EMA, PRIME, Adaptive pathways

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EMA’s efforts to enable timely access: PRIME, Adaptive Pathways

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Hans-Georg Eichler
EMA’s commitment to promote timely access

• **Front end**: PRIME; pilot programs to elicit patient preferences; early dialogues with HTA bodies (ample experience with early parallel scientific advice)

• **Back end**: data infrastructure/analysis development (registries project), ‘late’ interaction with HTA bodies (starting)

• **Product lifespan**: Adaptive Pathways pilots, IMI ADAPT SMART project

Requirement for multi-stakeholder engagement is high in all initiatives (no ‘regulator-only’ initiatives)
Focus on PRIME and Adaptive Pathways

Two complementary strands of activity:

• **PRIME**: focus on earlier, efficient interactions; resource prioritisation to address unmet medical need; fast-moving procedures

• **Adaptive Pathways**: focus on lifespan approach to drug development, authorisation, reimbursement and use of product
Added value? PRIME

• Reinforce scientific and regulatory advice → increase likelihood of robust and useful data generation

• Enable accelerated assessment → accelerated availability

• Dedicating extra resources to unmet medical need (→ steer R&D towards unmet need?)

• Provide platform for patient and HTA input

• Enhance transparency (active substances, broad characteristics,...)
Added value? Adaptive Pathways

- Address the ‘access versus evidence’ conundrum
- Reduce (unavoidable) uncertainties fast
- Enable development of non-conventional (‘difficult’) products
- Help enlarge the tool box for evidence generation
- Help address sustainability of access (?)
- Leverage multi-stakeholder collaboration
Thank you for your attention

Further information

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