

ANNEX I

GUIDANCE FOR NOMINATION AND INDICATIVE TIMELINE ON THE JOINT ACTIONS OF THE 2022 WORK PROGRAMME

Guidance for nomination

The deadline for the nomination is 1 September 2022.

The reference to “Member States’ authorities” means “authorities of Member States and of third countries’ associated to the EU4Health programme”.

List of Joint Actions

- EU4H-2022-JA-01: *Direct grants to Member States’ authorities: **implementation of AMR measures in Member States** (AWP¹ Ref: CP-g-22-02.01) – EUR 50 000 000 EU co-funding*
- EU4H-2022-JA-02: *Direct grants to Member States’ authorities: **Cancer and other NCDs prevention – action on health determinants** (AWP Ref: CR-g-22-08.01)– EUR 75 000 000 EU co-funding*
- EU4H-2022-JA-03: *Direct grants to Member States’ authorities: **prevention of NCDs – cardiovascular diseases and diabetes** (AWP Ref: DP-g-22-06.03) – EUR 55 000 000 EU co-funding. One or two thematic joint actions (to be confirmed)*
- EU4H-2022-JA-04: *Direct grant to Member States’ authorities: **contribution to the Cancer Inequalities Registry to monitor national cancer control policies** (AWP Ref: CR-g-22-10.03) – EUR 1 000 000 EU co-funding.*
- EU4H-2022-JA-05: *Direct grants to Member States’ authorities: **support ERNs integration to the national healthcare systems of Member States** (AWP Ref: HS-g-22-16.02) – EUR 11 200 000 EU co-funding.*
- EU4H-2022-JA-06: *Direct grants to Member States’ authorities: **increasing capacity building of the EU medicines regulatory network** (AWP Ref: HS-g-22-17.02) – EUR 8 000 000 EU co-funding.*
- EU4H-2022-JA-07: *Direct grants to Member States’ authorities: **piloting a new model approach for assessing and authorising novel Blood, Tissues and Cells (BTC) preparation processes** (AWP Ref: HS-g-22-18.01) – EUR 1 500 000 EU co-funding.*

¹ Annual work programme unique identifier

- EU4H-2022-JA-08: *Direct grants to Member States' authorities: reinforced market surveillance of medical devices and in vitro medical devices* (AWP Ref: HS-g-22-19.01) – EUR 4 000 000 EU co-funding.
- EU4H-2022-JA-09: *Direct grants to Member States' authorities: preparatory actions for a European Health Data Space; primary use of data (for healthcare) and reuse of data* (AWP Ref: DI-g-22-22.06) – EUR 4 000 000 EU co-funding.

Indicative timeline for proposal submission:

Opening submission date 15.09.2022

Submission deadline 13.01.2023



ANNEX II

GUIDANCE FOR NOMINATION AND LIST OF DIRECT GRANTS TO MEMBER STATES' AUTHORITIES (OTHER THAN JOINT ACTIONS) AND INDICATIVE TIMELINES

Guidance for nomination

The reference to “Member States’ authorities” means “authorities of Member States and of third countries’ associated to the EU4Health programme”.

Unless specified otherwise all Member States and third countries’ associated to the EU4Health programme are eligible to participate in each action.

List of Direct Grants and specific deadlines (per wave)

1st wave - deadline for the nomination is 22.04.2022

- EU4H-2022-DGA-MS-IBA-01: **Direct grants to Member States’ authorities: enhancing whole genome sequencing (WGS) and/or reverse transcription polymerase chain reaction (RT-PCR) national infrastructures and capacities to respond to the COVID-19 pandemic and future health threats (HERA)** (*AWP Ref: CP-g-22-01.04*) – EUR 39 000 000 EU co-funding.

- Sub-topic 1: Establishment of enhanced WGS and RT-PCR infrastructures and capacities in the Member States that have not already received support for such activities in 2021 from ECDC¹.

Consequently, only legal entities established in the following countries are eligible to participate to the action: Bulgaria, Cyprus, Denmark, Italy, and Slovakia.

¹ ECDC procedure Grant/2021/PHF/23776 “Enhancing Whole Genome Sequencing (WGS) and/or Reverse Transcription Polymerase Chain Reaction (RT-PCR) national infrastructures and capacities to respond to the Covid-19 pandemic in the European Union and European Economic Area”

- Sub-topic 2: Consolidation of WGS and RT-PCR activities in countries that received support in 2021 aiming to ensure the sustainable use and integration of enhanced infrastructure into routine surveillance and outbreak investigation activities, in synergy with relevant on-going work at international level.

Consequently, only the legal entities established in the following countries are eligible to participate to the action: Austria, Belgium, Croatia, Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Spain, Sweden.

- EU4H-2022-DGA-MS-IBA-02: **Direct grants to Member States' authorities: supporting the maintenance of the European Medical Device Nomenclature (AWP Ref: HS-g-22-19.02)** – EUR 1 800 000 EU co-funding. It is essential that the Italian Health Ministry continues to provide its support and competences, ensuring adequate maintenance of the EMDN.

Indicative timeline for submission of the proposal (1st wave):

Opening date 03.05.2022;

Submission deadline 30.06.2022

2nd wave - deadline for the nomination is 01.09.2022.

Information on countries that are eligible to participate to the actions of the 2nd wave will be provided timely before the nomination deadline and as soon as related policy developments are available.

- EU4H-2022-DGA-MS-IBA-03: **Direct grants to Member States' authorities: expansion of MyHealth@EU Digital Service Infrastructure (eHDSI) with new services and to more Member States (AWP Ref: DI-g-22-21.01)** – EUR 30 000 000 EU co-funding
- EU4H-2022-DGA-MS-IBA-04: **Direct grants to Member States' authorities: setting up services by Health Data Access Bodies – Secondary use of health data (AWP Ref: DI-g-22-22.01)** – EUR 30 000 000 EU co-funding

Indicative timeline for submission of the proposal (2nd wave):

Opening date 15.09.2022

Submission deadline 31.01.2023

3rd wave - deadline for the nomination is 01.09.2022.

- EU4H-2022-DGA-MS-IBA-05: **Direct grants to Member States' authorities: setting up a coordinated surveillance system under the One Health approach for cross-border pathogens that threaten the Union (AWP Ref: CP-g-22-04.01)** – EUR 20 000 000 EU co-funding

Indicative timeline for submission of the proposal (3rd wave):

Opening date 15.12.2022

Submission deadline 15.03.2022

ANNEX III

INFORMATION ON JOINT ACTIONS INCLUDING ELIGIBILITY CRITERIA

1. INTRODUCTION: WHAT IS A DIRECT GRANT CO-FINANCED WITH COMPETENT AUTHORITIES OF MEMBER STATES (JOINT ACTIONS) UNDER THE EU4HEALTH PROGRAMME

A Joint Action (JA) is a direct grant consisting in collaborative action among Member States and associated countries participating in the EU4Health Programme, inter alia, to develop, share, refine and test tools, methods and approaches to specific health issues, and engage in capacity building in key areas of interest.

2. CRITERIA FOR FINANCIAL CONTRIBUTION FROM THE UNION BUDGET FOR JOINT ACTIONS

Joint Action grants may be awarded without calls for proposals¹.

The Joint Actions will take into account the outcomes of past actions funded by the Health Programmes on similar topics and of ongoing negotiations of a legislative nature.

A Joint Action will involve co-financing by the Union, at the rates defined in Art. 8 (3) of the EU4Health Programme Regulation².

In line with Article 13(5) of the EU4Health Programme Regulation, Joint Actions will be co-financed by:

- competent authorities responsible for health in the Member States or in third countries associated to the Programme; or
- relevant international health organisations; or
- public sector bodies or non-governmental bodies that are mandated by those competent authorities, regardless of whether those bodies act individually or as a network.

¹ Article 195(d) of the Regulation (EU, Euratom) 2018/104 (Financial Regulation) and Article 13(5) of Regulation (EU) 2021/522.

² Regulation (EU) 2021/522 of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014.

Eligibility, selection and award criteria

Applicants' eligibility criteria

Under Article 13(5) of the Programme regulation, direct grants may be awarded without a call for proposals to fund actions:

- if such grants are duly justified, and
- if those actions have a Union added value that is explicitly provided for in the annual work programmes, and
- are co-financed by the competent authorities that are responsible for health in the Member States or in third countries associated to the Programme, by relevant international health organisations, or by public sector bodies or non-governmental bodies that are mandated by those competent authorities, regardless of whether those bodies act individually or as a network.

Member States' or associated countries' responsible authorities receiving the invitation are invited to nominate one competent authority³ responsible for implementing the action on their behalf. The nomination should confirm that:

- the nominated entity will be acting as a competent authority for the given action; and
- the nominated entity and its affiliated entities⁴ are eligible to participate in the action on behalf of the country concerned and under its responsibility.

Applicants' selection criteria

- financial capacity – applicants must have stable and sufficient sources of funding to maintain their activity throughout the duration of the grant and to participate in its co-financing⁵; and
- operational capacity – applicants must have sufficient operational and professional capacities to implement the activities and complete the proposed action.

³ A nominated competent authority will be one of the following: a Member State's or associated country's authority responsible for health, a relevant international health organisations or public sector bodies or non-governmental bodies that are mandated by those competent authorities, regardless of whether those bodies act individually or as a network.

⁴ 'Affiliated entities' are entities that satisfy the eligibility criteria, do not fall within one of the situations referred to in Articles 136(1) and 141(1) of the Financial Regulation and have a link with the beneficiary, in particular a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation.

⁵ The financial capacity of public bodies and international organisations will not be subject to verification.

Proposals award criteria

Proposals will be assessed based on the following **award criteria**:

- a) **Relevance:** clarity and consistency of project, objectives and planning; extent to which they match the themes and priorities and objectives of the call; contribution to the EU strategic and legislative context; European/trans-national dimension; impact/interest for a number of countries (EU or eligible non-EU countries); possibility to use the results in other countries; potential to develop mutual trust/cross-border cooperation (30 points)
- b) **Quality:**
 - Project design and implementation: technical quality; logical links between the identified problems, needs and solutions proposed (logical frame concept); methodology for implementing the project (concept and methodology, management, procedures, timetable, risks and risk management, monitoring and evaluation); feasibility of the project within the proposed time frame; cost effectiveness (sufficient/appropriate budget for proper implementation; best value for money) (30 points)
 - Project team and cooperation arrangements: quality of the consortium and project teams; appropriate procedures and problem-solving mechanisms for cooperating within the project teams and consortium (30 points)
- c) **Impact:** ambition and expected long-term impact of results on target groups/general public; appropriate dissemination strategy for ensuring sustainability and long-term impact; sustainability of results after EU funding ends (10 points).

3. ROLE OF THE NOMINATED COMPETENT AUTHORITIES

Each country participating in the EU4Health Programme is invited to nominate one competent authority, which will become the grant beneficiary and be responsible for the implementation of the action on its behalf.

The competent authority manages and carries out the Joint Action together with the coordinator (lead competent authority for the joint action) contributing with their own funding and ensuring that the objectives of the Joint Action are met.

The nominated competent authority may involve in the grant under its responsibility other participants, such as affiliated entities, subcontractors. Their names shall be indicated by the competent authorities when submitting the proposal, together with the activities they will perform.

3.1. Affiliated entities

Affiliated entities are formally established organisations, defined as: *"entities that satisfy the eligibility criteria and that do not fall within one of the exclusion situations⁶ and that have a link with the beneficiary, in particular a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation"*⁷.

For Joint Actions, affiliated entities in the public sphere cover:

- The different levels of the administrative structure in case of **decentralised administration** (e.g. national, regional or local administrations), or/and
- **Public sector bodies** (e.g. national institutes or schools for public health or national research centres) which and are (at least in part) publically funded to deliver a public or government service, or are in situation of control by a state organization/other public body.

What is **not** an affiliated entity?

- Entities that have entered into a (procurement) contract or subcontract with the competent authority (beneficiary), or who act as concessionaires or delegates for public services for the beneficiary.
- Entities that cooperate with the beneficiary on the basis of a memorandum of understanding or share some assets.

While affiliated entities do not sign the grant agreement, they actively contribute to the implementation of the action. Costs incurred by such entities for implementing the action will be accepted as eligible costs.

3.2. Subcontractors

These are entities subcontracted by the nominated competent authorities for the purpose of providing special expertise to the Joint Action. It should be noted that coordination and other essential tasks cannot be subcontracted.

Subcontracting must comply with the rules in force regarding public procurement, if applicable.

4. ELIGIBILITY CHECKS

After the submission deadline, nominations will be verified to ensure that the eligibility criteria are fulfilled.

The European Health and Digital Executive Agency (HaDEA) reserves its right to assess the regularity of the nomination procedure and to carry out checks. During this process, HaDEA may request supporting documents, such as legal act establishing the nominated organisation.

⁶ Referred in Articles 136 (1) and 141 (1) of the Financial Regulation.

⁷ Article 187 of the Financial Regulation.

5. SUBMISSION OF NOMINATIONS VIA EU SURVEY WEBSITE

There are two steps to follow:

Step 1 - Instructions and completion of the nomination form:

The editable .pdf template of the nomination form should be downloaded, completed, printed and signed by the nominating authority, in general by the Ministry of Health or Health Board.

The editable .pdf template has a limited number of characters; all filled fields should be visible and readable before signature.

Step 2 - Submission of the nomination form:

In this step, you should complete a short online registration form consistently with the completed .pdf nomination form. Upload the scanned signed version of the latter and submit the nomination.

In case you need assistance, please contact: HaDEA-HP-JA@ec.europa.eu

6. PRIVACY AND DATA PROTECTION POLICY

Participation in the Joint Action will involve the collection, use and processing of personal data (such as name, address and CV). This data will be processed in accordance with Regulation No 2018/1725⁸. It will be processed by HaDEA solely for the purpose of evaluating the proposal and subsequent management of the grant (e.g. list of participants of the Joint Action and share data among those participants) and, if needed, programme monitoring, evaluation and communication with DG Health and Food Safety, National Focal Points. Details are available on HaDEA's Data Protection page.

⁸ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of personal data by the European Union's institutions and bodies and on the free movement of such data.

