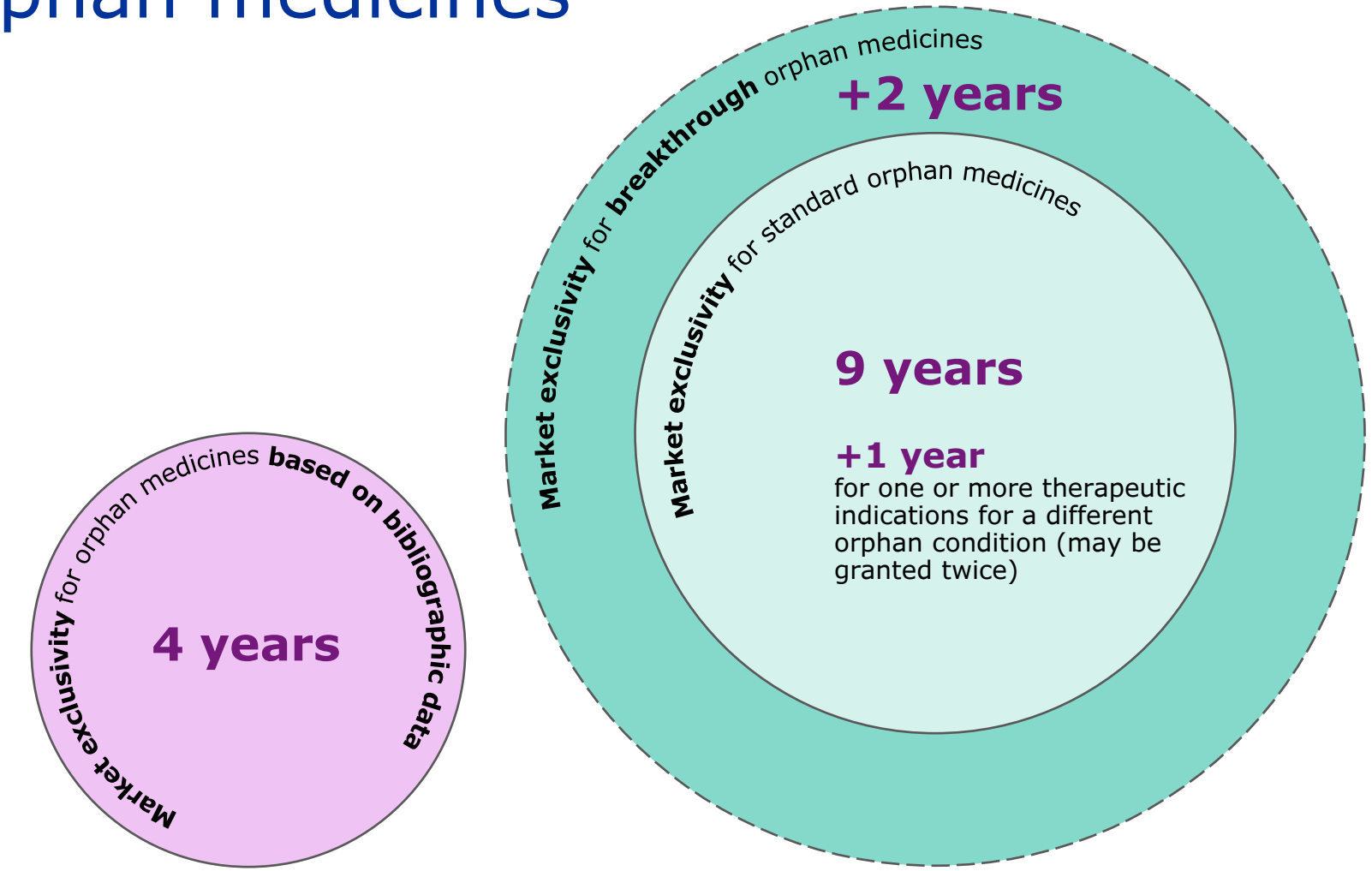


European Commission decision-making process



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Incentives to encourage innovation for orphan medicines



Maximum achievable market protection:

13 years

Breakthrough orphan medicines:
There is no medicine authorised and you have a clinically relevant reduction in disease morbidity/mortality.

Source: European Commission

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Reinforcing existing tools for developers

- **Scientific advice:** CAT involved in All SA for ATMPs

Scientific advice procedure for ATMPs							
	2009-2021	**2022**	**2023**	**2024**	**2025**	**2026***	**Total**
Number of procedures	506	53	57	61	76	53	806

- **PRIority MEdicines (PRIME) scheme:**

	PRIME[2] Eligibility for ATMPs						
	2016-2021	**2022**	**2023**	**2024**	**2025**	**2026***	**Total**
Discussed	105	10	13	17	21	88	194
Granted	46	4	9	6	6	11	82

* Period: January – September 2026

ATMP PRIME
46% of the total number of PRIME granted

In: CAT quarterly highlights and approved ATMPs up to october 2026

https://www.ema.europa.eu/en/documents/committee-report/cat-quarterly-highlights-approved-atmps-june-september-2026_en.pdf

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Reinforcing existing tools for developers (2)

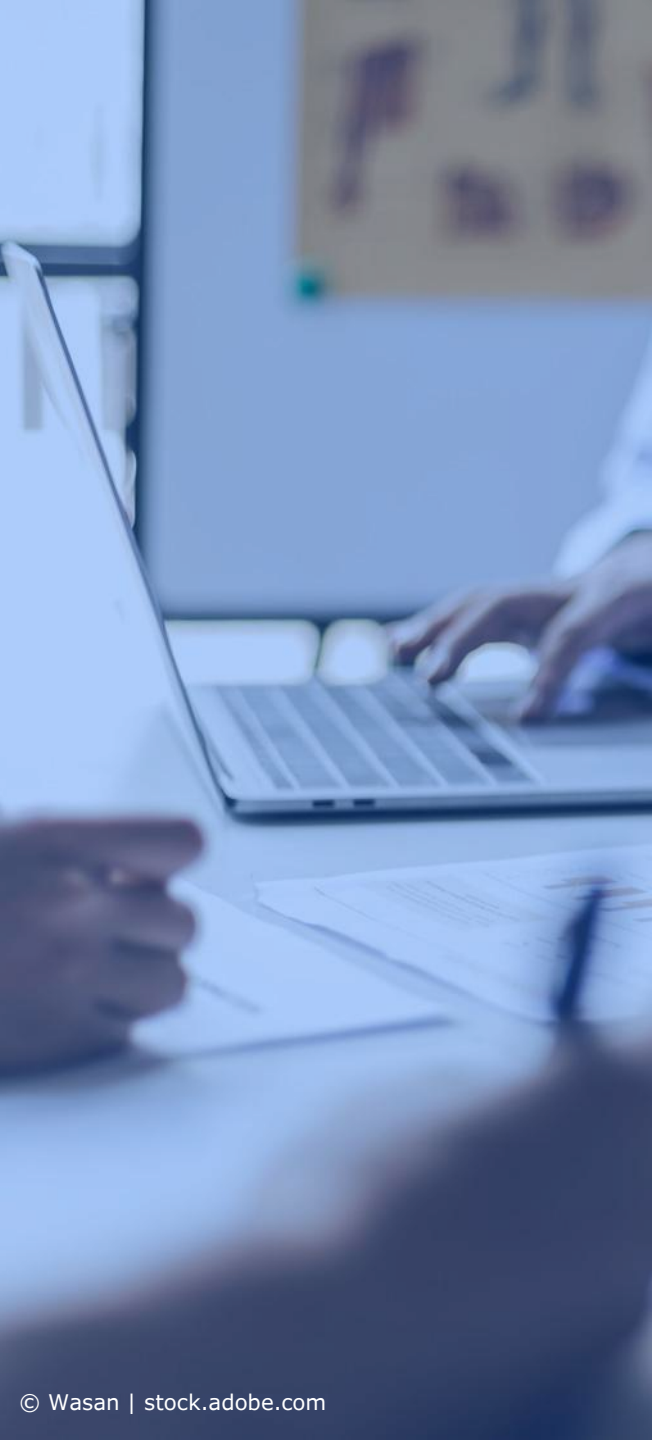
- **Scientific advice** extended to include medical device authorities/expert panels, health technology assessment bodies (HTAs), payers, etc.

- **PRIority MEdicines (PRIME) scheme:** embedded in legislation and scope broadened to:
  - medicines expected to be of major interest to public health, including potential to enhance **public health threats preparedness**
  - **priority antimicrobials** targeting pathogens on WHO priority list
  - medicines targeting **neglected tropical diseases**
  - possibility for **phased review**



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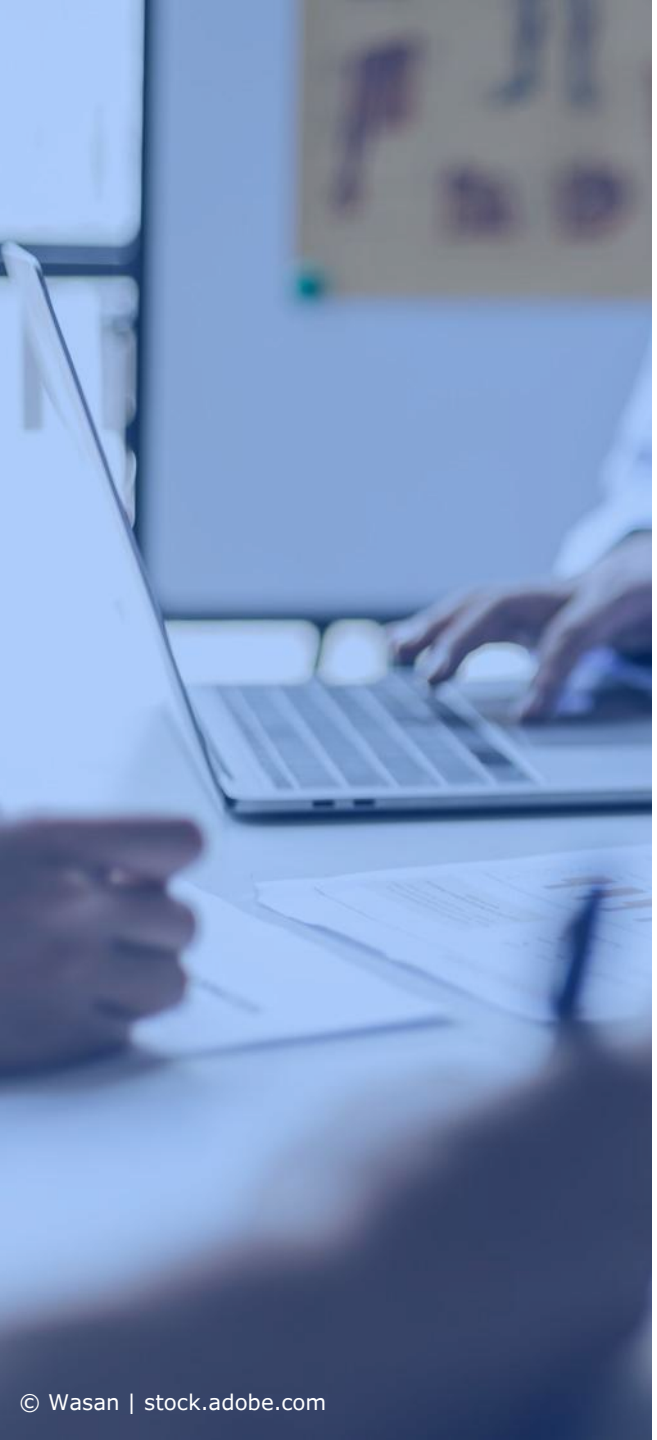
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New regulatory tools for certain medicines (1)

- **Regulatory sandbox:** EMA and EU Member States can set up environment to test adapted, waived or deferred requirements for products that provide major advantage to patients and cannot be developed in full compliance with current rules
- **Phased review for:**
    - products that address **unmet medical need** and are of major interest for public health
    - **priority antimicrobials** targeting pathogens on WHO priority list
    - Medicines for **public health emergencies**
- **Adapted frameworks:** European Commission can define adapted scientific or regulatory requirements for certain category of products (e.g., bacteriophages)

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New regulatory tools for certain medicines (2)

- **Repurposing:** CHMP can give a scientific opinion on **adding a new unmet-medical-need indication** to an authorised medicine based on information provided by a **not-for-profit** entity; marketing authorisation holder is then obliged to add the new indication.
- **Temporary Emergency Marketing Authorisation (TEMA):** set up at EU level for public health emergencies where there is a major interest in developing and authorising safe and effective medicines as quickly as possible

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Shortages – EMA's extended role

- EMA to compile an EU-wide list of **critical medicines** and the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) to assess supply chain vulnerabilities for those medicines
- EMA's role **extended to act on critical shortages of union concern** together with the MSSG
- More **transparency** in supply chain: earlier notification of withdrawals and shortages to EMA and NCAs; EMA to publish critical shortages
- **Shortage prevention plans** (SPPs) for prescription-only medicines: marketing authorisation holders to keep SPPs available for inspection and activate them when needed
- **Shortages monitoring**: new requirements for EMA and NCAs to continuously monitor any potential or actual shortage
- Scope of **European shortages monitoring platform** (ESMP) to be expanded
- **Voluntary solidarity mechanism**: codified in legislation and coordinated by the MSSG


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Strengthening rules for environmental risk assessment

- EMA to coordinate the ERA in **clinical trial applications** and **marketing authorisation applications** for medicines containing or consisting of a genetically modified organism (GMO)

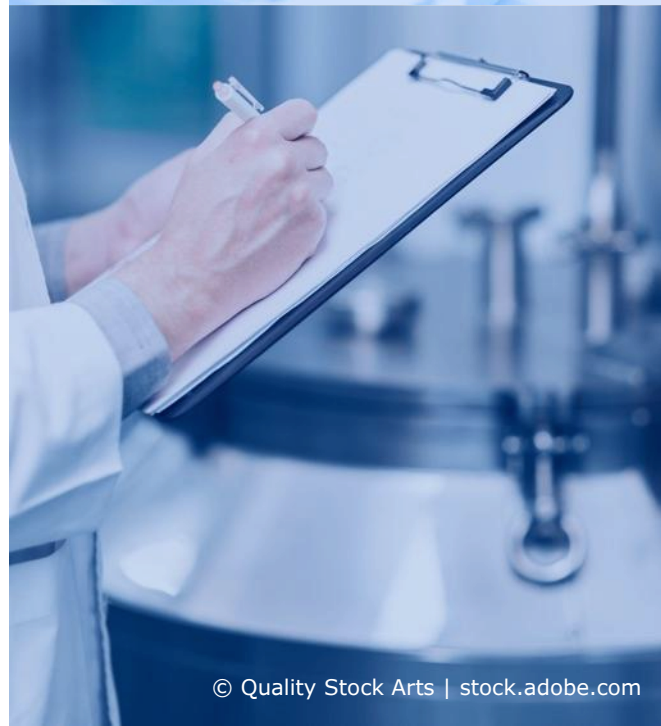
- Strengthening rules on **Environmental Risk Assessment** (ERA), e.g., ERA could be grounds for refusing a marketing authorisation (unless gaps can be sufficiently justified)

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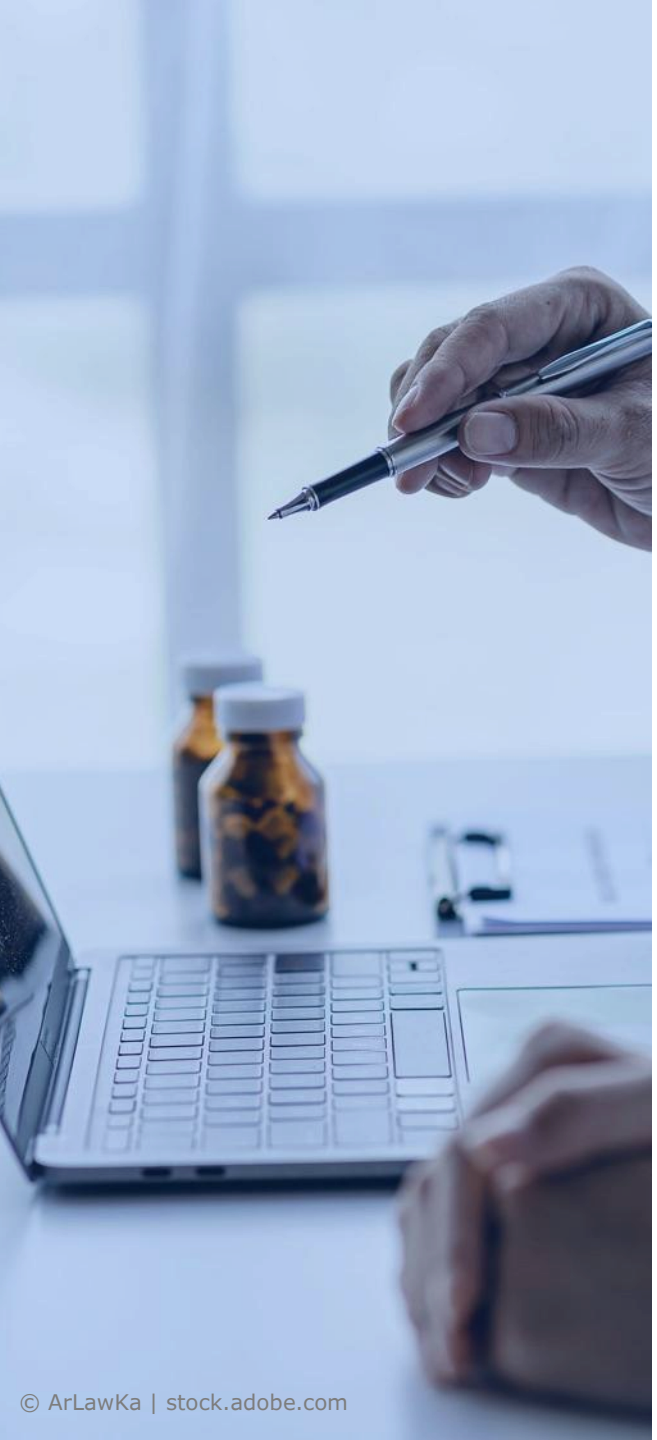
Inspections

- **EMA inspectorate** to support Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) inspections in third countries in the following situations:
  - If a Member States asks EMA to join a Member-State-led inspection (joint inspection)
  - If a Member State does not accept delegation for an inspection from another Member State
  - If Member States delegate to EMA ”inspections in interest of the Union” (e.g., if needed to prevent/mitigate a shortage or in the case of a public health emergency , address suspected non-compliance, enable CAP authorisation). In this case, EMA to grant the GMP certificate
- **Remote inspections:** explicit legal basis to conduct inspections remotely
- **Joint Audit Programme:** formally established within EMA to harmonise inspection standards and to support mutual recognition of inspection outcomes


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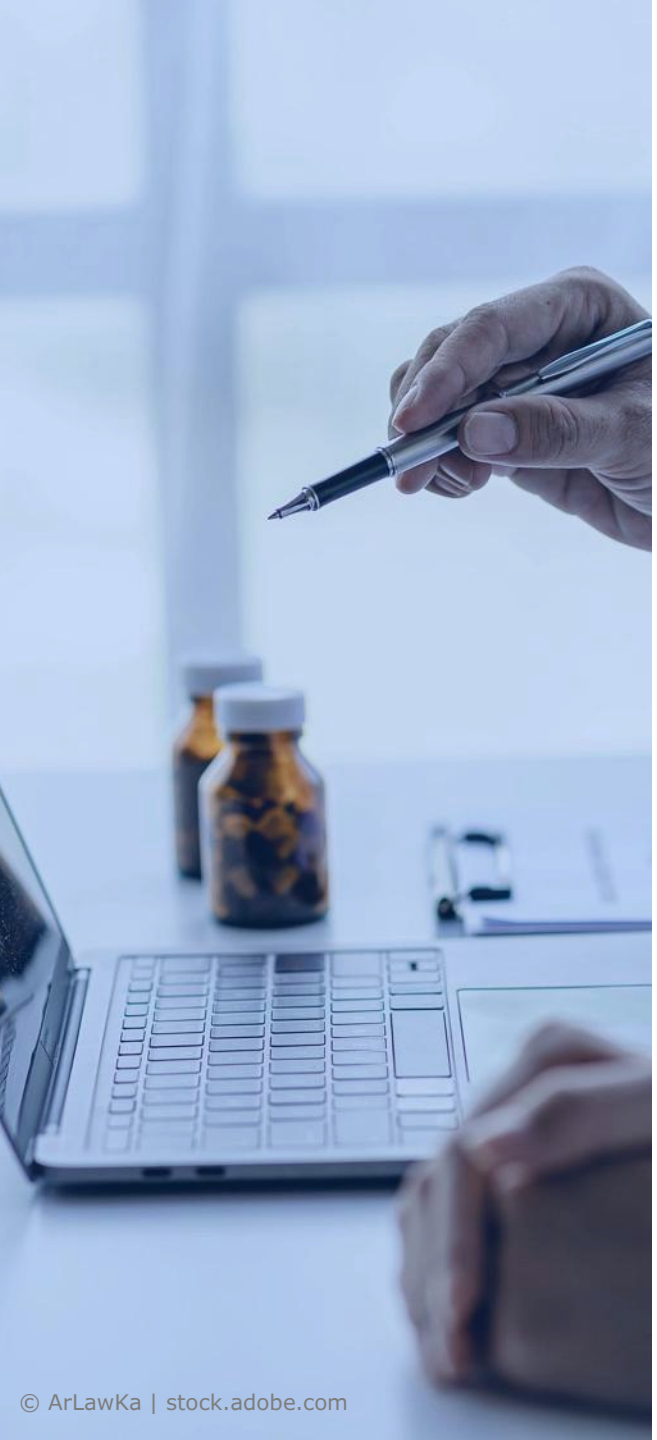
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Other changes (1)

- **Predictability of marketing authorisation application:** applicants to agree submission date with the Agency
- **Premature applications:** stop during assessment if the application has critical deficiencies or if the data are not sufficiently mature
- **Simplification:** waiver of **risk management plans (RMPs)** for generics and biosimilars, abolishing marketing authorisation renewals in most cases
- **Digitalisation:** mandatory submission of electronic marketing authorisation applications in a common format; electronic product information (ePI) mandatory for all medicines, to complement paper format
- New CHMP scientific **recommendation on regulatory status/new classification procedure**
- **Marketing authorisation** valid for an **unlimited period** by default (instead of five years), unless safety concerns arise
- Support office for **not-for-profit entities**

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Other changes (2)

- **Legal basis for Platform technologies:** new marketing authorisation procedure and new procedure for master files
- **Combinations with medical devices:** clarifications on dossier requirements and assessment procedures
- **Active substance master files:** to be certified by EMA
- **Use of colourants in medicinal products:** possibility for EC (in collaboration with EMA) to allow use of colourants not authorised in food
- **One substance one assessment:** obligation for EMA to exchange data on relevant active substances and to ensure coherence of scientific assessment with other EU agencies
- **Decentralised manufacturing:** to enable novel technology needs to be performed very close to the patient
- Improved **efficiency of process for studying medicines for children**; legal basis for initial paediatric investigation plan (PIP)

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Timelines for the revision



EC adopts new Directive & new Regulation

23 April 2023:

- European Commission adopts the proposal for the new Directive and a new Regulation, which revise and replace the existing general pharmaceutical legislation

Political agreement reached between European Parliament and Council

December 2025

Adoption and entry into force

Q4 2026 (tbc):

- adoption and entry into force
- publication in Official Journal
- some provisions apply immediately (see next slide)

Transition period

2026-2028:

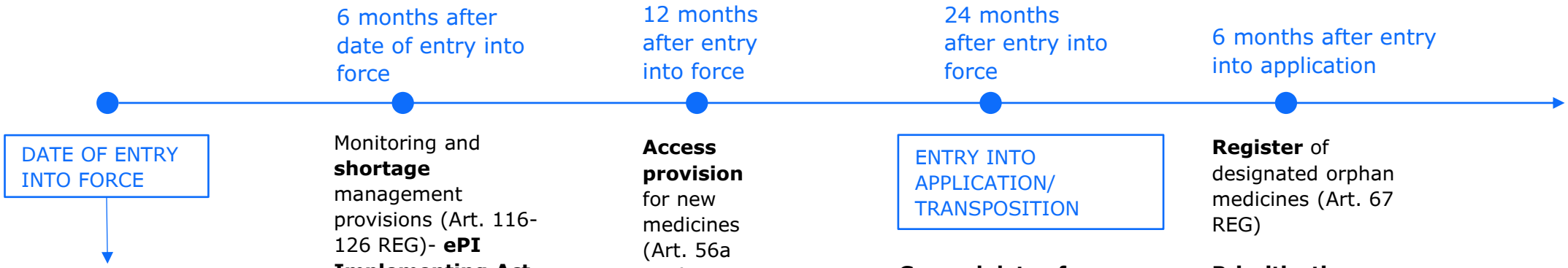
- transition period, including the development of delegated and implementing acts

Application

From late 2028

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Some provisions apply immediately on entry into force



- **AMR voucher**, Antimicrobial **Subscription** model (Art. 40-43a REG)
- Regulatory **sandboxes** (Art. 113-115 REG)
- Member State 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)

Source: European Commission

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Keeping stakeholders informed and involved throughout implementation



Industry Standing Group

Rely on the ISG for regular updates on NPL implementation, including reporting from Platform Focus Groups



PCWP/HCPWP*

Rely on the PCWP/HCPWP for regular updates on NPL implementation, including feedback from representatives involved in topic-specific consultations



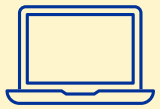
Topic-specific webinars

Join targeted sessions on specific implementation topics when additional clarification or guidance is required



Public consultation

Provide input on scientific guidelines as part of the standard EMA consultation process



NPL webpage

Visit the new EMA NPL webpage to stay informed on updates, key activities and implementation progress



Industry newsletter

Receive updates on progress and activities through the Industry NPL section of the EMA industry highlights newsletter

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Thank you

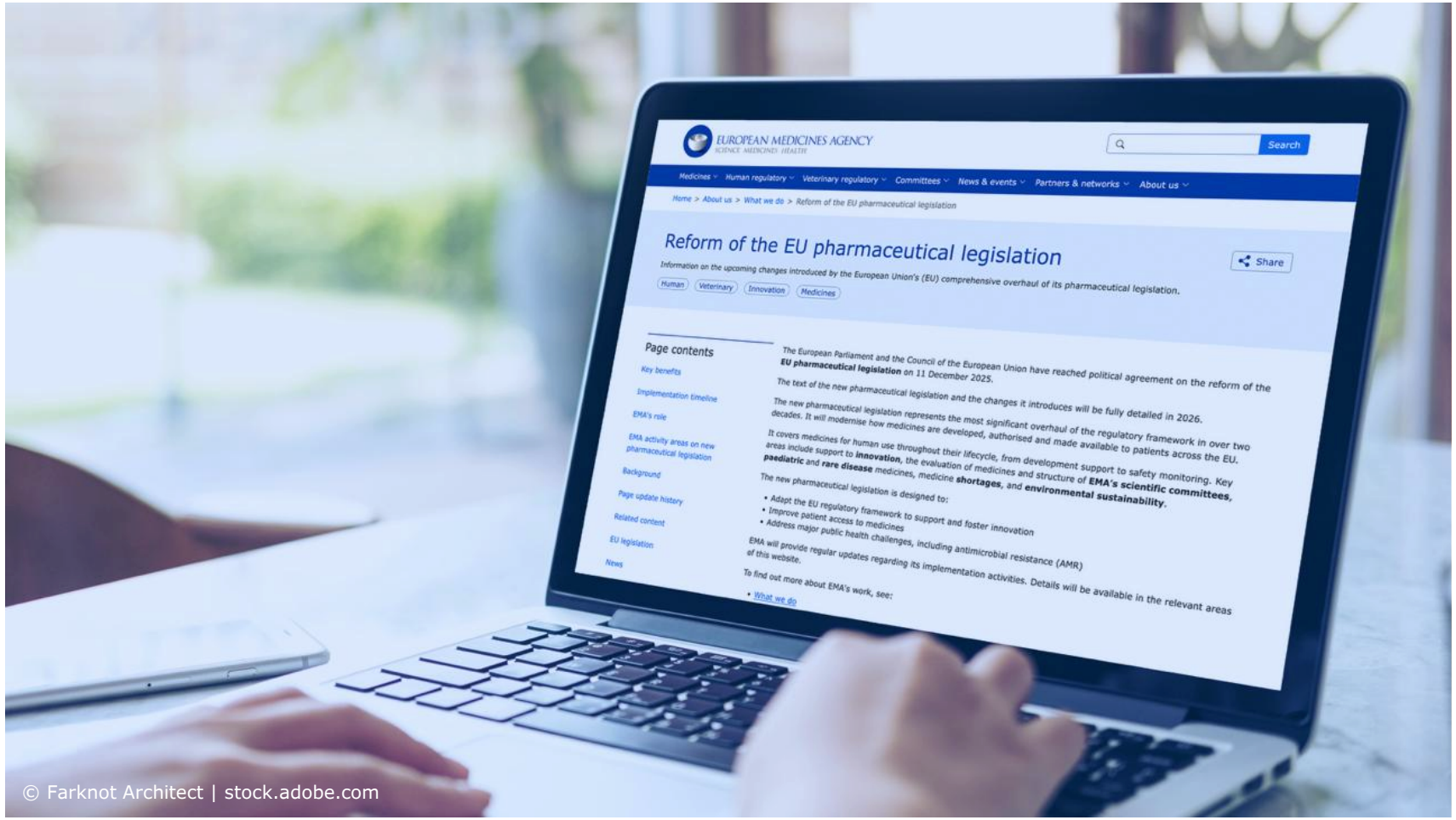
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EMA new pharma legislation web page



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EMA web page:

Reform of the EU pharmaceutical legislation

European Commission web page on the NPL:

Reform of EU pharmaceutical legislation - Public Health

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EMA/network governance structure

Strategic Direction & Decisions

NPL Oversight Group

EMA Programme Management

6 Delivery Streams

Delivery Streams Sponsorship:

- EMA member
- NCA MB member
- Civil society MB member

CP & Committees

Development Support

ERA & 3Rs

Quality & Manufacture

Shortages

Other Regulatory & Legal

Ad Hoc CxMP Chairs Participation

Implementation Execution

Existing EU Network Groups (+ ad hoc additional groups for NPL if/where gaps)
Existing IT/IT governance for IT deliverables

Stakeholder Engagement

Existing EMA stakeholder platforms for industry, HCPs and patients (connect with NCA and EC participation)

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