### EUROPEAN COMMISSION

CONSUMERS, HEALTH, AGRICULTURE AND FOOD EXECUTIVE AGENCY

Health and Food Safety Unit

### POLICY EXPECTATION FOR THE JOINT ACTIONS 2020

The numbering of the below Joint Actions corresponds to the numbering in the Annual Work Programme 2020<sup>1</sup>.

### Overview:

• Joint Action on Strengthening cooperation on tobacco control between interested Member States and Commission

(AWP Ref.: 1.2.2.5, Topic: JA-01-2020, EUR 2.500.000 EU co-funding).

• Joint Action on Support for Member States' implementation of best practices in the area of mental health

(AWP Ref.: 1.2.2.6, Topic: JA-02-2020, EUR 5.400.000 EU co-funding).

• Joint Action on Increasing the capacity of national focal points (NFPs) to provide guidance, information and assistance to national applicants on the implementation of the ESF+ health strand and possible support for health-related actions under other EU funding instruments

(AWP Ref.: 1.2.2.7, Topic: JA-03-2020, EUR 1.500.000 EU co-funding).

• Addressing differences in national General Data Protection Regulation (GDPR) implementation in the health sector, including the European Health Data Space and the health data use

(AWP Ref.: 1.2.2.8, Topic: JA-04-2020, EUR 1.500.000-2.500.000 EU co-funding. The drafting of the Code of Conduct for data processing in the health sector pursuant to Art. 40 GDPR may be externalized from the JA in a separate action).

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<sup>1</sup> https://ec.europa.eu/health/sites/health/files/funding/docs/wp2020\_annex\_en.pdf

### 1.2.2.5 Strengthening cooperation on tobacco control between interested Member States and Commission

### THEMATIC PRIORITY

1.5 of ANNEX I to the Programme Regulation

### TYPE OF APPLICANT<sup>2</sup>

Countries participating in the health programme (competent authorities).

### **OBJECTIVES**

To facilitate the exchange of good practices between Member States in order to improve implementation of the Tobacco Products Directive<sup>3</sup> (TPD) and related implementing and delegated acts in a number of areas of tobacco product and e-cigarette regulation, including laboratory capacity, analysis and assessment.

To ensure greater consistency in the application of the TPD to ensure a fair internal market for tobacco and related products.

Promote activities consistent with the objectives of the WHO Framework Convention on Tobacco Control.

### **EXPECTED RESULTS**

Identification of best practices for assessing product data and collaborating on data analysis.

A better understanding of the properties and regulatory implications of novel tobacco products and e-cigarettes.

Increased technical/laboratory capacities and cooperation.

### ACTIVITIES TO BE FUNDED

Building on/complementing the ongoing joint action on tobacco control.

Identification and dissemination of best practices to develop an effective and comprehensive tobacco control policy.

Improvement in participating Member States' capacities to assess, report and regulate

<sup>&</sup>lt;sup>2</sup> Grant to be awarded without a call for proposals under article 195c of the Financial Regulation

Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1).

ingredients of tobacco and related products.

Strengthening cooperation between Member States and the Commission in the area of tobacco control.

### **IMPLEMENTATION**

Chafea

### EU ADDED VALUE

Best practice exchange between Member States.

## 1.2.2.6 Support for Member States' implementation of best practices in the area of mental health

### THEMATIC PRIORITY

3.4 of ANNEX I to the Programme Regulation

### TYPE OF APPLICANT<sup>4</sup>

Countries participating in the health programme (competent authorities).

### **OBJECTIVES**

The roll out by participating Member States of best practices on mental health from our Best Practice Portal which were selected by the Members of the SGPP.

### **EXPECTED RESULTS**

Extending the benefits of these best practices to participating Member States.

### ACTIVITIES TO BE FUNDED

Support for participating countries that have expressed their commitment to widespread roll-out of the best practices.

### **IMPLEMENTATION**

Chafea

### EU ADDED VALUE

Best practice exchange between Member States.

Supporting networks for knowledge-sharing or peer learning.

Unlocking the potential of innovation in health.

<sup>&</sup>lt;sup>4</sup> Grant to be awarded without a call for proposals under article 195c of the Financial Regulation

# 1.2.2.7 Increasing the capacity of national focal points (NFPs) to provide guidance, information and assistance to national applicants on the implementation of the ESF+ health strand and possible support for health-related actions under other EU funding instruments

### THEMATIC PRIORITY

All priorities of ANNEX I to the Programme Regulation

### TYPE OF APPLICANT<sup>5</sup>

Countries participating in the health programme (competent authorities).

### **OBJECTIVES**

To have well-trained national focal points (NFPs) who understand the health objectives, priorities, procedures and rules, and can interact with other NFPs, EU programmes, stakeholders, etc.

The specific aims are to:

- improve understanding of the possibilities offered by different programmes;
- develop cooperation with NFPs for other EU funding programmes (e.g. Horizon Europe, the Employment and Social Innovation (EaSI) programme, etc.) and cohesion funds managing authorities in order to spread information about EU health funding and its impact;
- organise national knowledge-sharing activities on the results of co-funded actions to raise awareness and take-up of evidence-based practices and increase their impact;
  and
- help Member States build their capacity to design sustainable implementation actions, irrespective of the source of funding – European Social Fund Plus (ESF+) health strand or other EU funding instruments.

### **EXPECTED RESULTS**

NFPs, Member State authorities and other stakeholders are better able to identify funding instruments. They are also more aware of how best to implement the key recommendations of a given action and how to bridge any gaps.

Improved priority-setting under, and use of, other EU funding mechanisms for health purposes, e.g. Horizon Europe, the EaSI health strand, the cohesion fund, Structural Reform

<sup>&</sup>lt;sup>5</sup> Grant to be awarded without a call for proposals under article 195c of the Financial Regulation

Support Service technical assistance projects, etc.

### ACTIVITIES TO BE FUNDED

Support for the health programme NFPs' capacity-building activities, to ensure they are ready to implement the ESF+ health strand, in cooperation with the NFPs for other EU funds.

Identification of mechanisms that will support better coordination between national competent authorities, EU funds (e.g. for research), the EaSI NFP network(s) and the Commission. This could entail joint planning, implementation, monitoring and evaluation at national level.

The activities will focus on:

- information/promotion of EU funding;
- disseminating the results of co-funded actions; and
- feedback to the Commission on the evaluation of the programme, the use of results and the assessment of impact.

The health programme NFPs will complement the SGPP. Their role is defined in Article 15, which provides a legal framework for this action.

### **IMPLEMENTATION**

Chafea

### EU ADDED VALUE

Supporting networks for knowledge-sharing or peer learning.

## 1.2.2.8 Addressing differences in national General Data Protection Regulation (GDPR) implementation in the health sector, including the European Health Data Space and the health data use

### THEMATIC PRIORITY

3.2 of ANNEX I to the Programme Regulation

### TYPE OF APPLICANT<sup>6</sup>

Countries participating in the health programme (competent authorities).

#### **OBJECTIVES**

To examine national implementation of the General Data Protection Regulation (GDPR)<sup>7</sup> in the health sector and ensure that possible differences do not hamper the free flow of health and genetic data across borders. Building on the outcomes of the 2020 preparatory workshops with the Member States' and other experts (in particular the final report on Member States' rules on processing of health data).

To provide technical support for the development of guidelines on effective methods for enabling the use of medical information for public health and research.

To support the preparatory work towards the European Health Data Space, by developing proposals for governance model and options for data-sharing, including data governance structures and functions that ensure a fair, transparent, non-discriminatory and balanced relationship between the involved parties, between different Member States and across Europe. To develop, explore and analyse options on data governance, data quality and data infrastructure, as well as sustainability and ethical models.

To support EU, the national authorities and medical community to agree on semantic interoperability guidelines (e.g. data sets, data models, vocabularies), ways of anonymization etc. to facilitate use and re-use of health data by adhering to the FAIR principles of being Findable, Accessible, Interoperable and Reusable.

To support EU, national authorities and the IT community to agree technical interoperability guidelines (e.g. architecture, message exchange protocols – patterns - profiles, and building blocks) to provide a technical backbone for the European Health Data Space and take

<sup>&</sup>lt;sup>6</sup> Grant to be awarded without a call for proposals under article 195c of the Financial Regulation

<sup>&</sup>lt;sup>7</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

advantage of existing infrastructures.

The results of the JA may feed into future legislative or non-legislative framework for the European Health Data Space.

### **EXPECTED RESULTS**

- Options for a Data Governance model for the European Health Data Space, complementing the European Data Spaces horizontal framework. This should also include functions and responsibilities of the relevant actors;
- Options for guidelines on using health data for research and policy making;
- Options for guidelines on Ethical, Legal and Social issues in the European Health Data Space;
- Options for a Data Quality framework encompassing semantic interoperability and FAIR (findable, accessible, interoperable and reusable) principles relevant for the European Health Data Space, as well as anonymization and pseudomisation techniques;
- Options for an Infrastructure architecture and technical interoperability guidelines to enable European Health Data Space services;
- Options for Economics models focused on the sustainability of European Health Data Space.

The drafting of the Code of Conduct may be externalised from the Joint Action in a separate action

### **ACTIVITIES TO BE FUNDED**

The joint action will examine how Member States have applied the GDPR rules on processing health data and will contribute to ensuring the protection and free flow of data in the health sector<sup>8</sup>.

It will build on the outcomes of the 2020 preparatory workshops with Member States' and other experts (in particular the final report on Member States' rules on processing of health data) and on other existing national and EU initiatives (e.g. BBMRI-ERIC, European research infrastructure for biobanking, eHAction, e.g. FINDATA, Danish Data Authority, other countries health data authorities, EHDEN, OECD, WHO, and eHAction). The actions aimed to encourage and support the production of a code of conduct for health data processing may be externalised from the Joint Action in a separate action.

Special attention should be given to the secondary use of health data in Europe, including the application of big data and artificial intelligence in health and long-term care.

The action will also provide technical support for the development of guidelines on effective

<sup>&</sup>lt;sup>8</sup> With possible participation of health and other public authorities of the Member States.

ways of enabling the use of medical information for public health and research.

It will propose a governance model for data-sharing at EU level, for primary and secondary use. It will also carry out preparatory actions for making the governance model operational.

The Joint Action outcomes will put forward options on data quality framework, making health data FAIR (findable, accessible, interoperable and reusable), the building of an infrastructure and ensuring interoperability of health data.

It will also provide options for economics model ensuring sustainability of the European Health Data Space and guidelines on Ethical, Legal and Social issues in the European Health Data Space.

Overall, the Joint Action will contribute to creating a blueprint for the European Health Data Space.

### **IMPLEMENTATION**

Chafea

### EU ADDED VALUE

Supporting networks for knowledge-sharing or peer learning.

Supports the potential of e-health to provide high-quality healthcare and reduce inequalities. Contributes to the creation of a European Health Data Space, a European Commission priority, to promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes. As part of this, you should ensure citizens have control over their own personal data.