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Implementation of the New Pharmaceutical Legislation (NPL)

Delivery stream 1 (Centralised procedure and committees)

17th meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines, 20 November 2026

Michael Vogl, Business Data Lead and NPL Delivery Stream Lead

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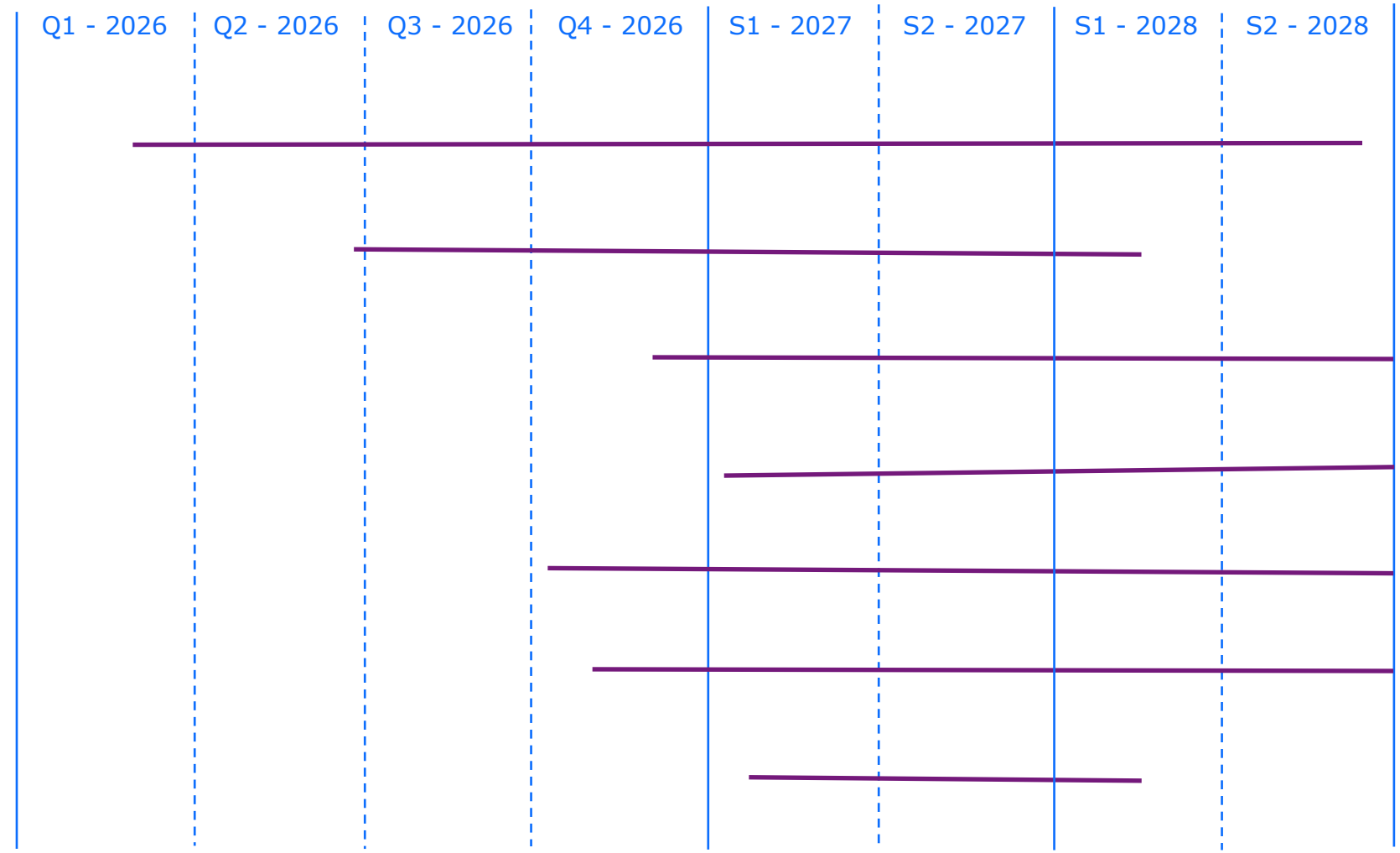
2026 – 2028 Roadmap

DELIVERY STREAMS:

1. Centr. procedure and committees



Timeframe Industry priority

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Key pillars for Stream 1

Two connected main areas of work

1 The centralised procedure

How medicines will be evaluated under the new framework



End-to-end procedural design

From validation through to opinion, timetables, IT systems



Roles and responsibilities

Committees, rapporteurs and the wider regulatory network; ensuring sound assessment and peer review



Interfaces and touchpoints

Interaction with applicants, streamlining questions and assessment reports

2 The expert ecosystem

How scientific expertise is organised around the procedure



Sourcing scientific expertise

Access to the right expertise across the network, retention of expertise currently in CAT, COMP & PDCO



Structures for expert input

How expert groups contribute to scientific advice, evaluation and to guidance



Developing and sustaining expertise

Training, knowledge continuity and safeguarding independence

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Scope and objectives of the Centralised procedure Workpackage

1. Redesign of initial MAA under centralised procedure
2. From pre-submission through to CHMP opinion at Day 180
3. Goal: faster, more efficient assessment, focusing resources where it matters most
4. Maintain high quality of assessment with necessary checks and balances
5. Out of scope: lifecycle management incl. pharmacovigilance, active substance master file, development support streams

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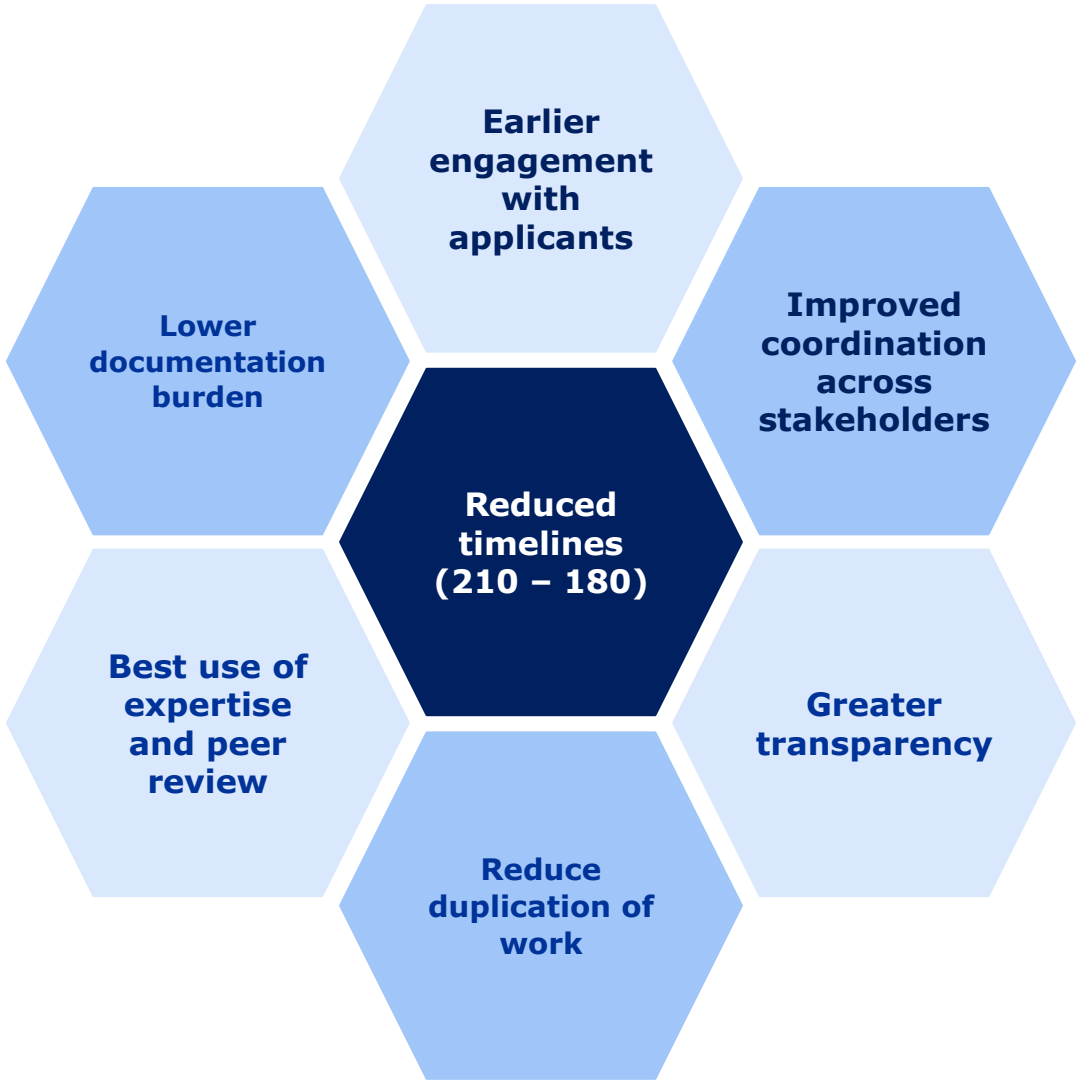
Key design themes



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