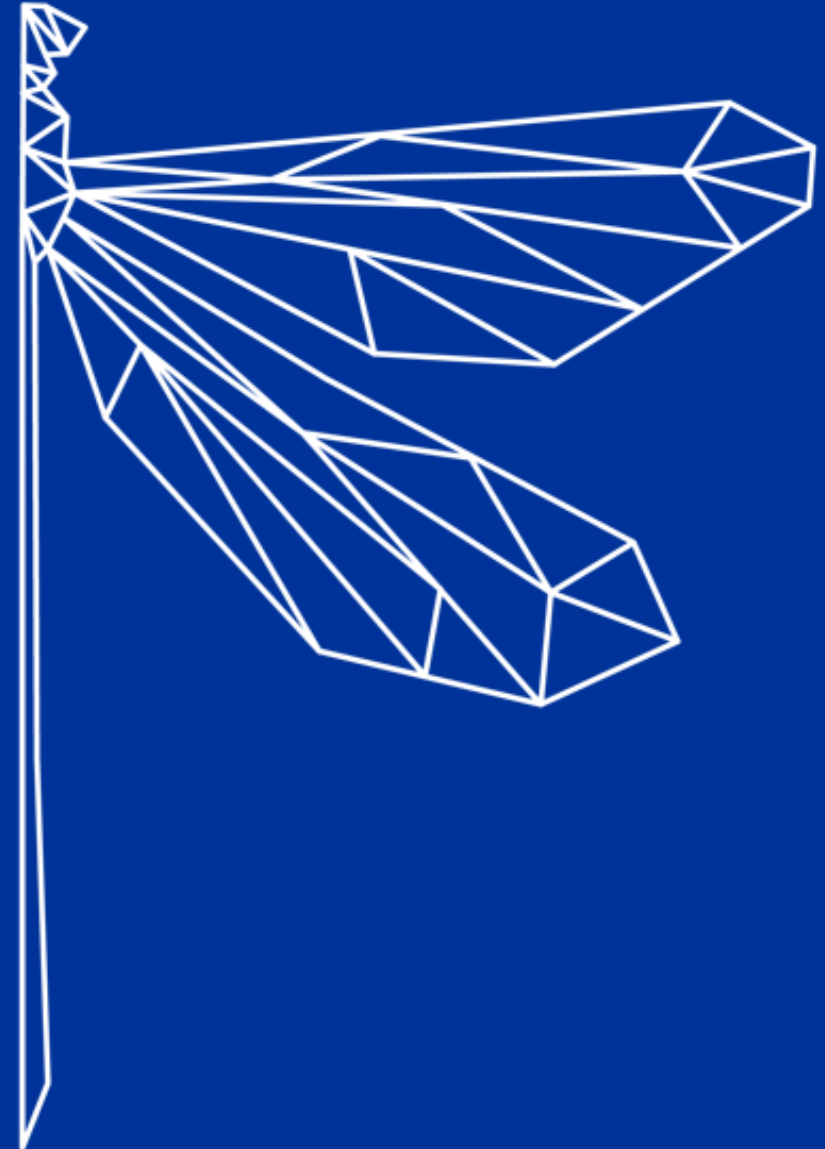


New pharma legislation

Update from the NPL programme management team and delivery streams

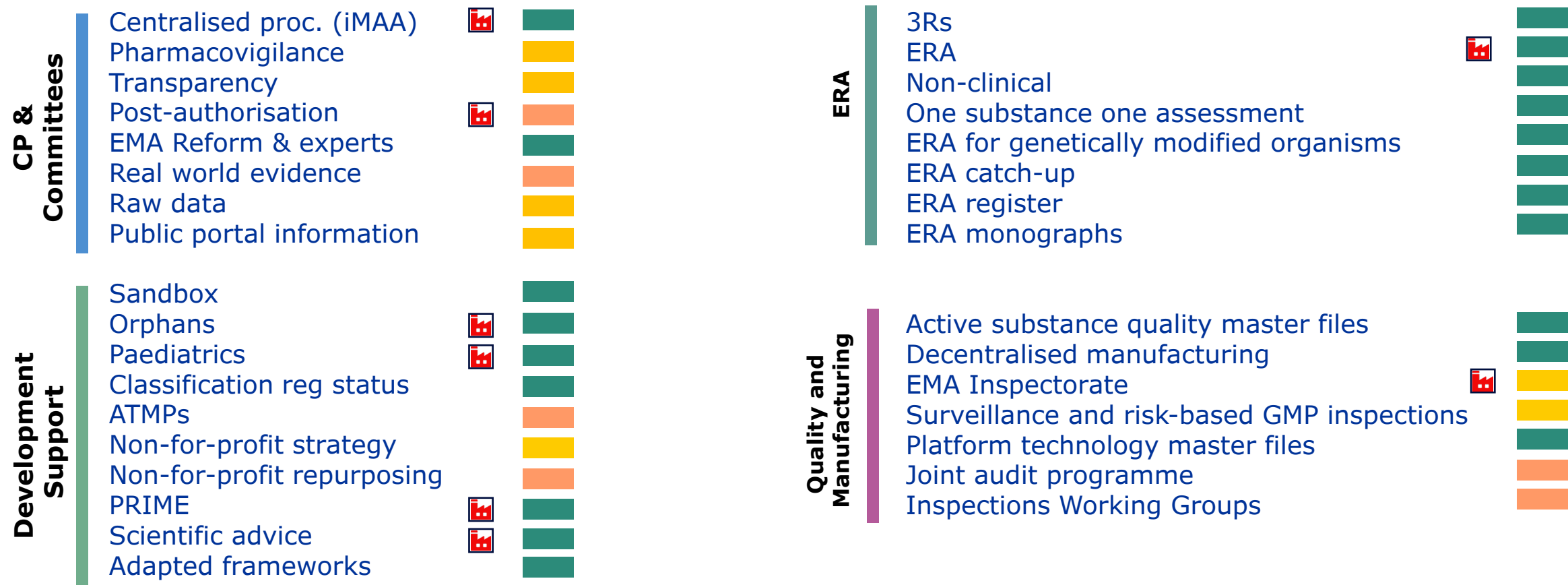
ISG meeting, 21.09.2026



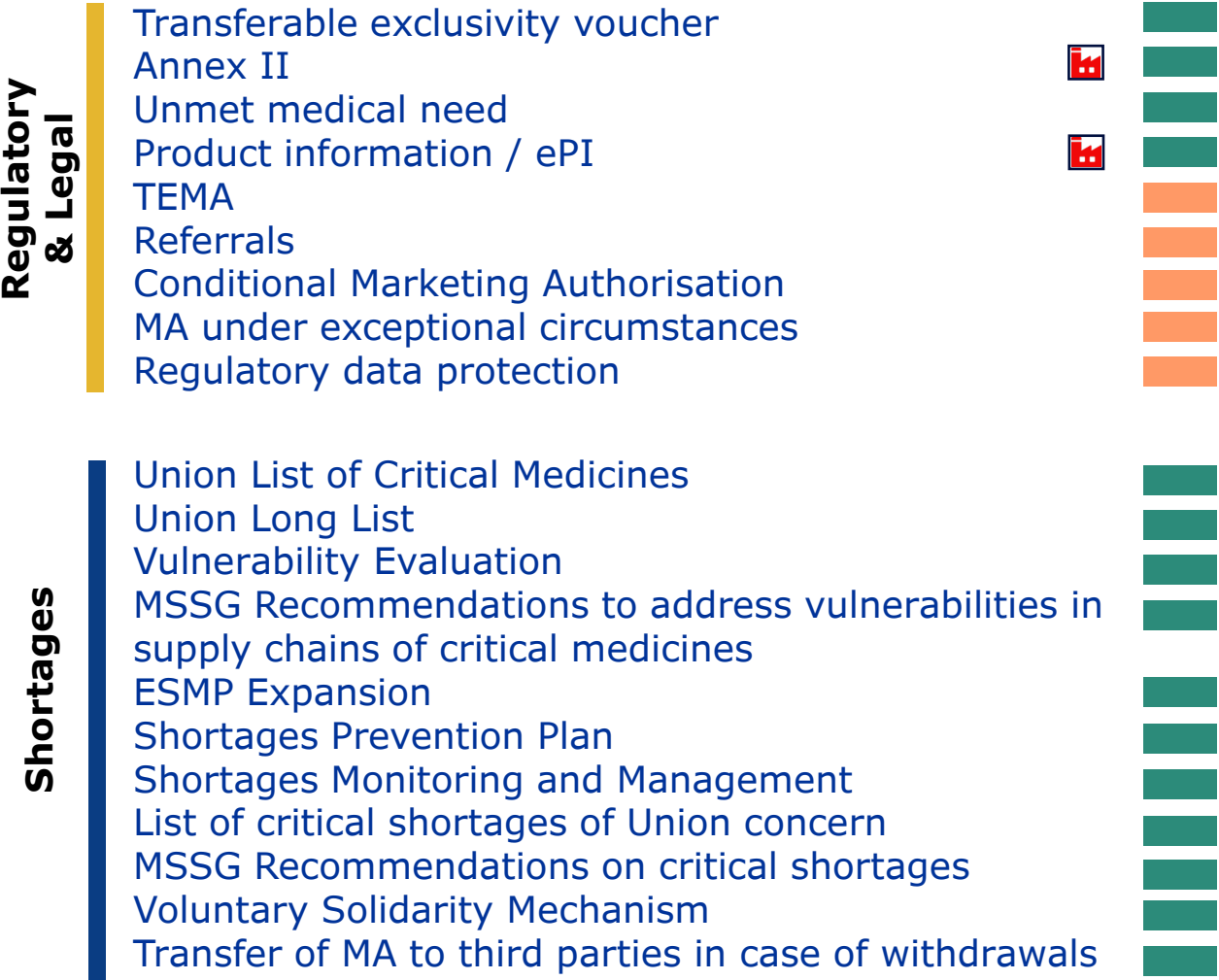
Summary of the NPL programme

- **The programme** remains on track against the master plan, with:
 - 65% of projects already started and progressing as planned and;
 - Of these, 23% directly support industry priorities, demonstrating early progress in addressing industry needs.
- **Change management** capabilities and a comprehensive communication plan have been established to ensure continuous updates to stakeholder, promote transparency, and support timely technical and organisational readiness.
- **The NPL digitalisation plan** is being defined in close collaboration with the value streams to ensure alignment on business needs, delivery priorities, and the successful implementation of NPL requirements.

Projects status overview (1/2)

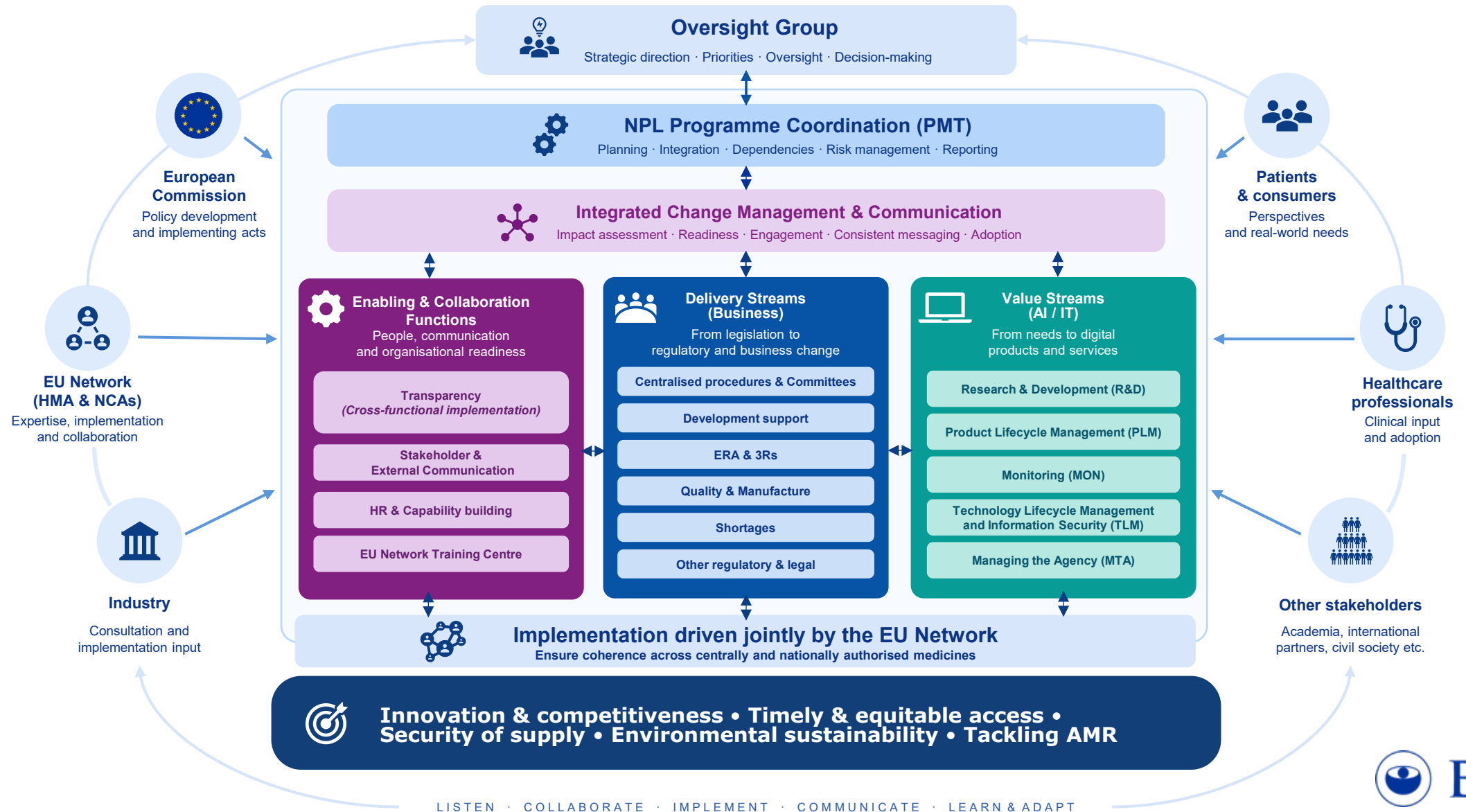


Projects status overview (2/2)



NPL integrated implementation model

Connecting business, digital, change and communication to deliver a consistent experience for our stakeholders.

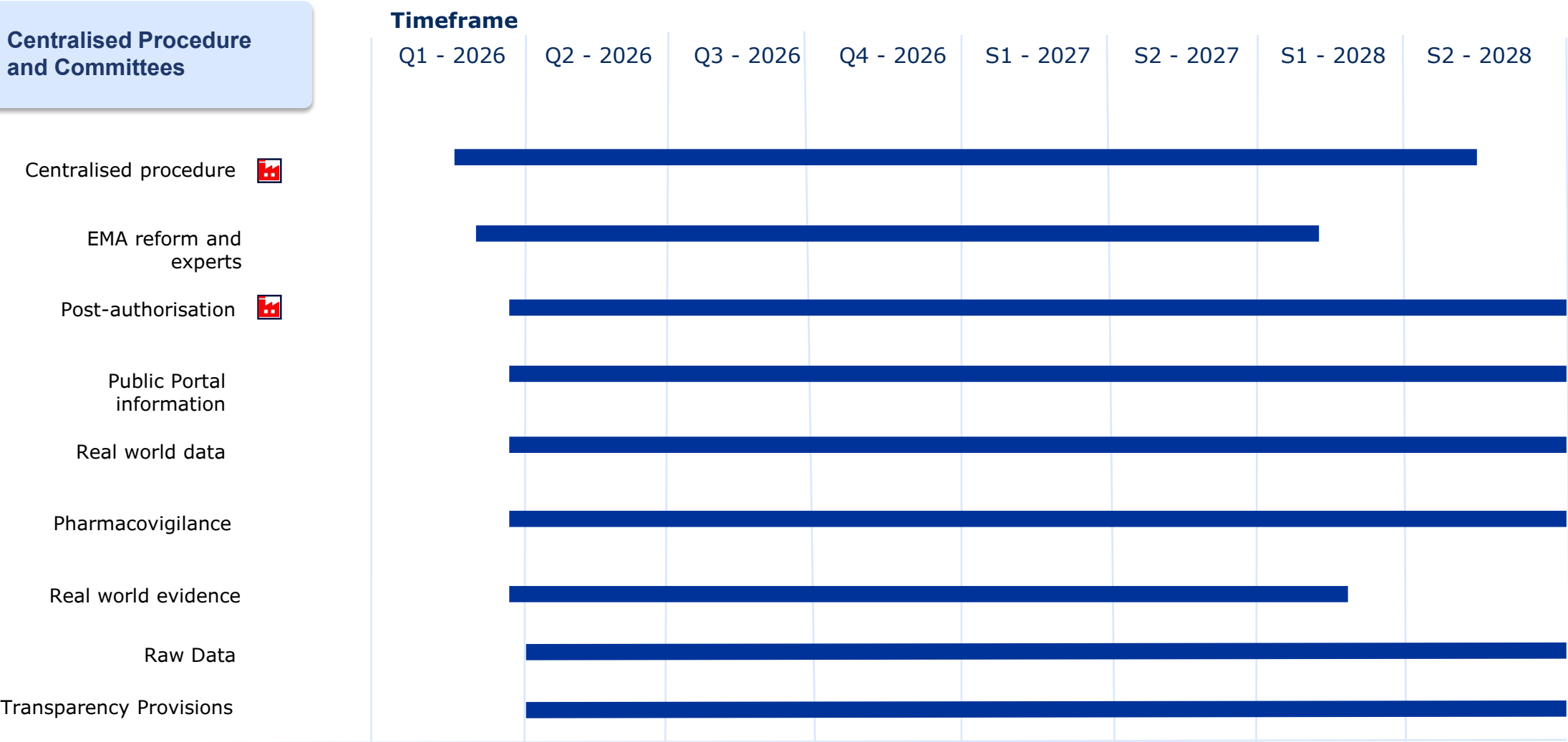


Classified as public by the European Medicines Agency

DELIVERY STREAM 1: Centralised Procedure and Committees

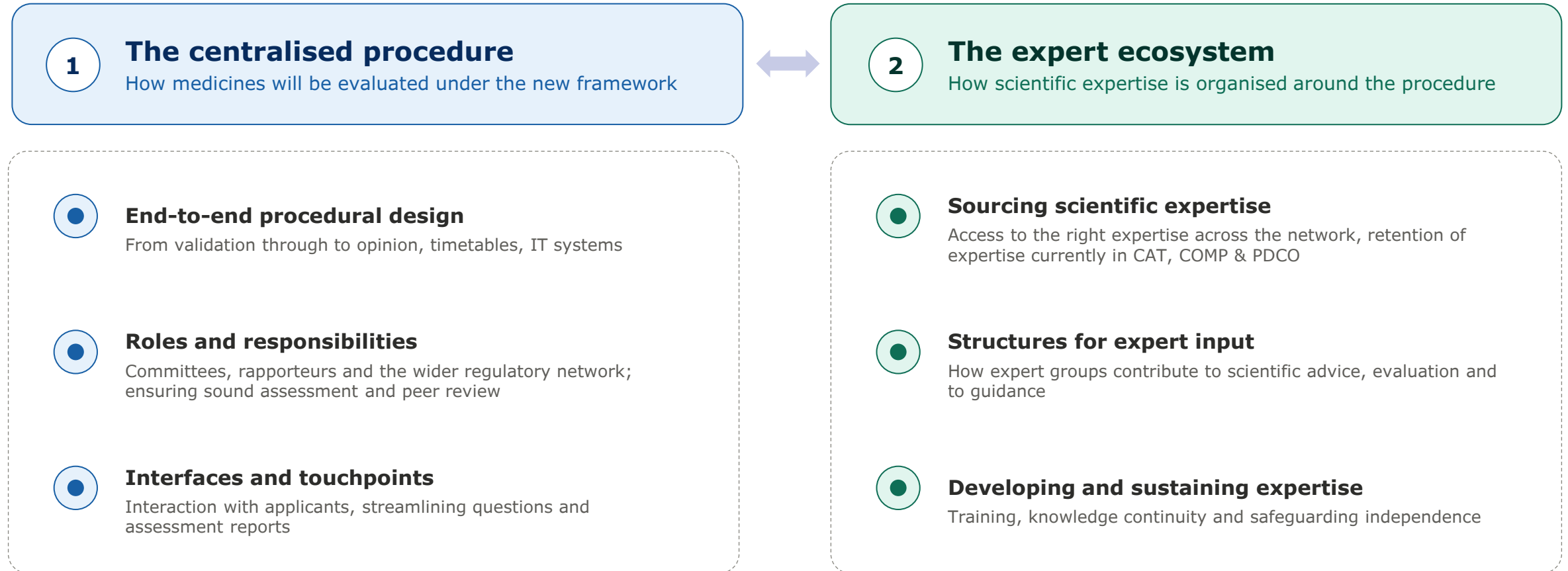
1

Centralised Procedure and Committees



Preparing to implement the new pharmaceutical legislation – Stream 1

Two connected main areas of work



Both areas are being developed together, in collaboration with the European medicines regulatory network and the European Commission.

Aim: agreement with HMAs, EMA Senior Management and EC by end of 2026 on key principles. External engagement in early 2027.

2 Development Support



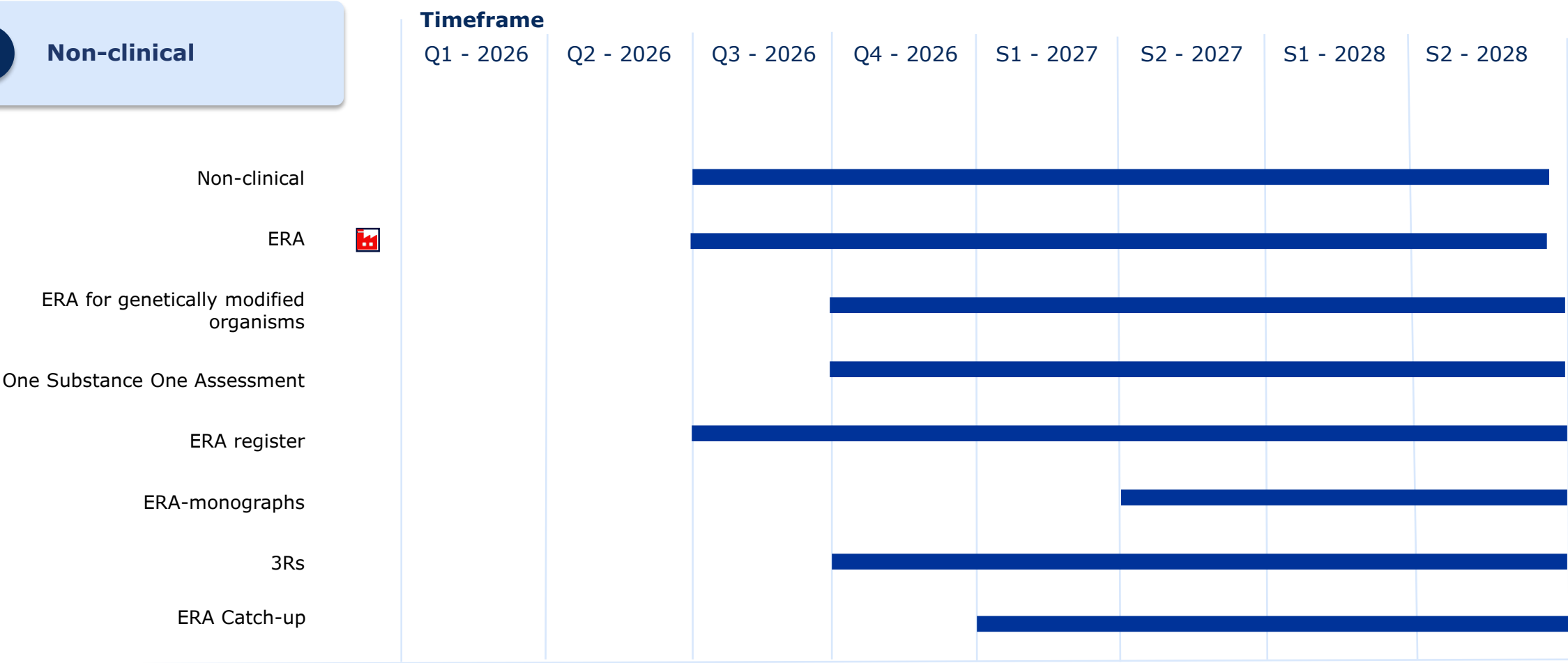
Topics and interaction proposals

- Regulatory sandbox – workshop today – Q&A and website – implementing act
- Responsibility shift from COMP and PDCO to EMA and CHMP/WPs/WGs for orphan procedures and PIPs.
 - Existing focus group for paediatrics
 - Create one for orphans
- Not-for-profit entities repurposing – impact on MAH?
- PRIME
 - Existing focus group
- Scientific advice – ready to meet current and future needs
 - Existing focus group and initiatives
- Regulatory status (classification) – borderline products – impact on developers?

DELIVERY STREAM 3: Non-clinical

3

Non-clinical



Non-clinical, ERA & 3Rs Delivery Stream - Projects

Non-clinical

- * Share non-clinical knowledge to avoid unnecessary animal testing
- * Facilitate joint animal testing

3Rs

- * Requirement to show 3Rs adherence in MAA
- * Support development & regulatory uptake of NAMs

OSOA

- * Ensure coherence and resolve divergence of scientific opinions with other Union bodies

ERA-general

- * Revise guideline to align with Art 22
- * Request MAHs to review & update ERAs
- * Establish ERA working party

ERA-registry

- * Establish public registry with ERA results
- * Request MAH to submit completed ERA studies

ERA-monograph

- * Establish risk-based prioritisation rules for substances
- * Initiate proof-of-concept pilot



Non-clinical/ERA focused - Interested party interaction via NcWP stakeholder meeting



3Rs focused – Interested party interaction via 3RSWP meeting

ERA-catch up

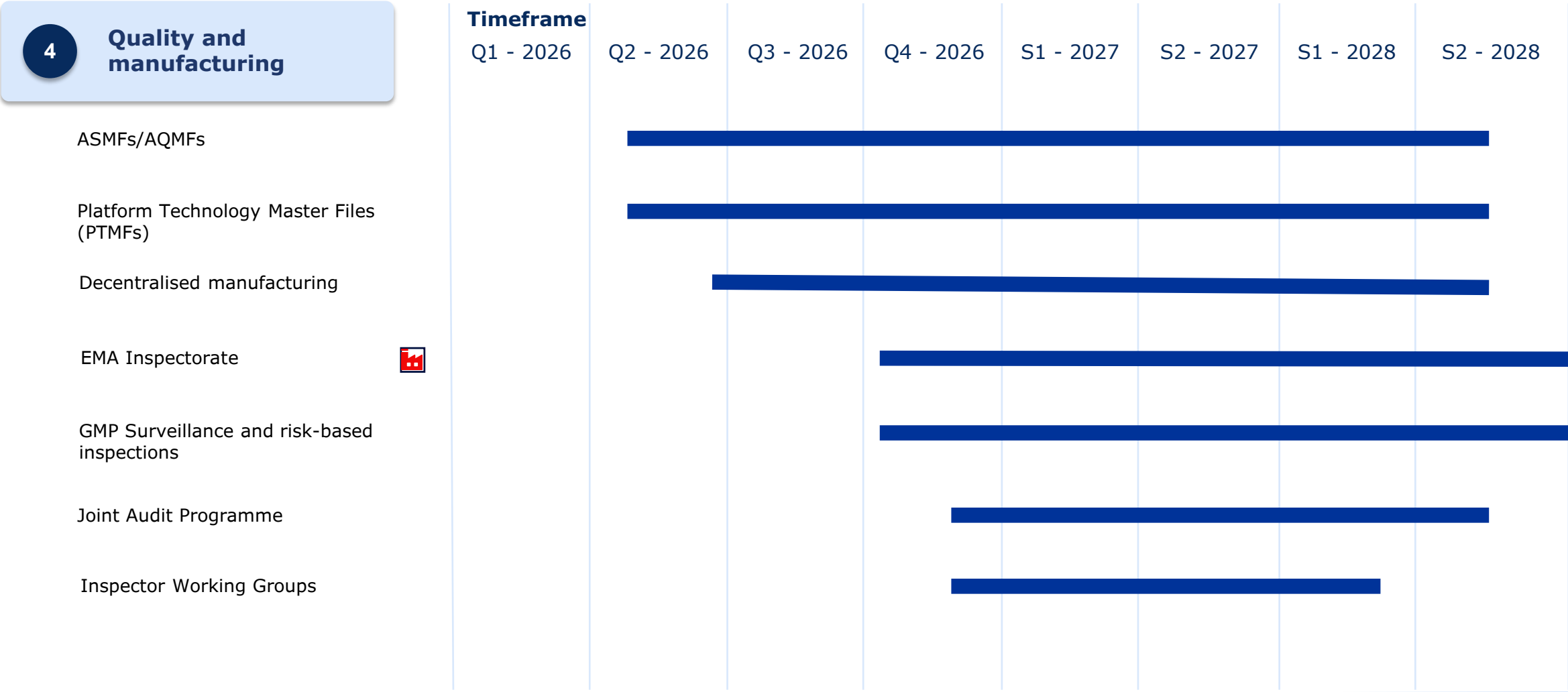
- * Identify environmentally harmful pre-2005 medicines that are required to submit ERA

ERA-GMO

- * Update CTIS to enable ERA module submission
- * Develop CHMP ERA assessment process for CTAs of GMOs



DELIVERY STREAM 4: Quality and manufacturing



Quality and Manufacturing Delivery Stream - Projects

Active Substance Master
Files (ASMFs)
(DIR Art. 25)

Additional Quality Master
Files (PTMFs)
(DIR Art. 26)

Platform Technologies
Master Files (PTMFs)
(DIR Art. 26a)

Decentralised
manufacturing
(DIR Art. 26b)

EMA Inspectorate
(REG Art. 52 & Annex III)

GMP Surveillance and
risk-based inspections
*(reliance, distant assessment, risk
based inspection for API, joint
inspections)*
(DIR Art. 188, 189, 190, REG Art 53)

Joint Audit Programme
(JAP)
(mandate and expansion to GDP)
(REG Art. 54)

GMDP, GCP, PV
Inspectors Working
Group
(establishment as EMA working group)
(REG Art. 142)



Quality focused – Interested
party interaction via QWP/BWP
IP Meeting



Inspection focused – Interested
party interaction via GMDP
IWG IP Meeting

13

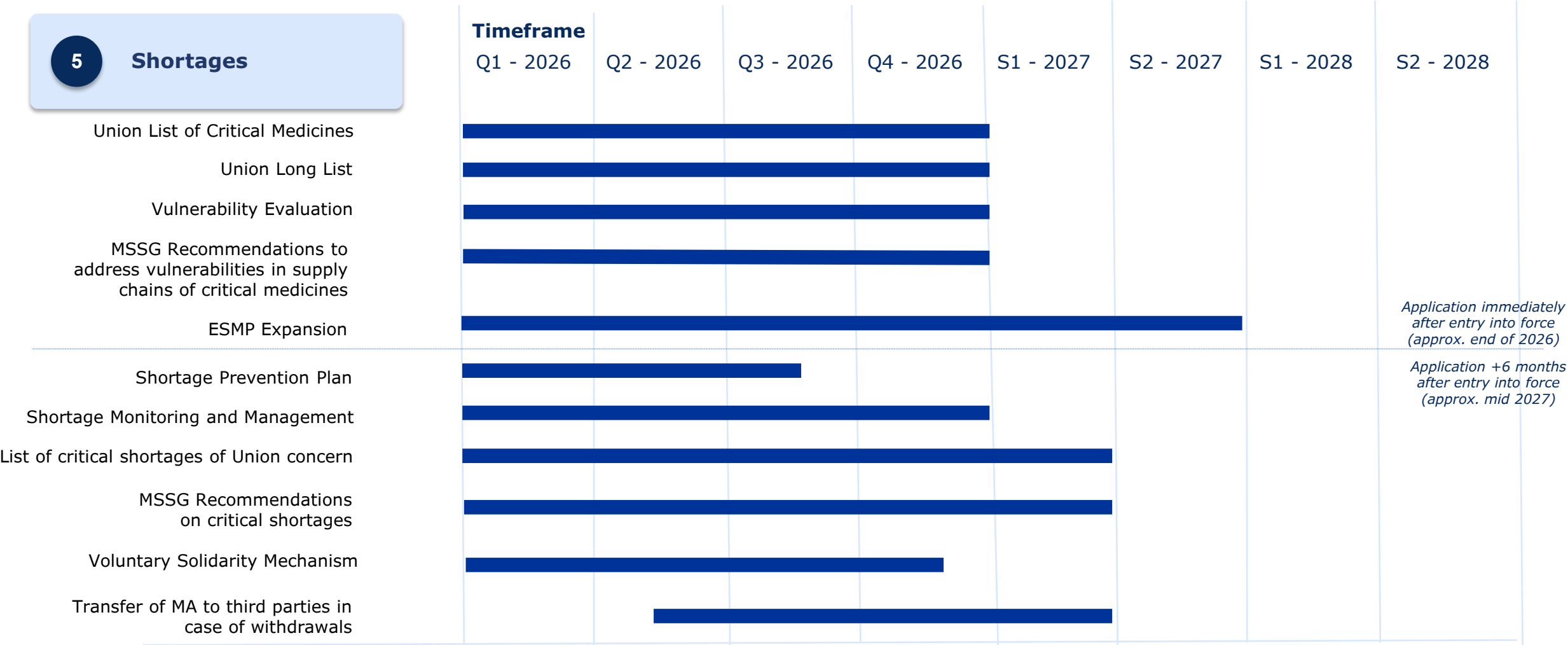


Further Delegated and/or
Implementing Acts

DELIVERY STREAM 5: Shortages

5

Shortages



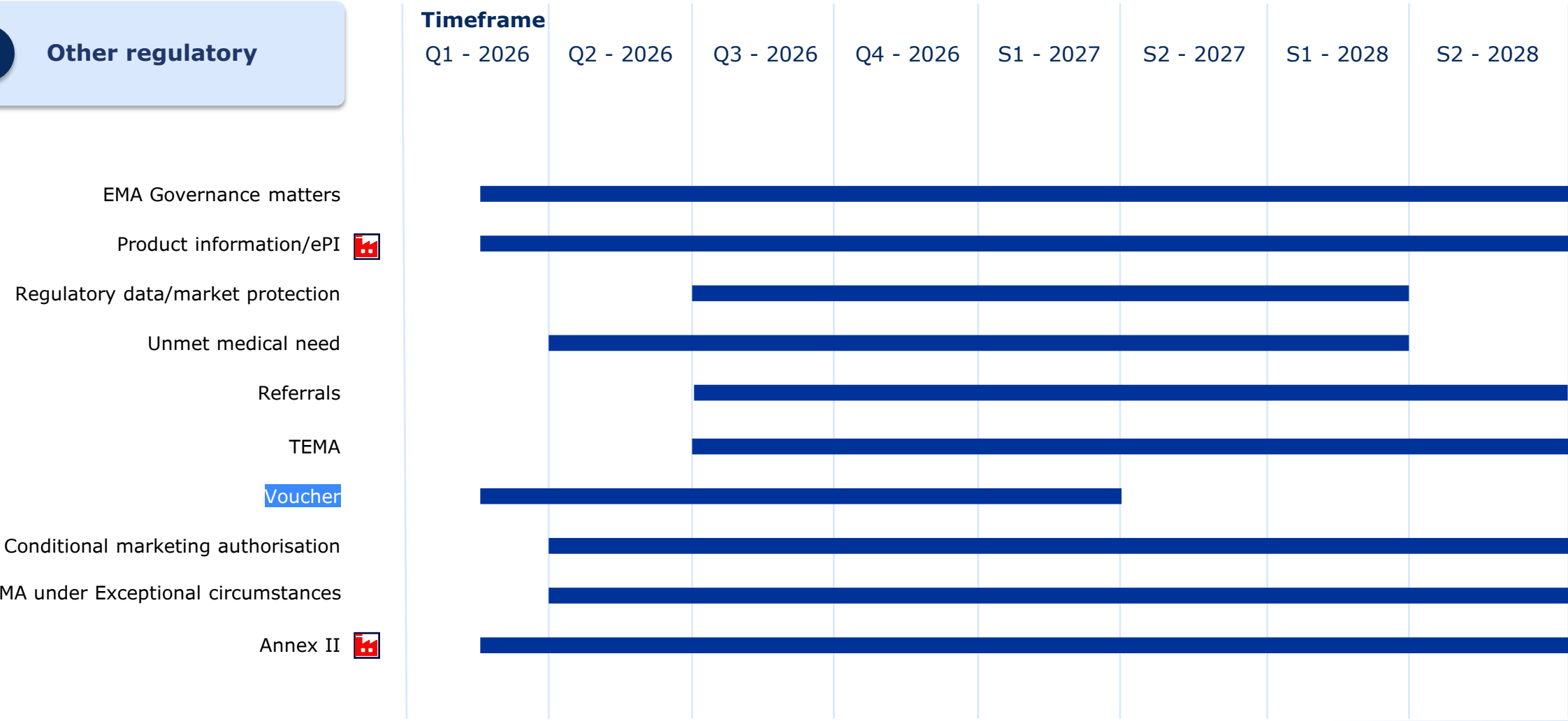
Delivery Stream 5: Key points for consideration

- Most activities driven through established and relevant entities (SPOC WP, MSSG and associated technical groups), under MSSG governance, as most activities are already ongoing. Industry involvement will continue to take place through these channels. This approach avoids duplication and ensures prompt implementation in line with shorter deadlines.
 - Latest updates:
 - The [guidance and template for industry on implementing Shortage Prevention Plans \(SPP\)](#) document is published and can be found on the [SPP webpage](#)
 - Shortage mitigation plan review (update of guidance and template) planned for Q4 2026. A written consultation will be launched for industry input soon (Q4).
 - Union list of critical medicines annual update 2026: Outcomes will be shared for stakeholder feedback in Q4 2026.
- Activities not discussed at MSSG and not frontloaded are handled through NPL implementation structure
 - De facto: 'Transfer of MA to third parties in case of withdrawals' only item handled through NPL governance under this topic.
 - Current progress: Develop overall process in collaboration with Delivery stream 1 on post-authorisation processes with next steps to follow

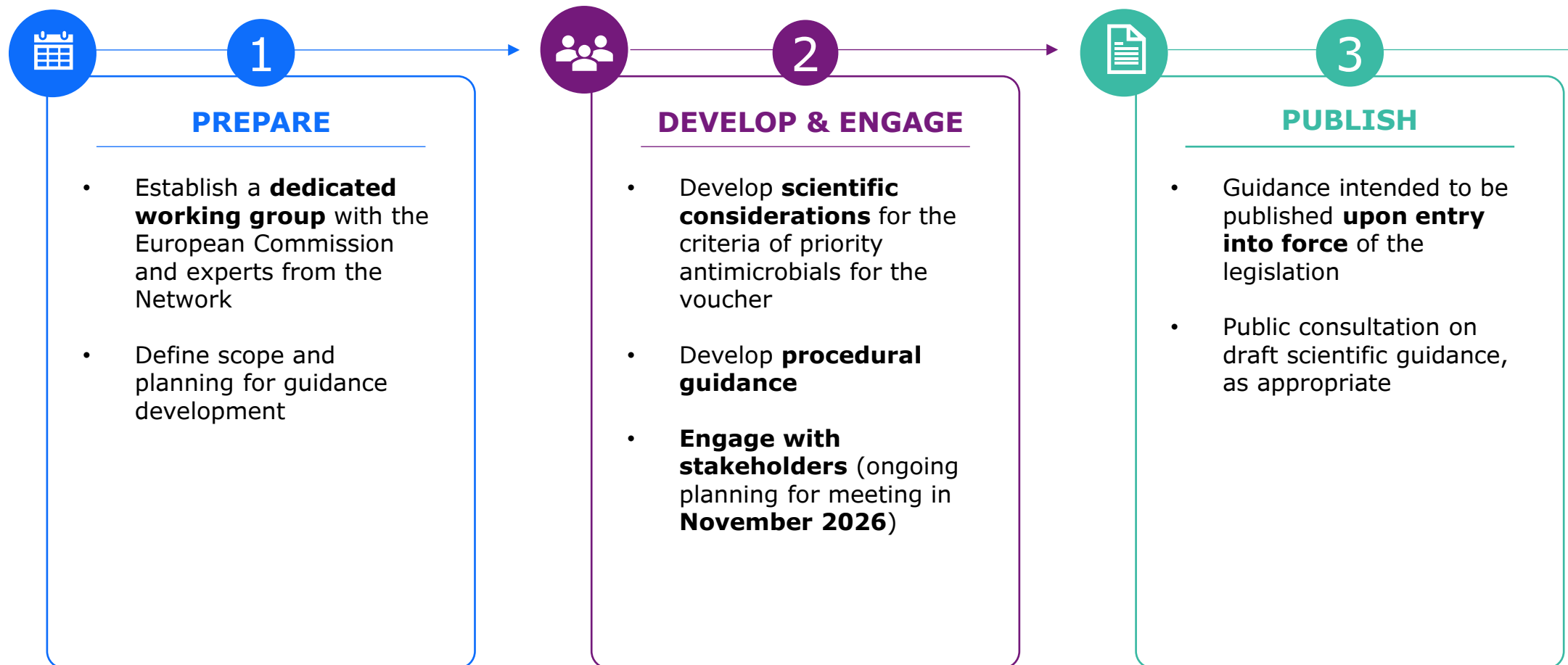
DELIVERY STREAM 6: Other regulatory

6

Other regulatory



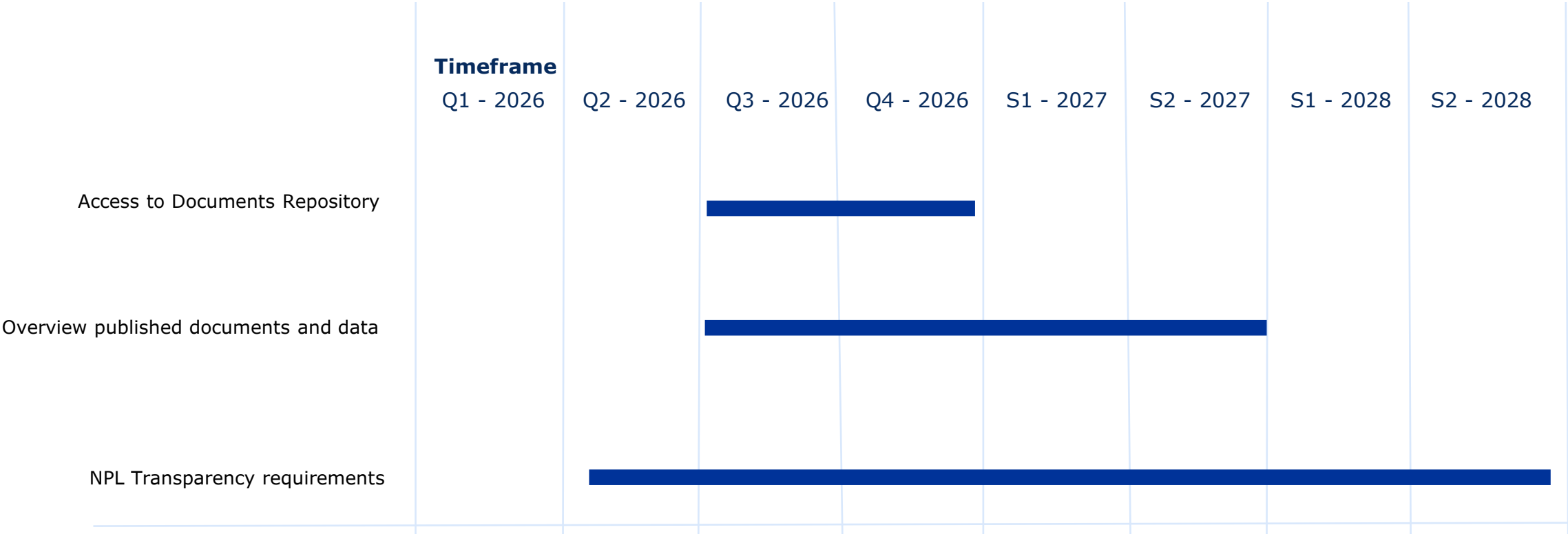
Transferable Exclusivity Voucher



TRANSVERSAL DELIVERY STREAM: Transparency

Ensuring a consistent, efficient, and effective approach to sharing information with the public

Collaboration across all workstreams





EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

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