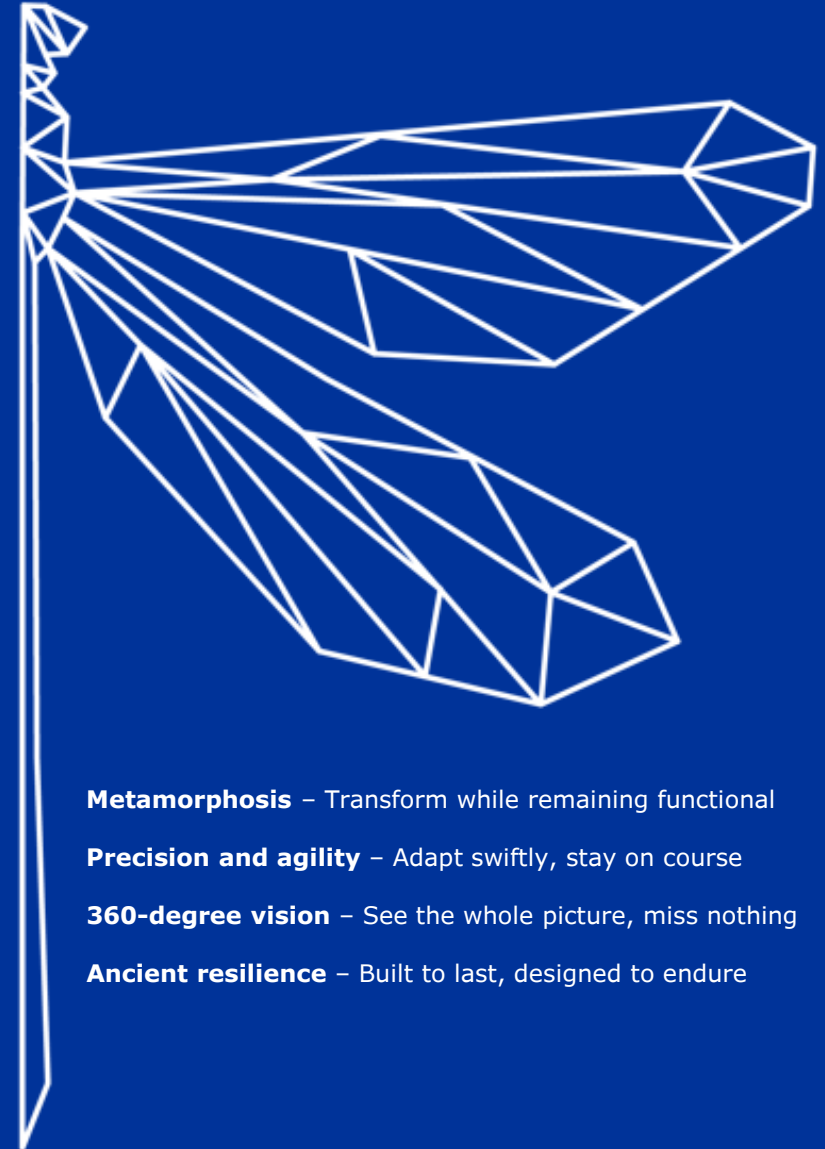


New Pharma Legislation

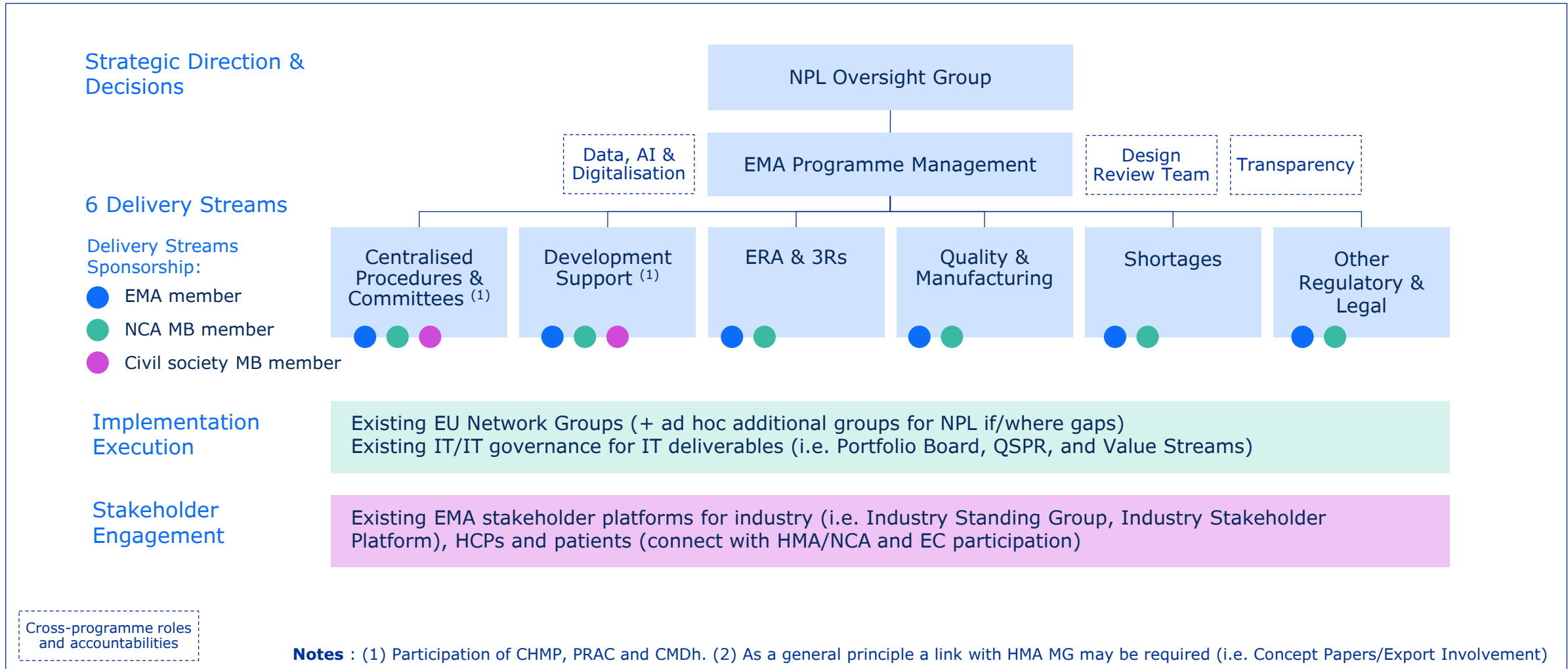
Update

Joint PCWP/HCPWP meeting, 01 July 2026



- Metamorphosis** – Transform while remaining functional
- Precision and agility** – Adapt swiftly, stay on course
- 360-degree vision** – See the whole picture, miss nothing
- Ancient resilience** – Built to last, designed to endure

Programme governance structure



What do we want to achieve

What is the Network Collaboration Model

Defines the involvement of EU network experts in Delivery Teams from the outset, ensuring that Concept Papers and associated deliverables are jointly designed, operationally feasible, and implementable across the EU by Q4 2028.

The importance of expert involvement and its key benefits

Ownership and Buy-In

Strengthen ownership and enable a smoother EU-wide rollout

Risk Management

Reduce downstream risks during endorsement and implementation

Transformation

Established experience and a future-oriented mindset that enables innovation

Network collaboration model

Experts input is needed for the design/development of 40 Concept Papers (*excluding shortages*)

Simplicity and proportionality

- Delivery streams propose expert profiles and experts aligned with the specific needs ⁽¹⁾
- These needs may include input for the development of Delegated and Implementing Acts

Expertise and mindset

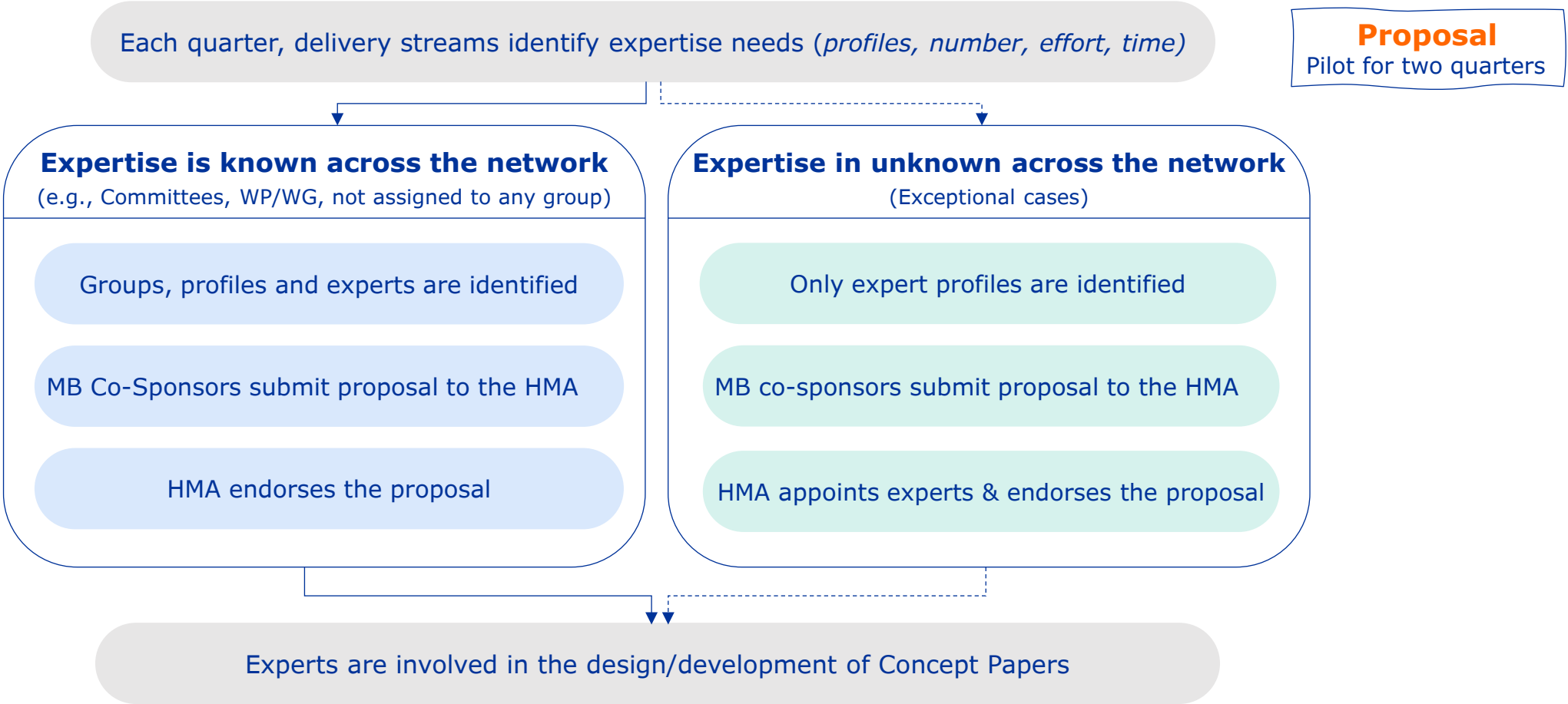
- The proposal may include different profiles (e.g., Forward-looking, scientific) and specific nominees
- Each quarter, proposals are validated and subsequently submitted to HMA by MB Co-Sponsors

Fit-for-purpose expert engagement

- Experts are assigned to specific time-bound tasks and deliverables
- HMA Management Group acts as the endorsing body
- Rapid response will be needed for endorsement (HMA to consider realistic timeframe)

⁽¹⁾ Each Concept Paper (scope, deliverables)

Network collaboration model: Decision-making



Topics/projects within DS 1 – Centralised Procedure and Committees

Centralised Procedure
– initial marketing
authorisation

Post-Authorisation
procedures

EMA reform and
experts

Pharmacovigilance

Real World Evidence

Public Product Portal

Raw Data

DS1 currently has a
priority on the iMAA and
the EMA reform/experts.

Topics/projects within DS 2 – Development Support

Scientific advice

PRIME

Paediatrics

Orphans

ATMPs and
hospital exemptions

Compassionate use

Not-for-profit
repurposing

Classification of
medicinal products

Sandbox

DS2 currently has a priority on the Sandbox as implementation is immediate.

Second priority is paediatrics and orphans

Topics/Projects within DS3 – Non-clinical, ERA & 3Rs

Non-clinical

(Reg. Art 6.1; Dir. Art 6.3;
Reg. Art. 138zi, zj, zk, zl)

3Rs

Reg. Art 6.5, 12(m), 16.3, 138(ze, zi, zl)
Dir. Art 6.7, 16.3

OSOA

Reg. Article 138(ze) & 139, Dir. Article
27

ERA-general & ERA-WP

(DIR Art. 22 & Reg. Art. 150)

ERA-registry

(Reg Art 104a)

ERA-monograph

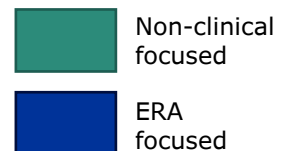
(Dir Art 24)

ERA-catch up

(Dir Art 23)

ERA-GMO

(Reg Art. 7-9 & 177)



Topics/Projects within DS4 - Quality and Manufacturing

Active
Substance
Master Files

(DIR Art. 25)

Additional
Quality Master
Files

(DIR Art. 26)

Platform
technologies
master files

(DIR Art. 26a)

Decentralised
manufacturing

(DIR Art. 26b)

Surveillance and risk-
based GMP
inspections

*(reliance, distant assessment, risk
based inspection for API, joint
inspections)*

(DIR Art. 188, 189, 190, REG Art 53)

Joint Audit
Programme

*(mandate and expansion to GDP)
(REG Art. 54)*

Inspectors
Working Group

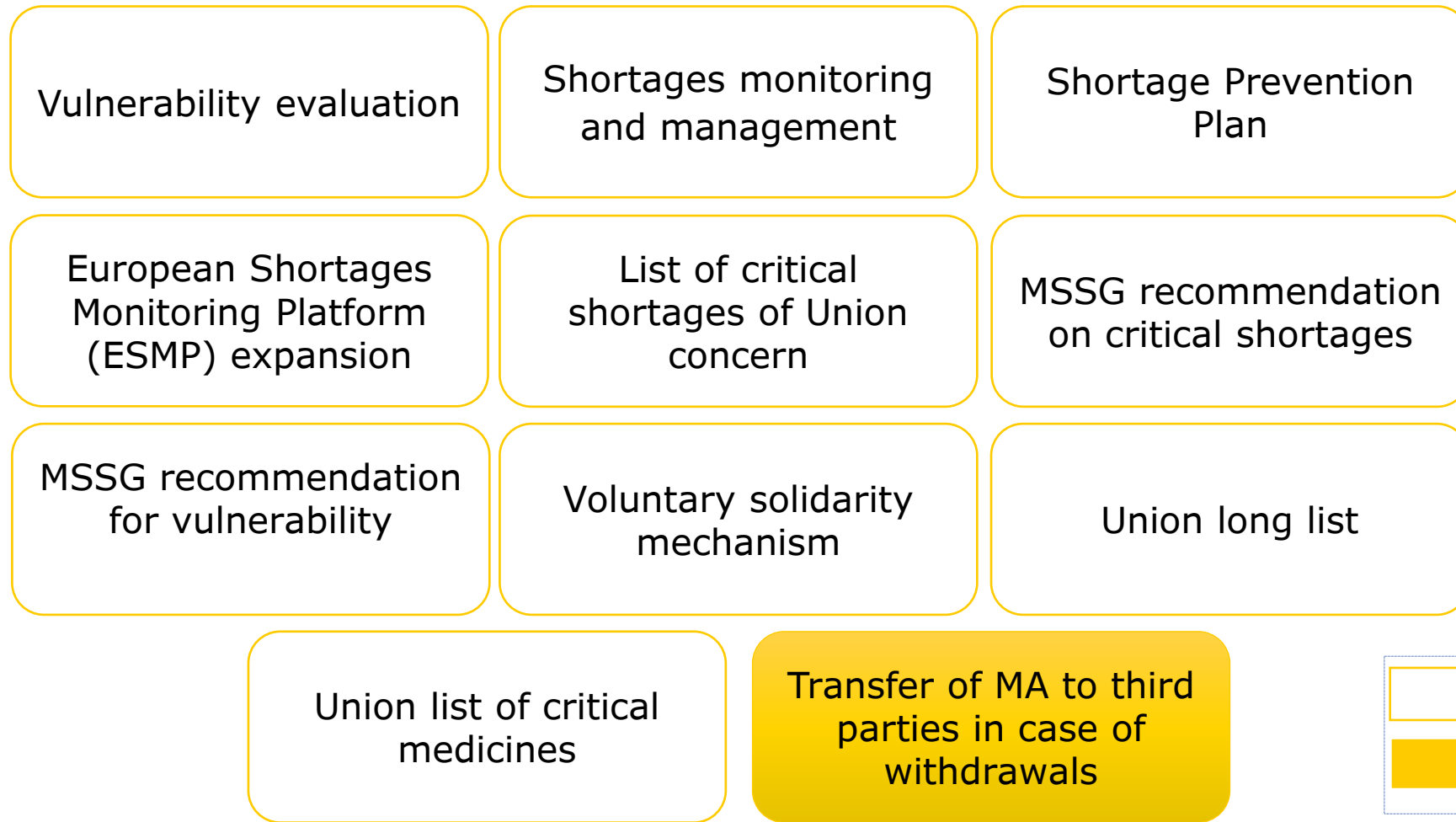
*(establishment as EMA WG)
(REG Art. 142)*

Agency
Inspectorate

(REG Art. 52 & Annex III)



Topics/Projects within DS5 - Shortages



Topics/projects within DS6 – Other regulatory & legal

- Annex II
- Transferable exclusivity voucher (TEV) for priority antimicrobials
- Conditional MA
- MA under exceptional circumstances
- Regulatory data protection, including scientific guidelines on unmet medical need and on criteria for proposing a comparator for a clinical trial
- Product information (ePI and PI-related guidances and template)
- Temporary emergency marketing authorisation
- Referrals
- EMA governance matters (e.g. international cooperation, security, protection against cyber attacks, budget)

DS6 has a strong focus on regulatory aspects – any process-related changes will be led by DS1

Other regulatory matters (eg definitions, legal basis, radiopharmaceuticals) will be incorporated within topics or other general guidance updates

Current priorities in DS6

Transferable exclusivity voucher for priority antimicrobials (TEV)

Implementation plan includes the development of relevant guidances in particular with respect to:

- Scientific considerations to support the justification that a product meets the criteria for 'priority antimicrobial' as defined in Article 40(3)
- Procedural guidance for the submission of requests for TEV in initial MA, transfer and use of voucher

Annex II

EMA and network to provide input on the content of Annex II for the drafting of the delegated act.

Main goals:

- Future-proofing while ensuring legal certainty
- Updating outdated content and integrating new concepts



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Thank you

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