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Considerations for research / project teams seeking
competent authority participation in externally funded
regulatory science and public health research projects
related to medicinal products

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1. Introduction

The [European Medicines Agencies Network Strategy to 2025](#) emphasises the desire and willingness of competent authorities to support and facilitate research related to the development and regulation of medicinal products. One of its key goals is to enable and leverage research and innovation in regulatory science. The strategy also notes the need to facilitate and support research in areas of significant public health interest such as antimicrobial resistance.

These strategic aims are also reflected in the [EMA Regulatory Science to 2025](#) strategy which commits to 'Develop network-led partnerships with academic / research centres to undertake research in strategic areas of regulatory science' and to 'Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions'. One of the key actions in this regard has been the publication of a list of [Regulatory Science Research Needs](#). This list captures existing gaps in regulatory science that need to be addressed to improve the development and evaluation of medicines, with the goal of encouraging researchers and funding organisations to address these needs.

The EU-Innovation Network (EU-IN) is comprised of representatives from innovation offices in national competent authorities and the EMA's Innovation Task Force (ITF). As part of its [Mandate](#), the EU-IN is tasked with promoting the involvement and collaboration of EMA/HMA in Innovative Health Initiative (formerly Innovative Medicines Initiative) projects and other EU level funding programs such as Horizon Europe. The EU-IN also seeks to foster and support engagement between competent authorities and researchers at academic research and development institutes in relation to regulatory-relevant research or development projects.

Some competent authorities regularly participate as partners in externally funded research projects with their own experimental research and development subprojects. In addition, competent authorities receive increasing number of requests to participate by providing regulatory expertise to externally funded research projects being performed on a national, European or wider international basis. The timing of such requests and the nature of the requested input may vary. There are a number of factors which competent authorities may wish to take into account when considering if their participation in or support for a research project is appropriate and feasible and if so when determining the nature and extent of their involvement.

The purpose of this paper is to provide guidance to researchers and project teams in relation to the circumstances in which competent authorities would consider involvement in externally funded research projects related to medicinal products and the information that should be provided to the competent authority when requesting their support or involvement in a research project.

2. Scope

This paper provides guidance to research / project teams on considerations prior to requesting the involvement of competent authorities in research projects related to medicinal products. It should be viewed as guidance which is not binding on competent authorities and does not replace or supersede any existing position / guidance that an individual competent authority may have in place in relation to such requests. Competent Authorities may wish to seek additional information or consider additional factors when considering such requests and may wish to discuss within relevant European and international fora to ensure the most efficient and effective collaboration.

Projects that relate to the development of a specific medicinal product or other regulated item should be viewed as outside the scope of this guidance. Regulatory guidance related to the development of individual medicinal products is available via several well-established mechanisms such as guidance available through innovation offices and scientific advice.

3. Considerations in advance of making a request

3.1. Suitability of the request

Prior to making any request for a competent authority to support or become involved in an externally funded research project, the suitability of the request should be considered. Requests for the involvement of competent authorities in research projects may be made with a view to obtaining regulatory advice as the project proceeds, e.g. via involvement in an advisory board. If the request relates to the provision of regulatory advice, the research / project team should consider whether the input that is being sought from the competent authority could be obtained via one of the established mechanisms for providing advice on matters related to medicines research and development. There are a number of such mechanisms at both national and European level including national innovation offices, EMA's SME office and Innovation Task Force, scientific advice, qualification of new methodologies and opportunities for interaction in relation to specific types of products, e.g. ATMPs, orphan medicinal products.

Alternatively requests for competent authority involvement may envisage a more active role in the project, e.g. if the project involves regulatory-science related research which may lend itself to the direct involvement of a competent authority. In such cases it would be particularly important to have early engagement with a competent authority, to discuss the appropriateness and feasibility of their involvement and to facilitate a more detailed discussion in relation to the project proposal and the role of the competent authority within the project (see also section 3.2 below).

Competent authorities will not be in a position to participate in research projects that are for commercial purposes. In particular, researchers should note that it will not be possible for competent authorities to participate in research projects which aim to develop a specific medicinal product, involve the submission of a clinical trial application to the competent authority or that will only benefit a limited number of companies. In cases where participation of a competent authority will not be possible, consideration should be given to using one of the existing mechanisms for obtaining advice related to the development of a medicinal product or associated technology, where there are well-established mechanisms in place to address any potential conflicts of interests and ensure the competent authorities impartiality during any subsequent regulatory reviews.

Projects which involve research and activities that are non-competitive in nature and whose outputs will not affect the impartiality of regulatory decision-making will be less likely to give rise to concerns to potential conflicts of interest preventing competent authority involvement in the project.

3.2. Timing of the Request

There is an increasing emphasis from funding bodies on the need to address all applicable considerations, including regulatory considerations, when planning research projects in order to facilitate the translation of research into clinical practice. Therefore, it is recognised that research / project teams may consider it desirable to obtain regulatory input or support when submitting applications for funding.

In the event that the research team believes that it would be desirable to have competent authority involvement in or support for a project, the optimal timing for such a request should be considered. Where it is envisaged that a competent authority could have direct involvement in a proposed project (e.g. for regulatory-science related research projects), early engagement with the competent authority is strongly advised.

The ability and willingness of a competent authority to provide a letter of support for a grant application or commit to participate in a research project during the competitive stage of a grant application will depend on a number of factors including their organisational policy, the nature of the proposed research project and funding call, the stage of the grant application process and any competent authority involvement in the selection process. Some competent authorities may not be in a position to provide a letter of support or commit to contributing to projects during the competitive stage of a grant application, whereas in other cases competent authority may be willing to engage at an earlier stage.

The research / project team should check the competent authority's website for information in relation to the optimal timing for the submission of requests for involvement in research projects and if necessary, this can also be clarified via the competent authority's customer service function, innovation office or any other dedicated contact point provided by the competent authority.

4. Information to be provided in the request

When submitting a request to a competent authority to consider involvement in a research project, the research / project team should provide a reference to the public call text and submit the draft project proposal. Ideally, the research / project team should ensure that those documents include clear and concise information in relation to each of the following points (if needed additional information can be provided in the cover letter / email):

- **Summary of the research project**

A clear and concise description of the research project should be provided. This should clearly specify the aims and purpose of the project and should briefly outline how these fit with the European Medicines Agencies Network Strategy and with the strategy of the individual Competent Authority whose involvement is being sought. It should be confirmed that the project will comply with applicable legal and ethical obligations and follow relevant good practices.

- **Organisation of the project**

An overview of the composition of the research team / project consortium and their affiliations (e.g. name of academic institution, company to which they are affiliated) should be provided. The proposed organisational structure of the project (reflecting the envisaged competent authority involvement as well as other stakeholders) should be outlined and the envisaged tasks / role for the competent authority should be clearly defined. This should take into account the need to maintain the competent authority's independence and impartiality. For example, if other organisations (e.g. pharmaceutical companies) falling within the regulatory remit of the Competent Authority will also be involved in the project, their roles within the project and the envisaged interaction between the Competent Authority and those organisations within the project should be clearly described. Competent Authority involvement can only be considered where there are no significant conflicts of interest. This is also acknowledged in [recommendations](#) previously issued by the Innovative Medicines Initiative (IMI) scientific committee regarding involvement of regulators and regulatory science in public private partnerships.

- **Source(s) of funding for the project**

Information should be provided on the intended source(s) of funding for the project (including any resources provided by organisations such as pharmaceutical companies falling within the competent authority's regulatory remit. It should also be indicated whether that funding has been secured and if not information on the current status of the funding application should be provided.

- **Any previous interactions with competent authorities that are relevant to the project**

Details should be provided of any previous or ongoing interaction with other regulatory authorities in relation to the proposed project including the nature and timing of the interaction and any outcomes.

- **Rationale for requesting competent authority involvement**

The rationale for requesting competent authority involvement in the project should be outlined. As part of the reasoning, it should be explained why competent authority involvement in the project is preferred to the use of existing supports for innovators offered by either national competent authorities or the EMA (e.g. engagement with innovation offices / innovation task force, scientific advice and protocol assistance etc.).

- **Envisaged role for the competent authority and resources involved**

The envisaged role (e.g. membership of an advisory board or consortium partner) for the competent authority in the project should be outlined along with an indication of the anticipated resourcing and time commitments associated with that role. It should be indicated whether funding will be made available to cover the competent authority's costs associated with involvement in the project.

- **Planned outputs from the project**

A brief summary of the planned outputs and envisaged milestones from the project should be provided including assurance that the results of the project will be made publicly available and the envisaged means of doing this (e.g. publication in a relevant journal or via a suitable website).

The request should be submitted directly to the competent authority whose involvement is being sought in the project. For national competent authorities requests may be submitted to the respective innovation office and for EMA requests should be sent to the Research Science and Innovation Task Force team via email to regulatory.science@ema.europa.eu.

5. Review of the Request by the Competent Authority

On receipt of a request, the competent authority will give consideration to its involvement in the project based on a number of criteria including the following:

- Potential benefits for the quality, safety and efficacy or the development and regulation of medicinal products as well as public health benefits and / or advances in regulatory science associated with the project
- Relevance of the project to strategic priorities as outlined in the European Medicines Agencies Network Strategy and the strategy of the individual competent authority
- Envisaged role for the competent authority in the project

- Involvement of relevant stakeholders and opportunities for collaboration
- Anticipated resource implications (personnel and time) associated with involvement in the project and funding of costs and the availability of resources with the appropriate expertise within the envisaged timeframe of the project
- Independence and impartiality of the competent authority and risk of (actual or perceived) conflicts of interests
- Expected outputs from the project and planned communication of the outcomes with a view to facilitating advancements in public health and /or regulatory science
- Benefits of competent authority involvement in the project taking into account other available regulatory supports
- Quality of the study design (hypothesis and methodology)

Each competent authority may consider additional criteria based on their individual policy relating to involvement in externally funded research projects and may also request additional information prior to making a decision on the request.

6. Outcome of the Competent Authority Review

The competent authority will advise the applicant of the outcome of the review of the request for involvement in the project. In the event that the competent authority agrees to participate in the project, further discussions will then take place in relation to the role of the competent authority and the arrangements for involvement in the project including the consortium agreement and the grant agreement.

If the competent authority decides not to become involved in the project, the reasoning for this decision will be provided and the competent authority may suggest alternative mechanisms for obtaining regulatory support or guidance to facilitate the project.

It should be understood that competent authority involvement in an externally funded research project does not imply that the competent authority endorses and / or will be bound by the outcomes of the project during any subsequent regulatory decision making. This will need to be clearly reflected in any communication related to the project or its outcomes.

The competent authority may also wish to suggest that the project would be discussed with other competent authorities via an appropriate forum (e.g. the EU Innovation Network) with a view to considering the potential involvement of other competent authorities with available expertise related to the project or identifying the most appropriate mechanism to provide regulatory input into the project.