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The European Medicines Agency has received 20 applications so far as part of its adaptive licensing pilot project. Following an in-depth review of nine of these applications, the Agency has selected the first two medicines to be included in the pilot. A further four applications are potential candidates for the pilot and may be considered at a later stage. The other three applications were not considered suitable for the pilot and the remaining eleven are currently being evaluated.

This is the first wave of medicine development programmes to be considered for this project and the Agency continues to accept applications from interested companies.

The adaptive licensing approach, sometimes called staggered approval or progressive licensing, is part of the Agency's efforts to improve timely access for patients to new medicines that address serious conditions with unmet medical needs. It is a prospectively planned process, starting with the early authorisation of a medicine in a restricted patient population, followed by iterative phases of evidence gathering and adaptations of the marketing authorisation to expand access to the medicine for increasingly broader patient populations. The approach seeks to maximize the positive impact of new medicines on public health by balancing timely access for patients, with the need to provide adequate evolving information on their benefits and risks.

The Agency launched its adaptive licensing pilot project in March 2014 to explore with real medicines development programmes how adaptive licensing can be implemented.

The Agency will now contact the sponsors of the selected applications to explore how adaptive licensing can be developed for these specific medicines. The discussions will involve a range of stakeholders, including health-technology-assessment bodies and patients' representatives, and will take place in a 'safe harbour' environment to allow free and confidential exploration of the strengths and weaknesses of all options for development, assessment, licensing, reimbursement, monitoring and utilisation pathways without commitment on either side. After this phase, these candidates may progress to more formal interactions, such as a regulatory scientific advice procedure and ultimately a marketing authorisation application.

"We are very pleased to have received this number of applications in a short period of time, explains Hans-Georg Eichler, the Agency's Senior Medical Officer. "The projects submitted came from very early responders, and we know that more proposals are on their way."

The Agency continues to welcome applications from interested companies as it intends to include as many programmes as necessary in the pilot to gather sufficient knowledge and experience, address a range of technical and scientific questions and further refine how the adaptive licensing pathway should be designed for different types of products and indications.

The general criteria that were used by the Agency to select promising candidates for the pilot project included:

- unmet medical need of patients likely to be addressed by the medicine;
- early stage of clinical development to enable actionable input from relevant stakeholders;
- positive prospects that regulatory requirements for expansion from a restricted indication to broader populations can be fulfilled (in terms of population/use);
- potential for use of real world data to substitute/supplement data from randomised clinical trials in fulfilling requirements for the expansion.