10 June 2024

Rev1

Advice on medicines for Human use in the EU medicines regulatory network

Mapped information on current voluntary procedures

With a view to clarifying the scope of current scientific and regulatory advice activities, ACT-EU Priority Action on consolidated advice has **mapped information** on current voluntary procedures available from EU regulators on Medicines for Human use and collated this information in the form of questions and answers. It should be noted that the scope of scientific advice options overlaps significantly with the type of product and applicant being important factors for selecting the most optimal option, e.g. products intended for a single or limited number of EU Member State(s), applicants operating nationally, including academic ones opting for national scientific advice.

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How can I get voluntary regulatory advice on my clinical trial application (CTA) from medicines regulators in Europe (Medicines for human use)?

Options and further information	Provider	Scope
Consolidated pre-Clinical Trial Application (pre-CTA) advice via CTCG. Contact point SNSA@fagg-afmps.be Guidance for applicants pre-CTA advice pilot	Member States national competent authorities (NCAs) coordinated via the Clinical Trial Coordination Group (CTCG)	Regulatory and technical questions prior to clinical trial application in the EU.

How can I get informal* regulatory and/or scientific advice on my product-specific development programme from medicines regulators in Europe (Medicines for human use)?

Options and further information	Provider	Scope
Nationally List of innovation office contacts	National innovation offices	Regulatory support to innovation by: Acting as an initial entry point for engagement with national competent authorities to encourage dialogue and the use of available regulatory supports from an early stage of development. While all developers may engage with national innovation offices, there is a particular emphasis on academic researchers and small and medium-sized enterprises (SMEs) Providing advice to developers on scientific, technical and regulatory aspects relating to innovative products or associated technologies

Options and further information	Provider	Scope
		falling within the remit of the national competent authority particularly in the early stages of development Sharing information in relation to the various regulatory supports that are available to innovators at both national and European level and how these can be accessed
Centralised support Innovation in medicines | European Medicines Agency (europa.eu)	Innovation Task Force (ITF)	Early dialogue with applicants, in particular micro, small and medium-sized enterprises (SMEs) and academia to proactively identify scientific, legal and regulatory issues of emerging therapies and technologies. Advice on eligibility to EMA procedures relating to research and development, with the Committee for Medicinal Products for Human Use (CHMP), the European Commission and National Competent Authorities (NCAs) as appropriate, in the case of uncertainties or borderline issues concerning medicinal products. For emerging therapies and technologies and borderline products for human for which there is no established EMA scientific, legal and regulatory experience.
Centralised support Support to SMEs | European Medicines Agency (europa.eu)	Small medium enterprise (SME) Office	Procedural and administrative assistance, support on a regulatory strategy of a medicinal product development and how to navigate the range of procedures and incentives available at EMA.

Options and further information	Provider	Scope
Centralised support Emergency Task Force (ETF) | European Medicines Agency (europa.eu)	Committee for Medicinal Products for Human Use (CHMP) on the basis of recommendations by the Emergency Task Force (ETF)	Provision of early guidance on a medicine development (when not yet suitable for scientific advice). For new or repurposed human medicines that are intended to treat, prevent or diagnose a disease causing a declared public health emergency. On a case-by-case basis, the ETF also provides advice on medicines targeting selected pathogens that can potentially cause a public health emergency.
Centralised support Paediatric medicines: Research and development | European Medicines Agency (europa.eu)	Paediatric Medicines Office	Procedural advice on application for a paediatric Investigation plan (PIP), deferral, waiver, or modification.

* Informal: process does not lead to an adopted regulatory opinion

How can I get voluntary scientific advice on my product-specific development from medicines regulators in Europe? (Medicines for human use)?

Options and further information	Provider	Scope
National scientific advice Heads of Medicines Agencies List of contacts for national scientific advice	Scientific advice/clinical trial office in the Member States.	Please contact local national competent authority in the member state.

Options and further information	Provider	Scope
Simultaneous National Scientific Advice (SNSA) Heads of Medicines Agencies: EU-Innovation Network (EU-IN) (hma.eu)	*Innovation office/clinical trial office/Scientific advice office in the Member States.*	*SNSA is intended to be used in situations where an applicant wishes to obtain national scientific advice from more than one NCA at the same time.* *In conjunction with ACT-EU, this phase of the SNSA pilot will have a specific focus on scientific advice to facilitate clinical trials within the EU.*
Centralised Scientific advice Scientific advice and protocol assistance | European Medicines Agency (europa.eu)	Committee for Medicinal Products for Human Use (CHMP) on the basis of recommendations by the Scientific Advice Working Party.	Product- and indication-specific prospective advice on any aspect of medicines development for a marketing authorisation, including details of paediatric developments (ideally following an agreed PIP) Protocol assistance (which is centralised scientific advice for orphan products) may include questions on demonstration of significant benefit (against other available therapies) as an orphan designation criterion. Centralised scientific advice excludes advice on a specific clinical trial application (CTA), eligibility to accelerated assessment, compassionate use, pre-assessment of data for a marketing authorisation application, products addressing public health emergencies.
Centralised Scientific advice for medicines targeting a (potential) public health emergency. Scientific advice and protocol assistance | European Medicines Agency (europa.eu)	Committee for Medicinal Products for Human Use (CHMP) on the basis of recommendations by the Emergency Task Force (ETF)	Product- and indication-specific prospective advice on any aspect of medicines development for a marketing authorisation, including details of paediatric developments, For medicines addressing declared and potential public health emergencies. Includes involvement of Clinical trial Advisory Group (CTCG), Clinical Trial Advisory Group (CTAG) and Member State (MS) representatives where the trial is expected to be conducted to align with national advice and facilitate CTA during emergencies.

Options and further information	Provider	Scope
		Support to clinical trial sponsors as per article 15(2)c of Reg 123/2022 to facilitate CT application and approval and the conduct of large multinational trials. This involves rapid scientific discussion and feedback on the clinical Trial protocol and involvement of CTCG/CTAG and MSs where the trial is expected to be conducted.
Centralised support PRIME scheme (PRIority MEdicines) PRIME: priority medicines | European Medicines Agency (europa.eu)	European Medicines Regulatory Network	Enhanced support for the development of medicines that target an unmet medical need and offer a major therapeutic advantage over existing treatments or benefit patients without treatment options.
SAWP CTCG scientific advice pilot Guidance for applicants Application via SAWP CHMP scientific advice	Consolidated advice from Member States National Competent Authorities (NCAs) coordinated by the Clinical Trial Coordination Group (CTCG), and from the Committee for Medicinal Products for Human Use (CHMP) on the basis of recommendations by the Scientific Advice Working Party (SAWP)	*Scientific* advice on scientific/methodological clinical trial topics that require SAWP/CHMP *and* CTCG feedback.

How can I discuss a new technology or methodology with regulators in Europe? (Medicines for human use)?

Options and further information	Provider	Scope
Nationally List of innovation office contacts	National innovation offices	Regulatory support to innovation by: Acting as an initial entry point for engagement with national competent authorities to encourage dialogue and the use of available regulatory supports from an early stage of development. While all developers may engage with national innovation offices, there is a particular emphasis on academic researchers and small and medium-sized enterprises (SMEs) Providing advice to developers on scientific, technical, and regulatory aspects relating to innovative products or associated technologies falling within the remit of the national competent authority particularly in the early stages of development Sharing information in relation to the various regulatory supports that are available to innovators at both national and European level and how these can be accessed

Options and further information	Provider	Scope
Centralised support Innovation in medicines | European Medicines Agency (europa.eu)	Innovation Task Force (ITF)	Early dialogue with applicants, in particular micro, small and medium-sized enterprises (SMEs) and academia to proactively identify scientific, legal and regulatory issues of emerging therapies and technologies; Advice on eligibility to EMA procedures relating to research and development, with the Committee for Medicinal Products for Human Use (CHMP), the European Commission and national competent authorities (NCAs) as appropriate, in case of uncertainties or borderline issues concerning medicinal products. For emerging therapies and technologies and borderline products for which there is no established EMA scientific, legal and regulatory experience.
Centralised Qualification advice Qualification of novel methodologies for medicine development | European Medicines Agency (europa.eu)	Committee for Medicinal Products for Human Use (CHMP) on the basis of recommendations by the Scientific Advice Working Party	Advice to support the qualification of innovative development methods (rather than a specific product) for a specific intended use in the context of research and development of pharmaceuticals. Qualification opinion further to assessment of data on innovative development methods for a specific intended use in the context of research and development of pharmaceuticals
Broad centralised scientific advice Research and development | European Medicines Agency (europa.eu)	Committee for Medicinal Products for Human Use (CHMP) on the basis of recommendations by the Scientific Advice Working Party or the Emergency Task Force (ETF)	Issues affecting multiple products and/or indications (e.g. Quality changes, platform trials). Should the need arise, the ETF can advise the CHMP on similar scientific advice procedures for emergencies.