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Delegations will find attached document COM(2020) 405 final.

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ANNEXES 1 to 2

ANNEXES

to the

**Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE
COUNCIL**

**on the establishment of a Programme for the Union's action in the field of health –for
the period 2021-2027 and repealing Regulation (EU) No 282/2014 (“EU4Health
Programme”)**

ANNEX I

LIST OF POSSIBLE ELIGIBLE ACTIONS PROVIDED FOR IN ARTICLE 13

- (a) **Investment in:**
 - (i) Precursory projects for high added-value up-scalable initiatives;
 - (ii) Critical health infrastructure relevant in the context of health crises, tools, structures, processes, production and laboratory capacity, including tools for surveillance, modelling, forecast, prevention and management of outbreaks.
- (b) Transfer, adaptation and roll-out of **best practices** and innovative solutions with established Union level added-value between Member States, and country-specific tailor made support to countries, or groups of countries, with the highest needs, through the funding of specific projects including twinning, expert advice and peer support.
- (c) Support **analytical activities and expert advice**, in particular:
 - (i) Surveys, studies, collection of data and statistics, methodologies, classifications, microsimulations, indicators, knowledge brokering and benchmark exercises;
 - (ii) The establishment and operation of a health intelligence and knowledge infrastructure;
 - (iii) Expert groups and panels providing advice, data and information to support health policy development and implementation;
 - (iv) Studies and analysis, and scientific advice to support policymaking, and support to the scientific committees on "Consumer Safety" and on "Health, Environmental and Emerging Risks".
- (d) **Development and implementation of Union health legislation and action**, in particular through support to:
 - (i) Implementation, enforcement, monitoring of Union health legislation and action; and technical support to the implementation of legal requirements;
 - (ii) Cross-border collaboration and partnerships, including in cross-border regions, with a view to transferring and upscaling innovative solutions;
 - (iii) Cross-sectoral collaboration and coordination;
 - (iv) Development and operation of databases and digital tools and their interoperability, including where appropriate with other sensing technologies, such as space-based;
 - (v) Auditing and assessment work in accordance with Union legislation;
 - (vi) Collaboration between the Union institutions, its Agencies, and international organisations and networks, and the Union's contribution to global initiatives;
 - (vii) Stakeholder consultation activities;
 - (viii) Networking by non-governmental organisations and their involvement in projects covered by the Programme;
 - (ix) Collaboration with third countries on the areas covered by the Programme;

- (x) National contact points providing guidance, information and assistance related the implementation of Union health legislation and of the Programme;
 - (xi) Stakeholders in view of transnational cooperation.
- (e) **Structural stockpile and crisis preparation:**
- (i) Establishment and support of a mechanism to develop, procure and manage crisis relevant products;
 - (ii) Establishment and management of EU reserves and stockpiles of crisis relevant products in complementarity with other Union instruments;
 - (iii) Establishment and support of mechanisms for the efficient monitoring and allocation of available care facilities (such as hospital beds and places in ICUs), for the distribution or allocation of goods and services needed in the case of a health crisis, and to ensure the supply and safe use of medicines, investigational medicines and medical devices;
 - (iv) Procurement of goods and services necessary for the prevention and management of health crises and action to secure access to those essential goods and services;
 - (v) Establishment and operation of a Union reserve of medical and healthcare staff and experts and of a mechanism to deploy such staff and experts as necessary to prevent or respond to a health crisis throughout the Union; establishment and operation of a Union Health Emergency team to provide expert advice and technical assistance on request by the Commission in the case of a health crisis;
- (f) **Preparedness, prevention and response to cross-border health threats:**
- (i) Actions to foster Union-wide and cross-sectoral health crisis prevention, preparedness, management and response capacity of actors at Union, national, regional and local level, including contingency planning and preparedness exercises and the upskilling of medical, healthcare and public health staff;
 - (ii) Setting up an integrated cross cutting risk communication framework covering all phases of a health crisis - prevention, preparedness and response;
 - (iii) Support and/or procure emergency production of medical countermeasures, including essential chemicals and active substances, and the financing of cooperation on emergency health technology assessments and clinical trials;
 - (iv) Preventive actions to protect vulnerable groups from health threats and actions to adjust the response to and management of crisis to the needs of those vulnerable groups;
 - (v) Actions to address the collateral health consequences of a health crisis, in particular those on mental health, on patients suffering from chronic diseases and other vulnerable groups;
 - (vi) Actions to strengthen surge capacity, research, development, laboratory capacity, production and deployment of crisis-relevant niche products;
 - (vii) Establishment and operation of a mechanism for cross-sectorial One-Health coordination.
 - (viii) Actions to support investigation, risk assessment and risk management work on the link between animal health, environmental factors, and human diseases, including during health crises.

(g) **Strengthen national health systems:**

- (i) Support knowledge transfer actions and Union level cooperation to assist national reform processes towards improved effectiveness, accessibility, sustainability and resilience, in particular to address the challenges identified by the European Semester and to strengthen primary care, reinforce the integration of care and aim at universal health coverage and equal access to healthcare;
- (ii) Training programmes for medical and healthcare staff, and programmes for temporary exchanges of staff;
- (iii) Support to improve the geographical distribution of healthcare workforce and avoidance of ‘medical deserts’;
- (iv) Support the establishment and coordination of Union Reference Laboratories and Centres, and of Centres of excellence;
- (v) Audit of Member States preparedness and response arrangements (such as crisis management, antimicrobial resistance, vaccination);
- (vi) Support upwards convergence of national systems’ performance through indicator development, analysis and knowledge brokering and the organisation of stress tests of national healthcare systems;
- (vii) Support capacity building for investing in and implementing health system reforms (strategic planning and access to multi-source financing);
- (viii) Support capacity building of national systems for the implementation of legislation on substances of human origin, and for the promotion of the sustainable and safe supply of such substances through networking activities;
- (ix) Support the establishment and implementation of programmes assisting Member States and their action to improve health promotion and disease prevention (for communicable and non-communicable diseases);
- (x) Support Member States’ actions to put in place healthy and safe urban, work and school environments, to enable healthy life choices and promote healthy diets taking into account the needs of vulnerable groups;
- (xi) Support the functioning of the European Reference Networks and the establishment and operation of new transnational networks set out in accordance with Union health legislation, and support Member States’ actions to coordinate the activities of these networks with the operation of national health systems;
- (xii) Support for Member States to strengthen the administrative capacity of their healthcare systems through benchmarking, cooperation and exchange of best practices.
- (xiii) Support an Union framework and the respective interoperable digital tools for cooperation among Member States and in networks, including those needed to enable Member States to deliver joint clinical assessments and joint scientific consultations to exchange outcomes of HTA cooperation.

(h) **Actions on cancer:**

- (i) Support Member States and NGOs in the promotion and implementation of the recommendations of the European Code against Cancer;

- (ii) Support the establishment of quality assurance schemes for cancer centres;
 - (iii) Support prevention programmes on the main cancer risk factors;
 - (iv) Actions to support secondary prevention of cancer, such as early detection and diagnosis through screening;
 - (v) Actions supporting access to cancer services and to innovative medicines for cancer;
 - (vi) Actions supporting the continuity of care (integrated care approaches for prevention, diagnosis, treatment and follow-up care);
 - (vii) Actions supporting quality in cancer prevention and care including diagnosis and treatment;
 - (viii) Actions supporting the quality of life of cancer survivors and care givers;
 - (ix) Support to the implementation of the Union's tobacco control policy and legislation;
 - (x) Establishment and support of a mechanisms for cross-specialty capacity building and continuous education in the area of cancer care.
- (i) **Actions on medicines, vaccines and medical devices:**
- (i) Support to initiatives to improve vaccination coverage rates in the Member States;
 - (ii) Support actions to fight vaccine hesitancy;
 - (iii) Support clinical trials to speed up the development, authorisation and access to innovative, safe and effective medicines and vaccines;
 - (iv) Support action to ensure greater availability in the Union of medicines and medical devices and contribute to their affordability for patients and health systems;
 - (v) Support action to encourage the development of innovative products and of less commercially interesting products such as antimicrobials;
 - (vi) Support action to monitor shortages of medicines and medical devices occurring in hospitals and community pharmacies, to address such shortages, and to increase security of supplies;
 - (vii) Support actions to encourage the development of innovative medicines and medical devices less harmful for the environment and promote greener manufacturing;
 - (viii) Action to strengthen the environmental risk assessment of pharmaceuticals;
 - (ix) Action to promote the prudent use and disposal of antimicrobials;
 - (x) Support action to foster international regulatory convergence on medicines and medical devices.
- (j) **Digital transformation of health:**
- (i) Support for the deployment, operation and maintenance of mature interoperable digital service infrastructures and data quality assurance processes for data exchange, access, use and reuse; support for cross border

networking, including through the use of electronic health records, registries and other databases;

- (ii) Support to the digital transformation of health care and health systems including through benchmarking and capacity building for the uptake of innovative tools and technologies; digital upskilling of health care professionals;
 - (iii) Support the deployment and interoperability of digital tools and infrastructures within and between Member States and with Union Institutions and bodies; develop appropriate governance structures and sustainable, interoperable Union health information systems, as part of the European Health Data Space and strengthen citizens' access to and control over their health data;
 - (iv) Support optimal use of telemedicine/telehealth, including through satellite communication for remote areas, foster digitally-driven organisational innovation in healthcare facilities and promote digital tools supporting citizen empowerment and person-centred care.
- (k) **Communication and outreach to stakeholders and citizens**, in particular:
- (i) Communication addressed to citizens in the context of risk management and crisis preparedness.
 - (ii) Communication addressed to citizens and stakeholders to promote Union action in the areas mentioned in this Annex.
 - (iii) Communication to promote disease prevention and healthy lifestyles, in cooperation with all concerned actors at international, Union and national level.

ANNEX II

INDICATORS FOR THE EVALUATION OF THE PROGRAMME

A Programme Indicators

- I. Quality and completeness of EU and MS preparedness and response planning for serious cross border threats to health
- II. Access to centrally authorised medicines, e.g. number of orphan authorisations, Advanced Therapy Medicinal Products, Paediatric Use Medicinal Products or vaccines, for unmet needs
- III. Number of actions and best practices directly contributing to the SDG 3.4/Member State
- IV. Implementation of best practices by EU Member States

B The following indicators will also be used to monitor the implementation of the Programme:

1. Number of Member States with improved preparedness and response planning
2. Vaccines, medicines, medical devices and other countermeasures during crises [made available by type and by MS]
3. Number of vaccine doses distributed
4. Number of entities benefiting of medicines and medical devices
5. EU Laboratory capacity index (EULabCap)
6. Age-standardised five-year net survival of cervical, breast and colorectal cancer
7. Ratio of Cancer Registries (CRs) and number of Member States (MSs) reporting information on cervical, breast, and colorectal cancer stage at diagnosis
8. Smoking prevalence
9. Number of shortages of medicines in the single point of contact network
10. Access to centrally authorised medicines for unmet needs
11. Number of audits conducted in the EU and in third countries to ensure good manufacturing practices and good clinical practices (Union control)
12. Deaths attributable to antimicrobial resistant infections
13. Number of hospital units involved in ERN and of patients diagnosed and treated by the members of ERN networks
14. Number of Health Technology Assessment reports jointly carried out