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EMA's New PRIME Scheme Gets 18 Applications In First Month

by Neena Brizmohun

Eleven applications to the European priority review program came from smaller companies.

The European Medicines Agency says it has received 18 applications for entry in its much-talked about PRIME (priority medicines) scheme since launching the initiative only one month ago[1].

The announcement, which the EMA made via Twitter* on April 7, follows the agency's prediction that it would be "flooded with applications" for the scheme, which aims to bring promising innovative medicines to patients faster by optimizing and supporting medicine development (Also see "*PRIME Time: Smaller Companies In Focus As EMA Launches Priority Medicines Scheme*" - Pink Sheet, 7 Mar, 2016.).

"The response shows that PRIME meets a need," a spokesperson said later.

Moreover, 11 of the applications were from small and medium-sized enterprises, indicating that the scheme is being "taken up by an important target audience," the spokesperson added.

Applications were received for a wide range of therapeutic indications, including Alzheimer's disease and antimicrobial resistance.

It is not yet clear how many of the applications will go on to meet PRIME's tough eligibility criteria and, as such, benefit from accelerated review under the scheme as well as early and enhanced regulatory and scientific advice from the EMA. The agency is planning to assess the applications "over the next few weeks." It has previously said it was prepared to turn down "a lot of applications" that do not meet the scheme's requirements (Also see "*EMA Advice On PRIME: 'If You Don't Meet The Criteria, Don't Apply'*" - Pink Sheet, 23 Nov, 2015.).

PRIME is open to companies of all sizes. However, the agency has strengthened the scheme's

focus on the needs of smaller firms – much to the annoyance of larger companies – by allowing them to apply for PRIME at an earlier stage of development. Giving smaller companies and applicants from the academic sector access to support under PRIME at an earlier stage of development "will help them progress through to the proof-of-concept stage, which is often a difficult step for these smaller actors with limited regulatory experience and knowledge," the EMA said. Big pharma, on the other hand, believes that any company regardless of size should be able to apply to have a product included in the PRIME scheme at the early phase of development.

More details on how PRIME is faring and what types of applicants are being accepted on the scheme are expected to be released on a regular basis soon. The EMA said that "statistics on PRIME, including numbers of applications received, accepted and rejected and the breakdown per type of applicant," would be published following the May meeting of its scientific committee, the CHMP, "and then on a monthly basis following each CHMP meeting."

PRIME, which launched March 7, is designed to identify at an earlier stage of development those substances that have the potential to address an unmet medical need – that is, that offer a major therapeutic advantage over existing treatments, or benefit patients with no current treatment options.

The scheme has been likened to the popular breakthrough therapy designation scheme in the US, though the US scheme does not have an early entry option.

The EMA previously said that it expected to be "flooded with applications" for PRIME largely because it anticipates that many of those companies that already have a designation under the breakthrough therapy designation program will also want an EU designation under PRIME (Also see "*EMA 'Mobilizing Correct Expertise' To Deliver On PRIME But Not Added Staff*" - Pink Sheet, 3 Dec, 2015.). There have been more than one hundred breakthrough designations since the US program was launched in 2012.

**[Editor's note: This article first appeared in Scrip Regulatory Affairs; "The Pink Sheet" DAILY brings selected complementary coverage from sister publications to our readers. EMA's April 7 Twitter post said that 19 applications had been received for the PRIME scheme. EMA subsequently confirmed to Scrip Regulatory Affairs that the number of applications received so far was 18 and that the extra one was a duplication.]*