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SCIENCE MEDICINES HEALTH

# Enhancement of the PRIME scheme

First reflections

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# The ambitions of the PRIME scheme

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**PRIME intends to provide enhanced support to transformative products during their development.**

- The concept goes beyond a "label", a series of Scientific Advices, and later Accelerated Assessment.
- The PRIME scheme is both a regulatory and a scientific support tool, acknowledging that evidence generation is a continuum.

**In line with the RSS goals, we should review the experience:**

**Is the ambition for PRIME fulfilled? How can we enhance the scheme?**

# 5-year PRIME review

**Review procedural and scientific elements of PRIME.**

Support might need to be **tailored** differently:

- Depending on the time-window of entry in the scheme
- Depending on the type of product (e.g. ATMP)
- Depending on the type of developer (Big Pharma, SME, Academia)
- Using resources efficiently by focusing on specific development hurdles

As it is a non-legally mandated procedure, there is scope for **flexibility** depending on the research question and the need to support true potential to address an unmet need. **Consistency and transparency** in applying the flexibility are also important.

# 5-yr review - possible analysis parameters

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## Clarification of the entry criteria

e.g. unmet medical need, criteria *vs.* Breakthrough/Sakigake

## Identification of objective criteria to measure:

- Trends PRIME accepted/rejected and MA outcomes
- Follow-up on kick-off plan / integrated development support
- Scientific advices *vs.* issues raised at MAA LOI
- Accelerated assessment (and reasons to revert to normal TT)
- Clock stop duration
- Acceleration of access for patients (incl. down-stream decision making)
- Trends for niche products/ATMP/SME/Orphan

# After the 5-year PRIME review

- Publication of  findings of the analysis
- Implementation of learnings to enhance the scheme
- Procedural review to focus assistance and impact at significant development points