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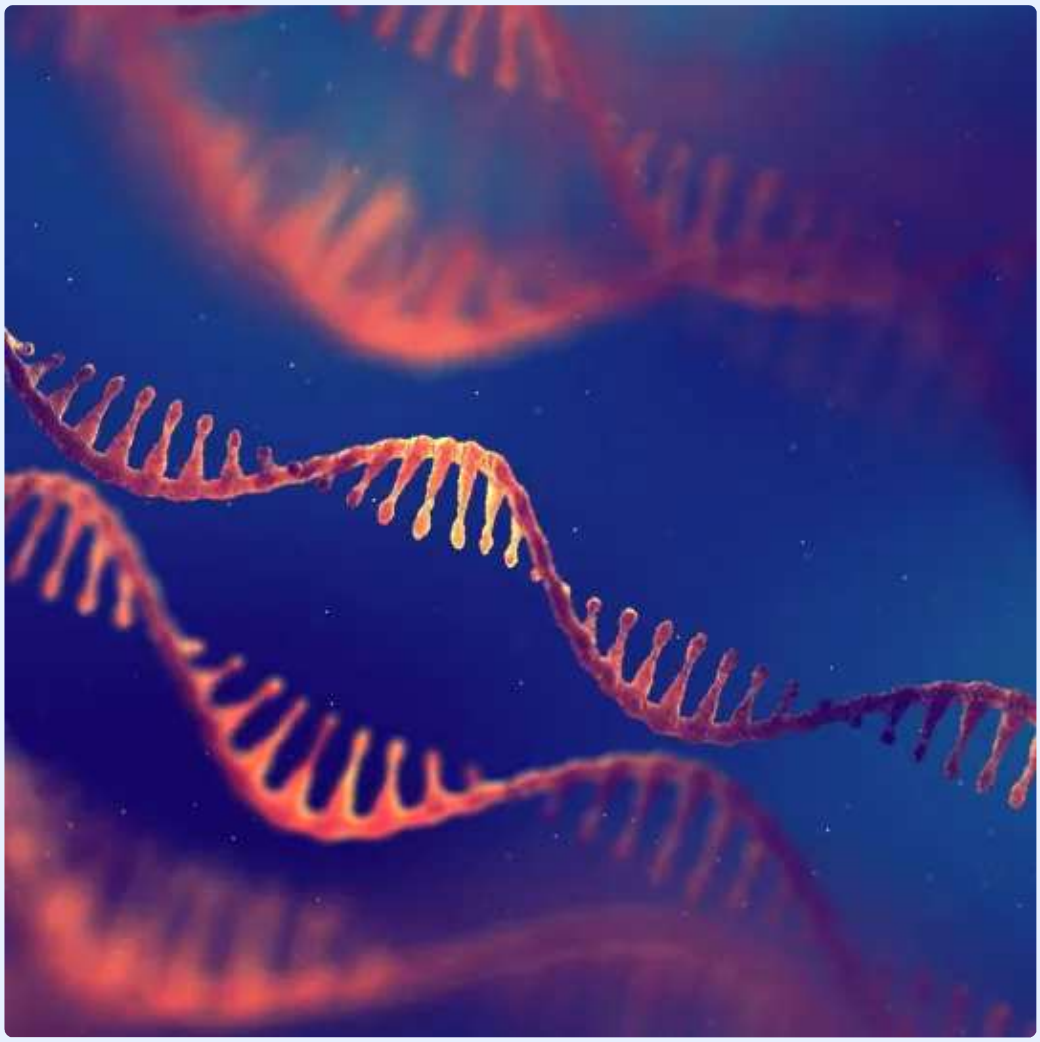

New PRIME tools to accelerate development of medicines in the EU

18 March 2026

Three new PRIME features streamline scientific dialogue and help developers to stay on track

News Human PRIME

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EMA launched three major new features of PRIME, the Agency's scheme to enhance support for the development of medicines targeting an unmet medical need. After the completion of a two-year pilot, the Agency has integrated these additional tools to support continued scientific dialogue, giving developers faster answers and better supporting preparation for the submission of a marketing authorisation application.

The first tool, the regulatory roadmap and product development tracker, helps chart a medicine's progress and flag potential issues early, making it easier for developers and EMA to stay aligned throughout development. The second tool, the expedited scientific advice, is a fast-track route for developers to receive timely and focused regulatory input on focused questions that are critical for the development process. The third tool, the submission readiness meeting, is a dedicated check-in, about a year before submission, where EMA and developers discuss the progress of the programme against the plan and identify any remaining evidence gaps to ensure that a comprehensive data package is available for a thorough evaluation by the Committee for Medicines for Human Use (CHMP).

> *"Over the ten years since its launch, PRIME has continued to evolve to keep pace with scientific innovation and accelerate the development and assessment of innovative medicines. The new features we are now rolling out following the pilot enhance our ability to identify and address critical issues early in the development process through continuous scientific dialogue with the developer."*
>
> — Head of Scientific Evidence Generation at EMA, Michael Berntgen

The results of the pilot indicate that the new PRIME features promote enhanced regulatory agility and better support to

developers. They also come at a crucial time as EMA prepares for operation under the revised EU pharmaceutical legislation. In fact, when the new EU legislative framework comes into force, it will formally codify PRIME within its provisions.

EMA will integrate all three features as permanent PRIME tools. Planned refinements include updated guidance based on the pilot experience, more agile expedited scientific advice, more flexible meeting scheduling, and exploration of future digital solutions for real-time product development tracking. At the same time, EMA is exploring the new concept of an EMA Product Development Coordination as primary point of contact for the developer to facilitate better support through the medicine's development.

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Progressing EMA's PRIority Medicines scheme through new pilot features

English (EN) (1.48 MB - PDF)
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