Call for proposals to support the implementation of the Regulation on HTA

Training of patient and clinical experts contributing to joint HTA activities

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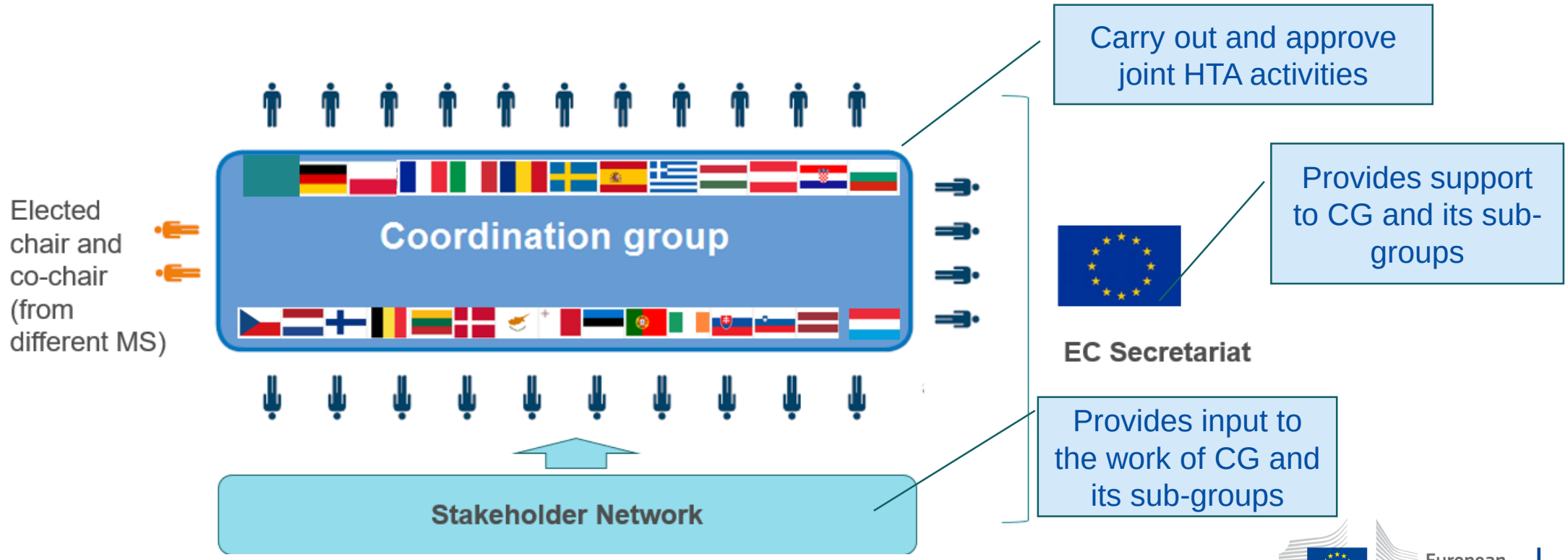
Background and policy context Regulation (EU) 2021/2282

- The Regulation on HTA entered into force in January 2022, with application from January 2025.
- It provides for sustainable and transparent framework for EU cooperation on HTA



(Art. 29. “in particular patient associations, consumer organisations, non-governmental organisations in the field of health, health technology developers and health professionals").

European Commission

Background and policy context Regulation (EU) 2021/2282

Joint HTA activities covered by the Regulation:

- **Joint Clinical Assessments/JCA** on:
  - **medicines** (first 3 years: oncology medicines and ATMP; following 2 years: + orphan drugs; after 5 years: full scope)
  - **a selection of high-risk implantable medical devices**
- **Joint Scientific Consultations/JSC**
  - HTA only
  - in parallel with regulators
- **Emerging Health Technologies**/Horizon scanning
- **Methodology for joint HTA work**

Individual patient experts and clinical experts

Individual patient experts and clinical experts

Patient organisations
Health professionals organisations

Patient organisations
Health professionals organisations

EUnetHTA joint Actions
EunetHTA21 Service contract

European Commission

Call EU4H-2022-PJ-04
Objective, budget, duration

The action will support a **timely implementation of the new legislation** through capacity building activities with focus on patients and clinical experts

Two dedicated sub-topics

a) patient experts – budget EUR 500 000

b) on clinical experts – budget EUR 500 000

Total budget EUR 1 000 000

Duration of the action: 24 - 36 months

European Commission

Call EU4H-2022-PJ-04
Description of activities and expected results

a) **Increasing the capacity of patient organisations and learned societies** to provide robust and meaningful input to HTA activities carried out by the Coordination Group and its sub-groups (→ D 1,2,3,4,5)

b) **Increasing the knowledge of patients and clinical experts on the new Union HTA legal framework**, clarifying their role when invited to contribute to joint HTA activities (→ D 1,2,5)

c) Ensuring the appropriate **implementation of the rules to ensure the independence and impartiality of patients and clinical experts** involved in joint HTA work. (→ D 1,2,5)

Training of patients and clinical experts participating to JSC and JCA (including rules for ensuring their independence and impartiality)

Increased awareness about the Regulation on HTA, stimulate engagement in HTA at national/EU level

NB. D = deliverables (see next slide)

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Specific mandatory deliverables for subtopic a)

1. **Training programme targeted to patients experts** (English; made available also online; translated in as many EU official languages as possible)
2. **Training sessions -** face to face (min. 6 if only F2F) OR online (min. 10 if only online) OR in combination.
3. **List of national and EU-wide patient organisations per disease area** (as a minimum on cancer, including rare cancers) who could support the joint work of Coordination Group
4. **List of candidate patient experts trained by the national and/or EU-wide patient organisations** who could provide input to JCA and JSC as set out by the Regulation on HTA (as a minimum in the area of cancer, including rare cancers).
5. **Dissemination tools** (e.g. website, newsletter, leaflet) to increase awareness about the Regulation on HTA among patient organisations.

Specific mandatory deliverables for subtopic b)

1. **Training programme targeted to clinical experts** (developed in English and made available, also online, in as many EU official languages as possible).

2. **Training sessions** - out face to face (min. 6 if only F2F) OR online (min. 10 if only online) OR in combination.

3. **List of national and EU-wide organisations such as healthcare professionals, clinical and learned societies per disease area** (as a minimum for cancer, including rare cancers) who could support the joint work of Coordination Group

4. **List of candidate clinical experts** who could provide high-level scientific input to joint HTA work (i.e. JCA, JSC), following the training programme (as a minimum in the area of cancer, including rare cancers).

5. **Dissemination tools** (e.g. website, newsletter, leaflet) to increase awareness about the Regulation on HTA

Thank you

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