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ANNEX II

SUMMARY: EU4Health – 2022 work programme

This Annex provides a summary of Annex I¹, which sets out priorities and actions, including the allocation of resources, for the implementation in 2022 of the EU4Health Programme as established under Regulation (EU) 2021/522 of the European Parliament and of the Council² ('the EU4Health Regulation').

Article 17 of Regulation (EU) 2021/522 requires the Commission to adopt, by means of implementing acts, annual work programmes setting out, in particular, actions to be taken and an indicative allocation of financial resources. The actions will implement four general objectives and ten specific objectives identified in Articles 3 and 4 of the EU4Health Regulation.

The overall budgetary envelope for 2022 amounts to **EUR 835 349 555**³ of which for grants 513 000 000, procurement 300 000 (both direct management), indirect management 18 000 000 and for other expenditure 5 000 000 (rounded amounts).

The EU4Health Programme represents an unprecedented level of financial commitment for the Union in health in comparison with the three previous health programmes. The EU4Health Programme is the Union's response to the current public health emergency; it will make a significant contribution to the post-COVID-19 recovery. Its general objectives and specific objectives are laid down in Articles 3 and 4 of the EU4Health Regulation and are respectively implemented based on the following **action strands** and **major actions**:

STRANDS & ACTION AREAS	2022 Budget (in million EUR)
1. CRISIS PREPAREDNESS	
01 Health Emergency Preparedness and Response Authority (HERA)	274.8
02 Tackling antimicrobial resistance (AMR)	50.3
03 Support to large scale vaccination, including against COVID-19	30.0
04 One Health approach for cross border pathogens	20.0
05 Reinforce Union cooperation with WHO on crisis preparedness	5.8
2. HEALTH PROMOTION & DISEASE PREVENTION	
06 Health promotion and prevention of non-communicable diseases (NCD) and related risk factors	74.0
07 Addressing mental health challenges	16.0

¹ Accessible at <u>https://ec.europa.eu/health/funding/programme_en</u> (English only).

Regulation (EU) 2021/522 of the European Parliament and of the Council 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 (OJ L 107, 26.3.2021, p. 1).
The emount includes the EETA contributions

³ The amount includes the EFTA contributions.

3. CANCER	
08 Health promotion, cancer prevention and related risk factors	105.5
09 Innovative approaches to prostate, lung and gastric cancer screening at EU level	31.2
10 Reducing inequalities in cancer care	2.1
11 Quality of life of cancer survivors	2.5
12 Tobacco control policy	4.1
13 Evaluation of Europe's Beating Cancer Plan (EBCP)	1.5
4. HEALTH SYSTEMS & HEALTHCARE WORKFORCE	
14 Reforming and strengthening health systems	0.7
15 Training for health workforce, including digital skills	29.0
16 Enhanced European Reference Networks (ERNs)	52.7
17 Implementation of the pharmaceutical legislation and strategy	10.2
18 Strengthening the implementation of the legislation on blood, tissues and cells and organs	6.9
19 Implementation of regulations on medical devices (MDR) and in vitro diagnostic (IVDR)	19.8
20 Preparation and implementation of Health Technology Assessment (HTA) regulation	7.2
4. DIGITAL	
21 European Health Data Space (EHDS) – Infrastructure and governance; primary use of data	41.2
22 European Health Data Space (EHDS)– Infrastructure and governance; secondary use of data	35.4
5. OTHER ACTIONS	
23 Other recurrent activities, conferences under Council Presidencies, memberships, IT and Communication support to evaluations	8.7
24 Recurrent activities Disease prevention	4.3
25 Recurrent activities Health System	1.2
27 Recurrent activities HERA	0.4

The actions proposed for funding are:

Action grants

Call for proposals to support:

- implementing relevant results of innovative public health research in relation to vaccination against COVID-19;
- structured dialogue at national or regional level on public procurement in the health sector HERA;
- monitoring and strengthening the implementation of innovative approaches to prostate, lung and gastric cancer screening at Union level;
- providing training for the health workforce, including digital skills;
- prevention of cancer and other non-communicable diseases prevention (e.g. health determinants, cardiovascular diseases, diabetes and mental health);
- the roll-out of the inter-speciality cancer training programme;
- developing early warning features and pricing guidance through EURIPID database;
- increased capacity of notified bodies for medical devices;
- implementation of the HTA regulation training of patient and clinical experts contributing to joint HTA activities;
- operating grants: financial contribution to support the functioning of non-governmental bodies.

Direct grants and contributions to international organisations:

- International Agency for Research on Cancer to map disparities and inequalities between Member States and regions, with a focus on socio-economic inequalities;
- WHO Regional Office for Europe to protect people in the Union and its neighbourhood from serious cross-border health threats;
- WHO Regional Office for Europe collaboration, coordination and knowledge to address mental health challenges;
- WHO Regional Office for Europe to address alcohol-related harm;
- European Observatory on Health Systems and Policies to monitor national cancer control policies.

Grants for actions co-financed with Member States' authorities / joint actions:

- enhancing whole genome sequencing and/or reverse transcription polymerase chain reaction national infrastructures and capacities to respond to the COVID-19 pandemic and future health threats HERA;
- implementation of AMR measures in Member States;
- setting up a coordinated cross-border pathogens surveillance system (One Health);
- prevention of cancer and other non-communicable diseases actions on health determinants, cardiovascular diseases and diabetes;
- to monitor national cancer control policies (Cancer Inequalities Registry);
- expansion of MyHealth@EU digital service infrastructure with new services and to more Member States;
- setting up services by health data access bodies secondary use of health data;
- support ERNs' integration into the national healthcare systems of Member States;
- increasing capacity building of the EU medicines regulatory network;
- piloting a new model approach for assessing and authorising novel blood, tissues and cells preparation processes;
- reinforced market surveillance of medical devices and in vitro medical devices;
- supporting the maintenance of the European Medical Device Nomenclature (EMDN);
- preparatory actions for the envisaged EHDS;
- Presidency events organised by the Council of the European Union.

Other direct grants to support:

- coordination, management, and operational activities of the ERNs;
- technical assistance and support for disease codification knowledge and information sharing through a direct grant with Orphanet.

Prizes not applicable.

Procurement:

- ever-warm facilities (EU FAB) for vaccines and therapeutics production HERA;
- pandemic influenza vaccines HERA;
- IT development for early warning, modelling, simulation and forecasting HERA;
- market research and mapping of innovative diagnostic testing solutions HERA
- monitoring and evaluation framework to strengthen the EU One Health Action Plan against AMR;
- tobacco control policy, implementation and modernisation of tobacco control legislation;
- o effectiveness of health information on alcoholic beverages;
- evaluation of the EU Action Plan on Childhood Obesity;
- o obstacles for cancer survivors to return to work;
- o code of conduct on fair access of cancer survivors to financial services;
- \circ evaluation of the implementation of the EBCP;
- o guidelines on access to healthcare for people with disabilities;
- enhanced ERNs;
- o implementation of pharmaceutical legislation and pharmaceutical strategy;
- supporting the cooperation between the national authorities and professional sector associations in the blood, tissue and cells and organs sectors;
- supporting the implementation of MDR and IVDR;
- o preparation and implementation of the HTA regulation;
- expansion of core services to support patients' access to their health data primary use of health data;
- developing and deploying the basic EHDS2 core services secondary use of health data;
- o operations of MyHealth@EU core services, ensuring compliance with the requirements of the planned EHDS and supporting data controllers – primary use of health data and support for capacity building;
- \circ secondary use of health data infrastructure governance.

<u>Other</u>: annual membership fees for international organisations and regulatory bodies and other contributions:

(a) International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use;

- (b) International Pharmaceutical Regulators Programme;
- (c) European Observatory of Health Systems and Policies;
- (d) meetings of standing committees, ad-hoc meetings, committees and other events;
- (e) expert evaluators;
- (f) European Medicines Agency (electronic product information).