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EMA Bolsters PRIME Scheme With Improvements

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The European Medicines Agency will hold submission readiness meetings with the sponsors of products in the priority medicines scheme around a year ahead of them submitting their marketing authorization applications for regulatory review.

The European Medicines Agency is implementing improvements to its PRIME (priority medicines) scheme – introducing a regulatory roadmap and product development tracker, providing expedited scientific advice, and holding submission readiness meetings to help avoid the submission of premature marketing applications.

PRIME was launched in 2016 to help speed up the development and regulatory review of medicines for unmet medical needs so that these treatments can reach patients faster. The implementation of the new features follows the agency's report on its first five years' experience with the scheme, which was published last year and highlighted some opportunities for further strengthening the scheme. (Also see "*Requests For EMA PRIME Designation Fall But Improvements Are On The Way*" - Pink Sheet, 26 Jan, 2023.)

The improvements aim to "facilitate and accelerate the generation of robust and relevant evidence for the evaluation of a marketing authorisation application, which will give patients earlier access to transformative treatments that can make a real difference," the EMA said on 4 April.

Companies in the PRIME scheme are offered early and enhanced support from the EMA to help optimize their development plans. The aim is for them to generate data to support an eventual marketing authorization application that is strong enough to undergo an accelerated assessment.

A roadmap for each PRIME-designated product is being established alongside a product development tracker to optimize the early scientific and regulatory support provided to sponsors

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with promising medicines in the scheme.

"Both tools will facilitate the continuous dialogue between regulators and developers as the progress of the development is continuously monitored and as critical aspects for further discussion can be identified throughout the development process," the EMA said. The roadmap and tracker are replacing the previous "PRIME action plan to marketing authorisation," the agency noted.

Expedited scientific advice can now be provided for PRIME-designated products in cases where there are issues with a specific development program that has already received comprehensive initial advice, the EMA said. "This agile setting for scientific advice will allow to address queries from PRIME applicants in a shorter timeframe." The expedited scientific advice feature is being tested in a 12-month pilot that will run until March 2024.

To qualify for expedited scientific advice, a newly updated *guidance* on PRIME says that all of the following criteria must be met:

- The initial scientific advice procedure has already been sought on the overall development (in the PRIME indication), ie, the request is for follow-up advice.
- The advice concerns issues with a specific, well-defined scope (not limited to a single quality/non-clinical/clinical discipline).
- The advice is justifiably required more urgently than the standard scientific advice timelines allow.

As for the submission readiness meetings, a new *guidance document* says that these will be held with the drug developer approximately 9-12 months ahead of them submitting their marketing authorization application for review by the agency.

The scope of the submission readiness meeting is to discuss the status of the product's development including the implementation of previous regulatory advice and the resulting data package intended to support the marketing authorization application. Prospective applicants would also be expected to present mature plans for post-marketing evidence generation, as applicable, the EMA said.

According to the EMA's five-year report on PRIME, the submission readiness meeting "would also assess the realistic chance of obtaining and maintaining an accelerated assessment timetable by avoiding the submission of premature applications."