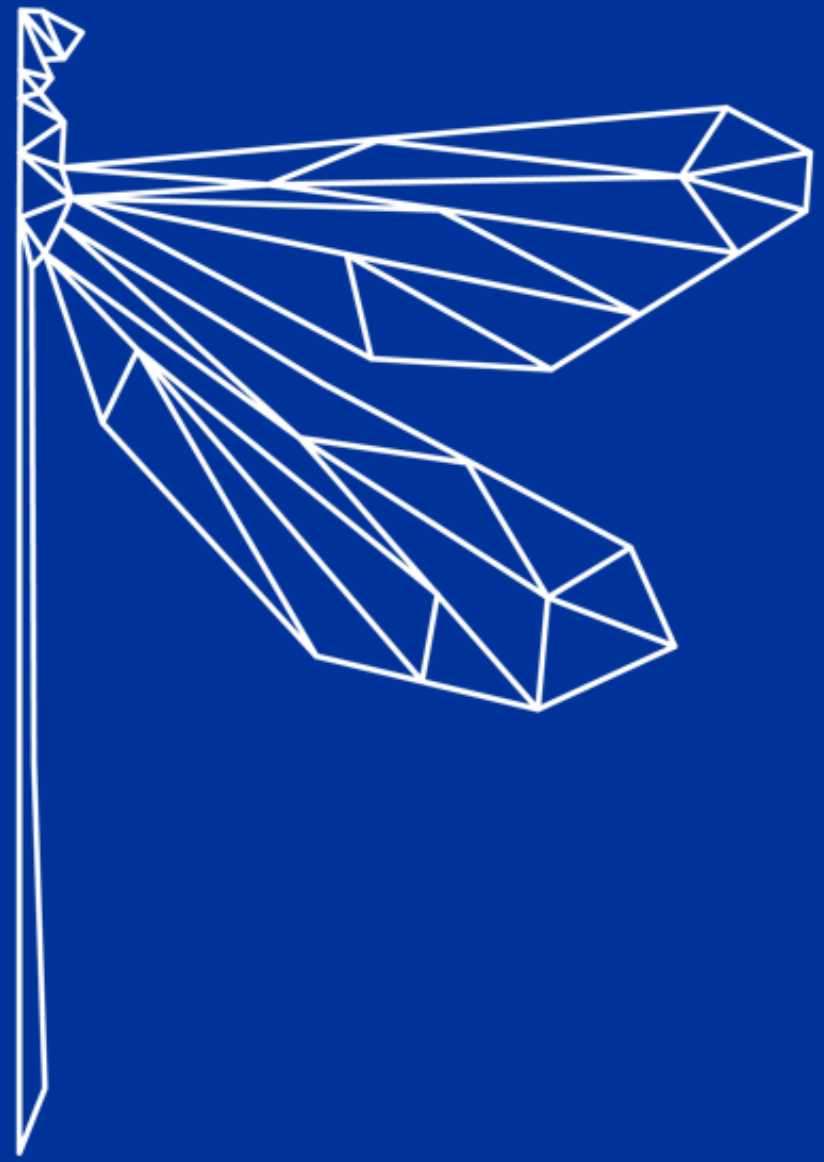
EMA
EUROPEAN MEDICINES AGENCY

New pharma legislation

Implementation & Stakeholder engagement



Joint PCWP/HCPWP meeting, 04.02.2026

Key elements of the new pharma legislation (NPL)

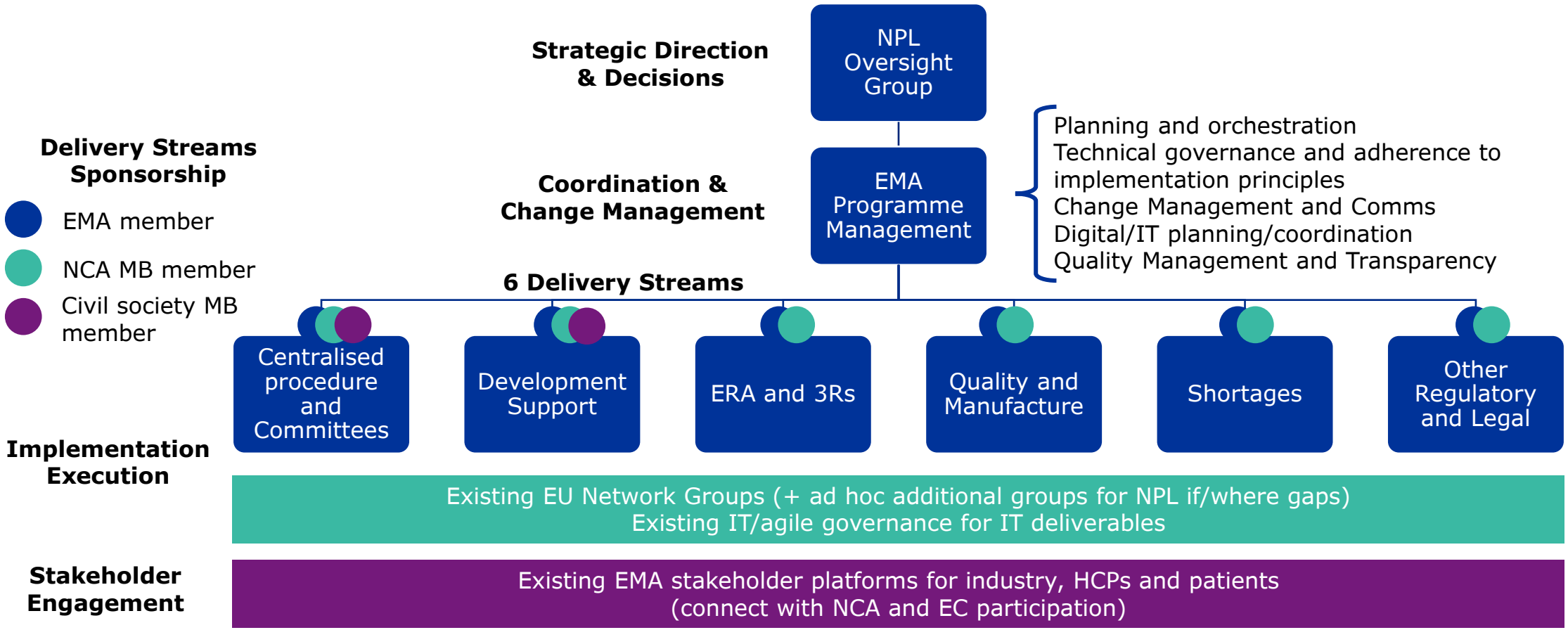
A **simpler** regulatory environment

Stronger **safeguards** against **medicine shortages**

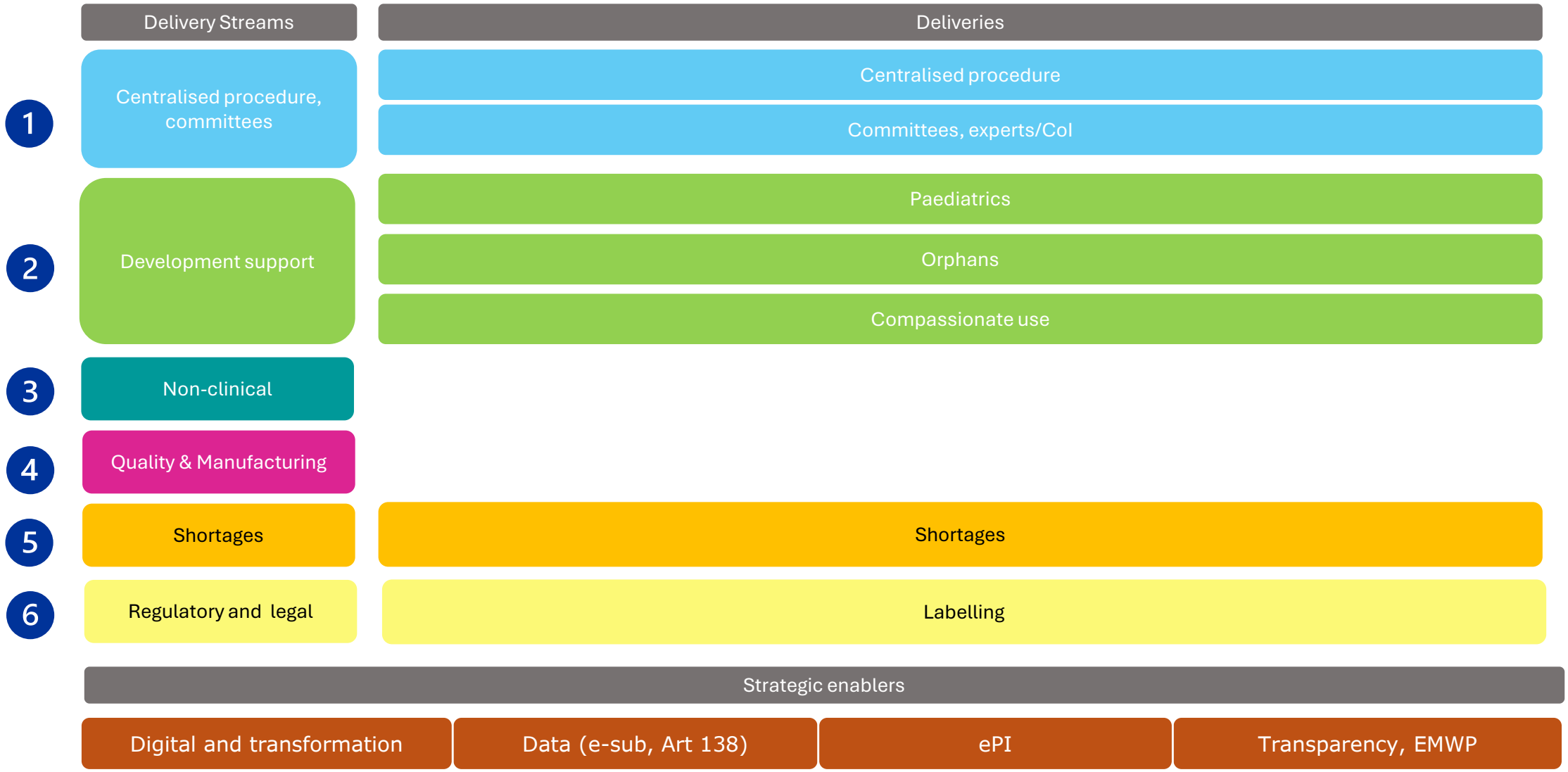
More **support** and **improved** conditions for **innovation**

Enhanced **environmental protection** and focus on **antimicrobial resistance**

Proposed NPL governance structure



Delivery streams requiring patient and HCP input



Engaging patients and HCP representatives during NPL implementation

Multi-stakeholder workshop

What: High-level workshop with all stakeholder groups (EMA, EC, NCAs, industry, patients, HCPs).

When: Organised as soon as practicable after the publication of the final legislative text in the Official Journal.

Purpose: Provide an overview of the foreseen changes and gather early reflections to guide implementation planning.

PCWP & HCPWP

What: Main reference forum for patients and healthcare professionals during NPL implementation.

When: In line with the regular PCWP/HCPWP meeting cycle (topics brought as needed).

Purpose: Share overarching progress and upcoming milestones, clarify questions, gather high-level input, and keep alignment with patient/HCP representatives as implementation evolves.

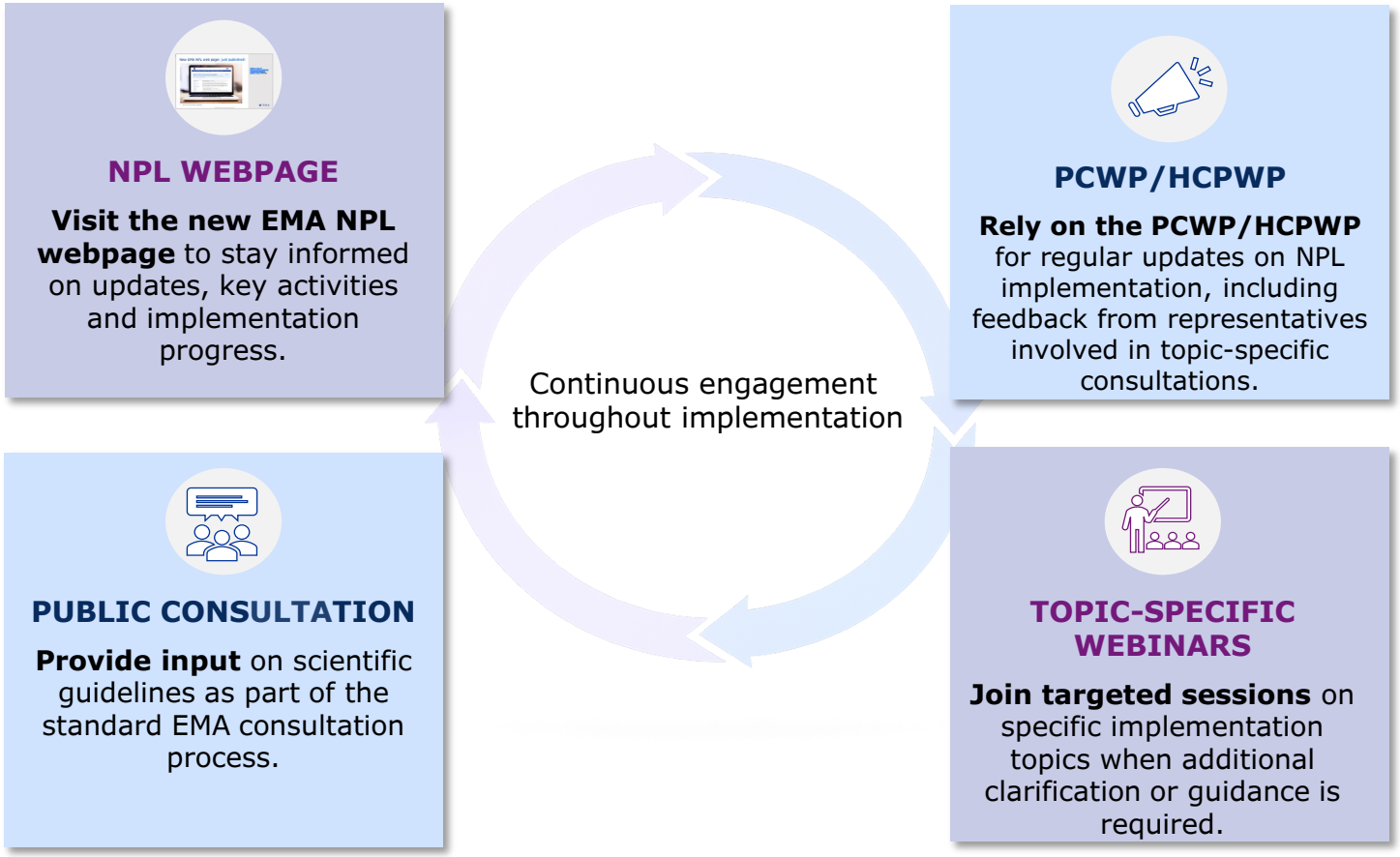
Topic-specific consultations

What: Targeted consultations with patients and/or HCP representatives for specific implementation topics.

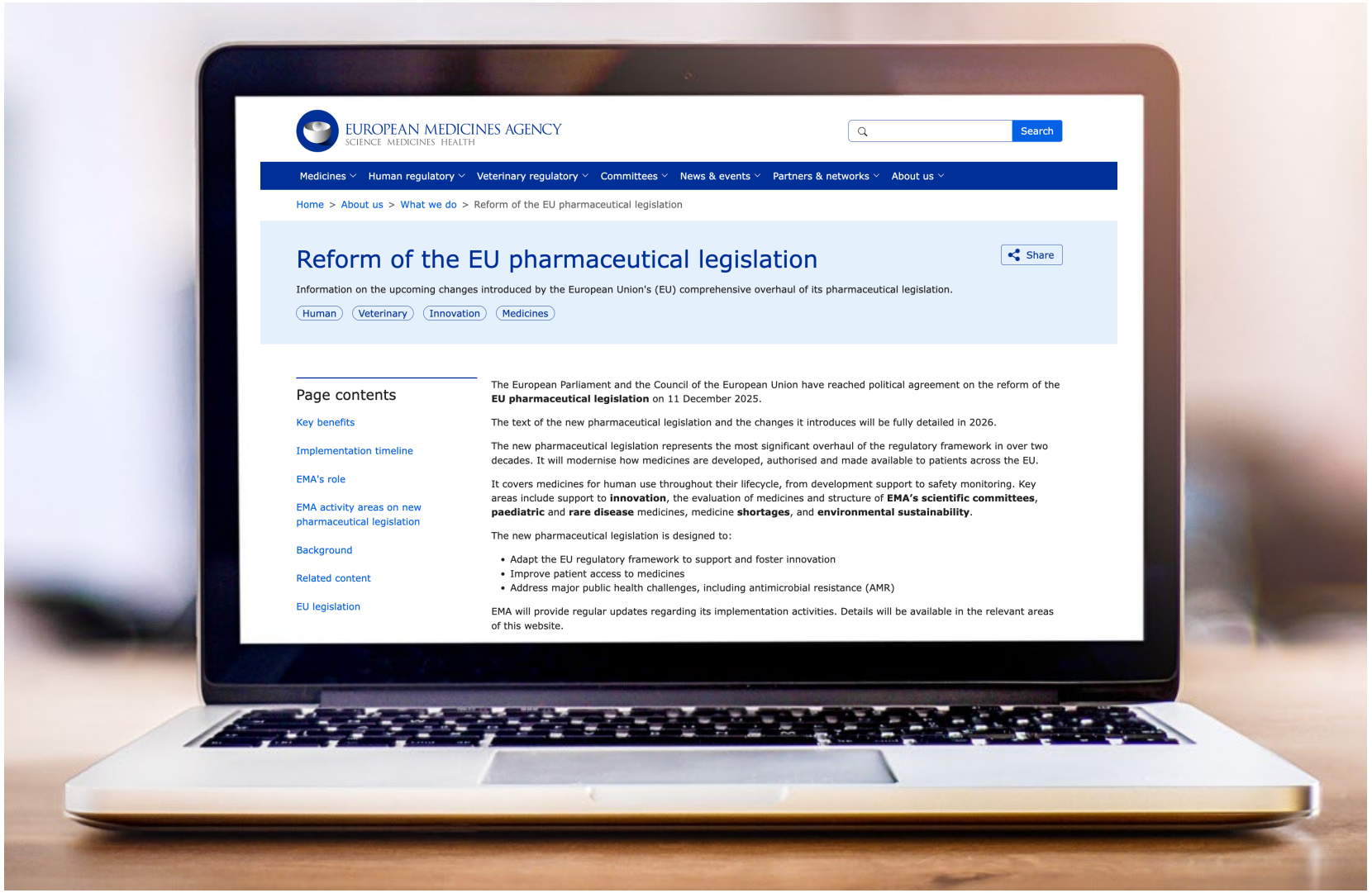
When: On a needed basis, triggered by concrete implementation questions and timelines.

Purpose: Work through practical implications, validate approaches, and collect operational input to inform implementation deliverables (e.g., guidance, communications, user needs, roll-out plans).

Keeping stakeholders informed and involved throughout implementation



New EMA NPL web page: just published!



[Reform of the EU pharmaceutical legislation | European Medicines Agency (EMA)](#) webpage

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

Follow us