EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PRI*ority* ***ME****dicines (****PRIME****)*

Support to development of priority medicines for unmet medical needs.

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Drivers for change

Reinforcing ***PREDICTABILITY*** *of the EU regulatory system.*

Patients

- *Areas of unmet need*
- *Focus on accelerating regulatory approval of new medicines*

Research & Development

- *Scientific and regulatory challenges*
- *Importance of early dialogue with regulators and scientific advice*
- *Difficulty in access to capital investment for academia & SMEs*

EU Network Perspective

- *Optimising support to innovation*
- *Complementary approach to national initiatives*
- *Supporting global development*

Vision of the EU Medicines Regulatory Network

EU Medicines Agencies Network Strategy to 2020

- *Ensure timely access to new beneficial and safe medicines for patients*
  - *Better understanding of existing tools (conditional MA, accelerated assessment…) and prospective planning of their use*
- *Support for patient focused innovation and contribute to a vibrant life science sector in Europe*
  - *Facilitate innovation to ensure patient access to new medicines*
  - *Greater collaboration across network to support innovation*
  - *Consider further regulatory incentives for innovation, particularly in certain areas of public health need*

PRIME - Legal base

Regulation (EC) No 726/2004

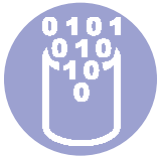
According to Recital 33 and Article 14(9) of Regulation (EC) No 726/2004, the applicant may request an accelerated assessment procedure in order to meet, in particular the legitimate expectations of patients and to take account of the increasingly rapid progress of science and therapies, for medicinal products of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation.

Goal & Scope

To foster the development of ***medicines with high public health potential.***

Reinforce scientific and regulatory advice

- *Foster and facilitate early interaction*
- *Raise awareness of requirements earlier in development*



Optimise development for robust data generation

- *Focus efficient development*
- *Promote robust data generation*

Enable accelerated assessment

- *Promote generation of high quality data*
- *Facilitated by knowledge gained throughout development*

Building on existing framework;

Eligibility according to existing Accelerated Assessment criteria.

Reinforcing the concept of Accelerated Assessment

Current approach

- *Confirmation of evaluation of a centralised MAA to an accelerated timetable has only been possible just prior to filing.*

With PRIME

- *Identifying products fulfilling the criteria for accelerated review earlier*
- *Enhancing the regulatory support on offer to these products through advice at key milestones in development*

Eligibility to PRIME scheme

For products under development which are yet to be placed on the EU market.

- *Entry to scheme at two different stages in development:*
  - *at the earlier stage of **proof of principle** (prior to phase II/exploratory clinical studies) focusing on SMEs.*
  - *at **proof of concept** (prior to phase III/confirmatory clinical studies).*
- *Must be based on adequate data to justify a potential major public health interest.*

Applicants not eligible to PRIME can still request accelerated assessment.
Guideline of the procedure for Accelerated Assessment pursuant to Article 14(9) of Regulation (EC) No 726/2004.

Enriched support through PRIME scheme

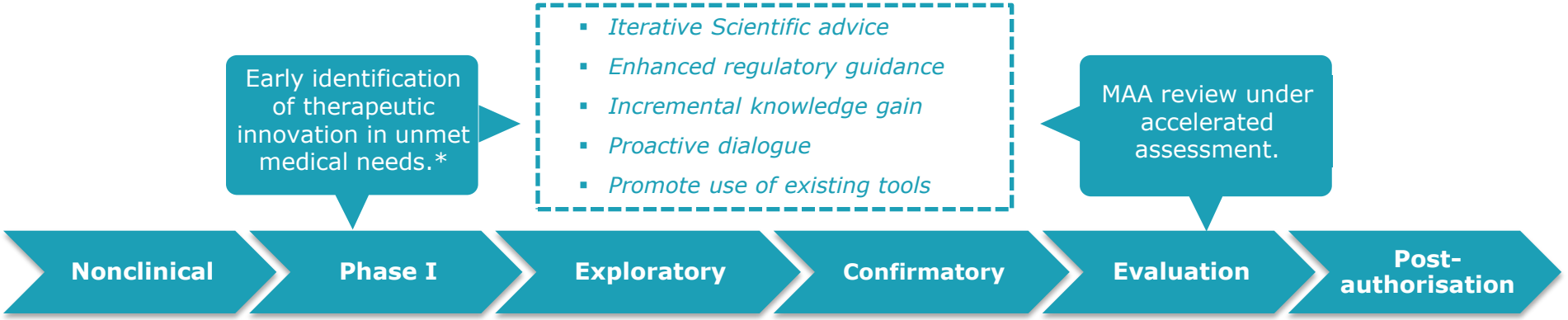
- *Tailored to the stage of development and provided up to submission of MAA;*
- *CHMP Rapporteur appointment for products at proof of concept stage;*
- *Kick-off meeting with the Rapporteur and experts from relevant committees to discuss development options and regulatory strategy;*
- *Iterative scientific advice at major development milestones;*
- *Fee incentives for SMEs throughout the development.*

Benefits of the PRIME scheme

Early access tool, supporting patient access to innovative medicines.

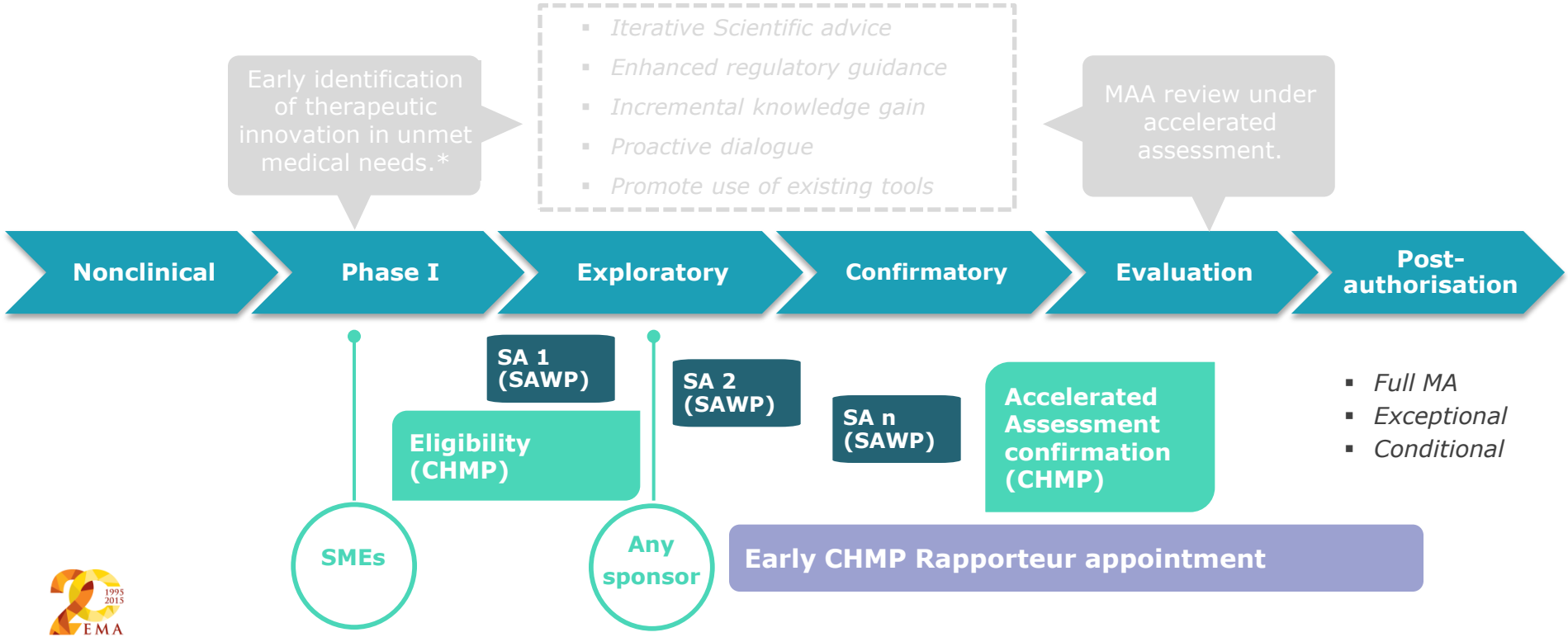
- *Early confirmation of potential for accelerated assessment;*
- *Written confirmation of PRIME eligibility;*
- *Timely CHMP Rapporteur appointment;*
- *Scientific advice at key development milestones/decision points;*
- *Early, proactive, continuous and strengthened regulatory support;*
- *Promote awareness and better use of existing development and authorisation tools;*
- *EMA dedicated entry point;*
- *Complementarity and collaboration with National innovation schemes;*
- *Fee incentives for SMEs on Scientific Advice requests.*

Supporting patient access to innovative medicines



* Based on existing Accelerated assessment criteria

Supporting patient access to innovative medicines



Summary

- *Timely approval and patient access to important new medicines;*
- *Builds on accelerated assessment criteria;*
- *Promote better use of existing tools;*
- *Optimise current regulatory tools by increasing efficiency of development and quality of data;*
- *Opportunity for collaboration with partners across the EU network.*

Thank you for your attention

Further information

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Early access tools: Overview

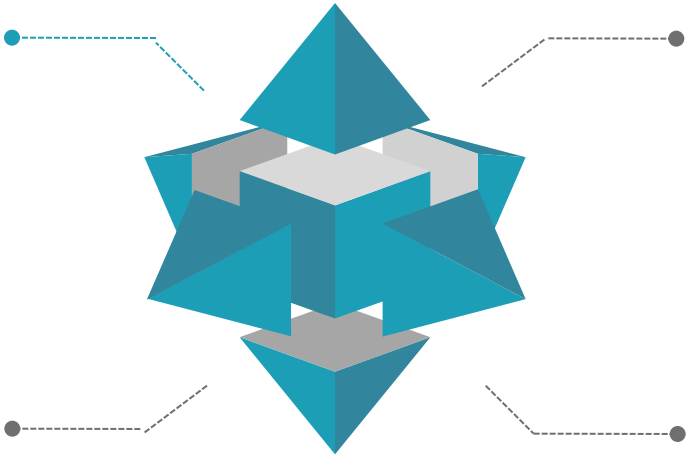
PRIME

Major public health interest, unmet medical need.

Dedicated and reinforced support.

Enable accelerated assessment.

Better use of existing regulatory & procedural tools.



Adaptive Pathways

Scientific concept of development and data generation.

Iterative development with use of real-life data.

Engagement with other healthcare-decision makers.

Accelerated Assessment

Major public health interest, unmet medical need.

Reduce assessment time to 150 days.

Conditional MA

Unmet medical need, seriously debilitating or life-threatening disease, a rare disease or use in emergency situations.

Early approval of a medicine on the basis of less complete clinical data.

Early access tools: Ongoing activities

PRIME

New scheme.

Relevant Q&A, scientific guidance and templates under development for launch

Adaptive Pathways

Pilot ongoing.

ADAPT-SMART

Accelerated Assessment

Ongoing revision of the guideline.

More detailed guidance on justification.

Optimisation of the assessment timetable.

Emphasis on the importance of early dialogue.

Conditional MA

Ongoing revision of the guideline.

Emphasis on importance of prospective planning early dialogue.