



EU4Health 2022 Work Programme

Information Session – Joint Actions and Directs Grants other than Joint Actions

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Increasing Capacity Building of the EU medicines regulatory network

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Policy Context

- **Aim of the Pharmaceutical Strategy:** To improve the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the EU.
- **Medicines regulators face multiple challenges:** increase of workload due to the COVID-19 pandemic, scientific and technological developments;
- It is crucial that regulators, scientific assessors and inspectors are up to date with the latest scientific developments;
- It is necessary to provide **training** for medicinal products assessors; scientific experts supporting the regulatory network and inspectors;

Objectives, Scope and Activities

- **Objectives:**
 1. To increase the necessary regulatory expertise and competences in the European medicines regulatory network;
 2. To develop additional capacities to face the challenges represented by upcoming scientific developments.
- **Scope:** Identification by Member States authorities of the most pressing needs in relation to the available and required competences of the network.
- **Activities:** Identification and exchange of knowledge capacity to support a better collaboration; Training actions; Best practice sharing; Exchange programmes...

Expected results and Impact

- To develop skills to maintain and improve regulatory experience in handling marketing authorisation procedures including on applications involving upcoming scientific developments;
- To foster the exchange of experts and expertise among Member States authorities;
- To foster work sharing in DCPs and increasing cooperation in Multinational Assessment teams;
- To complement existing similar actions organised by the network and by EMA (EU Network Training Centre...).

Indicative Timetable, Budget, Implementation and Procedure Type

Call topic/ sub-topic	Estimated call publication	Budget
Direct grants – HS-g-22-17.02	Q4/ 2022	EUR 8 000 000
Procedure Type	Implemented by	Type of applicants targeted
Direct grant to Member States (joint action) in accordance with Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/ 1046	HaDEA	Member States' authorities

Thank you



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