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ANNEX II

BACKGROUND INFORMATION FOR THE NOMINATION PROCESS

Nomination of Multiple Competent Authorities and Affiliated Entities

Each country participating in the EU4Health Programme is invited to **nominate one or more competent authority(ies)** in Joint Actions[1]. The nominated authority(ies) shall act as grant beneficiary(ies) and shall bear responsibility for implementing the action on behalf of the nominating country.

The competent authority(ies) manage and carry out the action together with the project coordinator (lead competent authority for the action) contributing with their own co-funding and ensuring that the objectives of the action are met.

The nominated competent authority(ies) may **involve in the grant under their responsibility** other participants such as **affiliated entities and** subcontractors. The names of the affiliated entities shall be indicated by the competent authorities in the project proposal, together with the activities they will perform[2].

Legal Entities Eligibility

In order to be eligible for funding under the EU4Health Programme, competent authorities and affiliated entities shall, in addition to the criteria set out in Article 200 of the Financial Regulation[3], be established in a Member State or an overseas country or territory linked to it, or a third country associated to the Programme[4]. The invitation to submit proposals for the action in question may also include additional specific eligibility criteria for the given action.

Direct grants to Member States in the framework of the implementation of the EU4Health Programme[5] are co-financed by the competent authorities that are responsible for health in the Member States or in third countries associated to the Programme, or by public sector bodies, by relevant international health organisations or non-governmental bodies that are mandated by those competent authorities, regardless of whether those bodies act individually or as a network[6].

Understanding the Concept of Affiliated Entities

An entity affiliated to a beneficiary is an entity that fulfils the following conditions[7]:

a) complies with the eligibility and non-exclusion criteria applying to applicants, specifically, does not fall within one of the situations referred to in Articles 138(1) and

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[1] Article 7 of the EU4H Model Grant Agreement.
[2] It is worth noting that while the specific tasks of the affiliated entities and subcontractors shall be detailed in the proposal, only the affiliated entities need to be explicitly identified in the proposal, due to their special status, as outlined in Article 8 of the EU4H Model Grant Agreement.
[3] Article 200 of the Regulation - EU, Euratom - 2024/2509 - EN - EUR-Lex (Financial Regulation).
[4] Article 13(1) of the 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.
[5] A direct grant to Member States (MS) in the form of a **Joint Action** is a grant consisting of a collaborative action among MS and third countries associated to 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 for several MS.
A direct grant, without necessarily being a JA, can also be awarded to nominated competent authorities from the MS or third countries associated to the EU4Health Programme, in line with the relevant rules set up in the EU4Health Regulation.
Direct grants involve co-financing by the Union, at the rates defined in Article 8(3) of the EU4Health Programme Regulation (EU) 2021/522.
[6] Article 13(5) of EU4Health Programme Regulation (EU) 2021/522.
[7] Article 190 of the Regulation - EU, Euratom - 2024/2509 - EN - EUR-Lex (Financial Regulation).

143(1) of the Financial Regulation[8].

b) has a structural link with a beneficiary, in particular a legal or capital link.

c) the structural link is neither limited to the action nor established for the sole purpose of its implementation. This means that the link would exist independently of the award of the grant; it should exist before the call for proposals and remain valid after the end of the action.

Affiliated entities are **entities with a legal link to the beneficiaries** which implement parts of the action and are allowed to charge costs directly to the grant.

'Legal link to the beneficiaries' means a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation. This covers:

- permanent legal structures (e.g., the relationship between an association and its members);
- contractual cooperation not limited to the action (e.g., a collaboration agreement for research in a particular field);
- capital link. i.e., direct or indirect control of the beneficiary.

In the public sphere, affiliated entities 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 are (at least in part) publicly 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 based on 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. Affiliated entities do not have direct access to the Funding & Tenders Portal, this is done via the beneficiaries to which they are affiliated.

Beneficiaries' Responsibility for Compliance by Affiliated Entities

Where **beneficiaries** (competent authorities) involve affiliated entities to implement the action, they shall retain **full and sole responsibility** towards the granting authority and the other

[8] Articles 138 (1) and 143 (1) of the Regulation - EU, Euratom - 2024/2509 - EN - EUR-Lex (Financial Regulation).

beneficiaries for the compliance of such entities with the terms of the Grant Agreement (GA)[9].

Beneficiaries shall ensure that:

- all **obligations** arising from the GA are **equally binding upon their affiliated entities** involved in the action;
- the bodies referred to in Article 25 of the GA[10], including but not limited to the granting authority, the European Anti-Fraud Office (OLAF), and the European Court of Auditors, are granted the same rights of access and control in relation to the affiliated entities or other participants as they have with respect to the beneficiaries themselves.

Any **breach** of the GA by an affiliated entity is handled in the same manner as breaches by beneficiaries. Any amounts unduly paid as a result of such breach shall be subject to **recovery from the beneficiary**, who shall remain liable for the reimbursement.

Please note that, before signing the Grant Agreement, the beneficiaries will have to sign a Declaration of Honour where they must acknowledge to be fully responsible for their affiliated entities which participate in the action.

Submission of the nominations via the EUSurvey Platform

The submission of nominations of competent authority(ies) and affiliated entity(ies) per action under the 2026 EU4Health Work Programme shall be done through the **EUSurvey Platform** according to the instructions available there.

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 acts establishing the nominated organisation.

The two main steps for submission via the EUSurvey platform are as follows:

Step 1 - Instructions and completion of the nomination form:

The editable PDF template of the nomination form must be downloaded, duly completed, printed, and signed by the nominating authority—typically the Ministry of Health or the national Health Board.

Please note that the form has a character limit; all completed fields must remain fully visible and legible prior to signature.

Step 2 - Submission of the nomination form:

The short online registration form must be completed in a manner that is fully consistent with the information contained in the completed PDF nomination form. The scanned, signed version of the nomination form must then be uploaded and the nomination submitted.

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

[9] Articles 8 and 9 of the EU4Health Programme Grant Agreement.
[10] Articles 25 of the EU4Health Programme Grant Agreement.

Privacy and Data Protection Policy

The nomination of Competent Authorities and their Affiliated Entities via the above EUsurvey involves the processing of personal data in accordance with Regulation No 2018/1725[11]. To understand how these personal data will be collected, used and protected, we encourage you to review the Privacy and Data Protection Statement.

[11] 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.