famhp
federal agency for medicines and health products

Repurposing of authorised medicines: European pilot project to support non-profit organisations and academic institutions

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The FAMHP takes part in the European pilot project, launched by the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA), to support the repurposing of medicines as follow up to the European Commission's Expert Group on Safe and Timely Access to Medicines for Patients (STAMP) discussions on a proposal for a medicines repurposing framework.

The aim of this initiative is to support non-profit organisations and academic institutions to gather or generate sufficient evidence on the use of an authorised medicine in a new indication with the view to have this new use formally authorised by a regulatory authority. This is a way of making new treatment options available to patients.

As part of the pilot project, the EMA and a number of national medicines authorities, including the FAMHP, will provide regulatory support (scientific-technical advice, STA), primarily through scientific advice, to help these stakeholders generate a data package robust enough to support a future marketing authorisation application. Non-profit organisations and academic institutions can submit their application free of choice either to EMA or a national medicines authority which will select relevant applications at pre-entry phase which are then allowed to proceed to the scientific advice phase of the pilot.

Selection criteria
Candidate medicines for the pilot should fulfil the following criteria.

- Contain a well-established active substance.
- Be an authorised medicine (containing the concerned active substance) out of data exclusivity and market protection periods and out of basic patent/supplementary protection certificate (SPC) protection.
- Target an indication in a condition distinct from the currently authorised indication(s).
- Target an indication in an area where important public health benefits are likely to be achieved. Conditions for which no or few medicines are currently authorised, or which are associated with high morbidity and/or mortality despite available medicines, will be the focus of the pilot.

Scientific advice fee reductions or waivers
For repurposing applications submitted to the FAMHP and which are selected at pre-entry phase to enter the pilot, non-profit organisations and academia, can normally benefit from a 75 % fee reduction for a national STA request. Further information can be found in the detailed guidance on the FAHMP website.

For repurposing applications submitted to EMA, eligible academic institutions developing orphan medicines will automatically benefit from a fee waiver. Additional fee waivers will be granted to a subset of selected applications taking into account the extent of the expected public health benefits and the strength of the evidence to substantiate the promise held by the proposal. More info can be found on the EMA website.

Scope
While marketing authorisation holders may develop medicines for uses in other indications, sometimes they lack the incentives or the commercial interest to pursue the necessary research and development and complete the regulatory process necessary for the authorisation of a new indication for existing medicines which are no longer protected by a patent or data exclusivity. This could be a wasted opportunity for public health. At the same time, academic institutions and/or patient organisations may be interested in carrying out this development for the benefit of public health. However, they may not have the necessary regulatory experience and also have no intention of becoming a marketing authorisation holder themselves.

The pilot is open to non-profit stakeholders and academic institutions or academics who have a particular interest in repurposing an authorised medicine for a new indication in an area of public health interest, have a scientific rationale for their repurposing programme and would like to seek scientific advice with a regulatory authority.

Repurposing of medicines for COVID-19 falls outside the scope of this pilot project since the development and authorisation of treatments for COVID-19 is coordinated by the COVID-19 EMA pandemic Task Force (COVID-ETF) and should follow the steps outlined in this guidance document. Repurposing programmes for medicines intended for COVID-19 will therefore not be considered for this pilot.

Applications
All practical information on the pilot project and how to apply for a repurposing pilot project for authorised medicines is available in a questions and answers document. The list of voluntary national

medicines authorities participating in the project and their contact information can be found in annex I of the questions and answers document.

A first wave of applications was closed on 28 February 2022. However, at European level an extension of the submission period has been approved. Subsequently, the FAMHP will extend the deadline for submissions **until 15 May 2022**. Once the period for applications has been closed, the validity of the applications will be assessed before the end of June 2022.

Sponsors who want to request FAMHP scientific advice, should submit the repurposing submission form to innovationoffice@fagg-afmps.be **by 15 May 2022**.

The pilot project will run until the completion of scientific advice(s) for the selected repurposing candidate projects and ideally until the filing of an application by a pharmaceutical company for the new indication.

A report will be published after the pilot project.

More information

- FAMHP – Scientific-technical advice
- European Commission – Commission Expert Group on Safe and Timely Access to Medicines for Patients - STAMP
- EMA - Scientific advice on medicine repurposing

Contact

innovationoffice@fagg-afmps.be