EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

**Press release**

# European Medicines Agency launches adaptive licensing pilot project

## Improving timely access for patients to new medicines: pilot explores adaptive licensing approach with real medicines in development

The European Medicines Agency (EMA) is inviting companies to participate in its adaptive licensing pilot project. Companies who are interested in participating in the pilot are requested to submit ongoing medicine development programmes for consideration as prospective pilot cases.

A framework to guide discussions of individual pilot studies has been published.

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. 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 to broader patient populations.

As a holistic approach, adaptive licensing requires the involvement of all stakeholders who have a role in determining patient access, including the EMA, the industry, health technology assessment (HTA) bodies, organisations issuing clinical treatment guidelines and patient organisations. All discussions will take place in a 'safe harbour' environment to allow free exploration of the strengths and weaknesses of all options for development, assessment, licensing, reimbursement, monitoring, and utilisation pathways in a confidential manner and without commitment from either side.

"With the adaptive licensing pilot project we intend to explore with real medicines in development a progressive licensing approach that would allow timely access for patients to new medicines that address serious conditions with unmet medical needs," explains Hans-Georg Eichler, the Agency's Senior Medical Officer. "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."

Adaptive licensing builds on existing regulatory processes and intends to extend the use of elements that are already in place, including scientific advice, centralised compassionate use, the conditional marketing authorisation mechanism (for medicines addressing life-threatening conditions), patients'

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registries and pharmacovigilance tools that allow collection of real-life data and development of risk management plans.

The Agency intends to include as many programmes as necessary in this pilot phase in order 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.

Ongoing medicine development programmes submitted by companies should be experimental medicines in the early stage of clinical development, i.e., prior to the initiation of confirmatory studies, to enable actionable input from relevant stakeholders.

As the project progresses, the European Commission will examine the legal and policy aspects related to adaptive licensing in collaboration with the EU Member States and by consultation with relevant stakeholders, as necessary.

## Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The framework document to guide discussions of individual pilot studies and application form are available on the Agency's website at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000571.jsp&mid=WC0b01ac0580665b62
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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