Basic information

2020/0102(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Programme for the Union's action in the field of health for the period 2021-2027 (“EU4Health Programme”) Repealing Regulation 2014/282 2011/0339(COD) **Subject** 4.15.15 Health and safety at work, occupational medicine 4.20 Public health 4.20.01 Medicine, diseases 4.20.02 Medical research 4.20.05 Health legislation and policy 4.20.06 Health services, medical institutions	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	BUŞOI Cristian-Silviu (EPP)	02/06/2020
	Shadow rapporteur CERDAS Sara (S&D) TRILLET-LENOIR Véronique (Renew) RIVASI Michèle (Greens /EFA) KOPCIŃSKA Joanna (ECR) REGIMENTI Luisa (ID) KONEČNÁ Kateřina (GUE /NGL)	

Committee for opinion	Rapporteur for opinion	Appointed
BUDG Budgets	ȘTEFĂNUȚĂ Nicolae (Renew)	18/06/2020
EMPL Employment and Social Affairs	The committee decided not to give an opinion.	
ITRE Industry, Research and Energy	The committee decided not to give an opinion.	

	IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	
	FEMM Women's Rights and Gender Equality	ZACHAROPOULOU Chrysoula (Renew)	25/08/2020

Council of the European Union	
European Commission	

Commission DG	Commissioner
Health and Food Safety	KYRIAKIDES Stella

European Economic and Social Committee
European Committee of the Regions

Key events

Date	Event	Reference	Summary
28/05/2020	Legislative proposal published	COM(2020)0405	Summary
17/06/2020	Committee referral announced in Parliament, 1st reading		
14/10/2020	Vote in committee, 1st reading		
20/10/2020	Committee report tabled for plenary, 1st reading	A9-0196/2020	Summary
12/11/2020	Debate in Parliament		
13/11/2020	Decision by Parliament, 1st reading	T9-0304/2020	Summary
13/11/2020	Matter referred back to the committee responsible for interinstitutional negotiations		
14/01/2021	Approval in committee of the text agreed at 1st reading interinstitutional negotiations	PE689.581 GEDA/A/(2021)001000	
09/03/2021	Decision by Parliament, 1st reading	T9-0069/2021	Summary
09/03/2021	Results of vote in Parliament		
09/03/2021	Debate in Parliament		
18/03/2021	Act adopted by Council after Parliament's 1st reading		
24/03/2021	Final act signed		
25/03/2021	End of procedure in Parliament		
26/03/2021	Final act published in Official Journal		

Technical information

Procedure reference	2020/0102(COD)

Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Amendments and repeals	Repealing Regulation 2014/282 2011/0339(COD)
Legal basis	Treaty on the Functioning of the European Union TFEU 168-p5
Other legal basis	Rules of Procedure EP 165
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/9/03163

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE653.803	17/06/2020	
Amendments tabled in committee		PE653.822	16/07/2020	
Amendments tabled in committee		PE655.706	16/07/2020	
Committee opinion	BUDG	PE653.947	01/09/2020	
Committee opinion	FEMM	PE657.308	14/09/2020	
Committee report tabled for plenary, 1st reading/single reading		A9-0196/2020	20/10/2020	Summary
Text adopted by Parliament, partial vote at 1st reading /single reading		T9-0304/2020	13/11/2020	Summary
Text agreed during interinstitutional negotiations		PE689.581	18/12/2020	
Text adopted by Parliament, 1st reading/single reading		T9-0069/2021	09/03/2021	Summary

Council of the EU

Document type	Reference	Date	Summary
Coreper letter confirming interinstitutional agreement	GEDA/A/(2021)001000	18/12/2020	
Draft final act	00069/2020/LEX	24/03/2021	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2020)0405	28/05/2020	Summary
Commission response to text adopted in plenary	SP(2021)234	03/05/2021	
Follow-up document	SWD(2024)0223	13/09/2024	
Follow-up document	COM(2025)0709	25/11/2025	

Follow-up document	SWD(2025)0369	25/11/2025	
Follow-up document	SWD(2026)0299	01/10/2026	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	ES_PARLIAMENT	COM(2020)0405	03/07/2020	
Contribution	PT_PARLIAMENT	COM(2020)0405	29/07/2020	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES2821/2020	18/09/2020	
CofR	Committee of the Regions: opinion	CDR2917/2020	14/10/2020	

Additional information

Source	Document	Date
European Parliament	Briefing	01/10/2020
European Commission	EUR-Lex	

Final act

Regulation 2021/0522
OJ L 107 26.03.2021, p. 0001

Programme for the Union's action in the field of health for the period 2021-2027 (“EU4Health Programme”)

2020/0102(COD) - 28/05/2020 - Legislative proposal

PURPOSE: to establish a programme for the Union’s action in the field of health for the period 2021-2027 (EU4Health programme).

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure on an equal footing with the Council.

BACKGROUND: while Member States are responsible for their health policies, the experience gained during the COVID-19 crisis has shown the need to significantly strengthen the EU's capacity to respond effectively to major health threats. Europe needs to give higher priority to health, to have health systems ready to provide state-of-the-art care and to be prepared to deal with epidemics and other unpredictable health threats, in line with the International Health Regulations (IHR).

The Commission proposes that an ambitious stand-alone programme, called the EU4Health Programme, is the key instrument to implement this strategy.

The new programme will be essential to ensure that the EU remains the healthiest region in the world, that it has all possible tools to address health challenges at national and European level and that it is ready to respond to any new and emerging health threats that may endanger the population of the EU.

CONTENT: the proposed Regulation aims to establish a new programme for EU action in the field of health, entitled '***EU4Health Programme***' (EU4Health) for the period 2021-2027.

General objectives

The Programme shall pursue the following general objectives:

(1) protect people in the Union from serious cross-border threats to health;

(2) improve the availability in the Union of medicines, medical devices and other crisis relevant products, contribute to their affordability, and support innovation;

(3) strengthen health systems and the healthcare workforce, including by digital transformation and by increased integrated and coordinated work among the Member States, sustained implementation of best practice and data sharing, to increase the general level of public health.

From the point of view of recovery from the COVID-19 crisis, the Programme should help to ensure that the EU is better prepared to deal with future health threats that would affect all or a large part of its territory.

The Programme shall:

- support Member States in the transition to better preparedness and the reinforcement of their health systems and support them in achieving the health-related United Nations Sustainable Development Goals (SDGs);

- set out key action areas such as improvement of national health systems, measures against communicable and non-communicable diseases, availability and affordability of medicines and other crisis relevant products;

- address inequalities by benchmarking, providing support and closing identified gaps between countries, regions, population groups and citizens;

- provide tools for enhanced solidarity in preparedness and crisis response, as well as in finding common ground to improve prevention and in addressing non-communicable diseases, and in particular cancer, and for better coordinating between different policies, tools and financial instruments;

- contribute to tackling the negative impact of climate change and environmental degradation on human health;

- support actions to enable the Commission to complement the necessary regulatory framework and contribute to addressing the significant structural needs identified in the COVID-19 crisis.

Implementation

The Programme shall be implemented through direct or indirect management and shall make use of the most commonly used spending mechanisms of the Union budget, including public procurement, prizes and grants.

Funding for health under the next Multiannual Financial Framework (MFF) for the period 2021-2027 includes several instruments such as the European Social Fund plus (ESF+), the European Regional Development Fund, the Horizon Europe Programme, the Digital Europe Programme and the Interconnection in Europe 2 mechanism.

Working across programmes and sharing objectives between strategies will be key to channelling health funds between strategies and supporting the achievement of their objectives more effectively than before.

Proposed budget

The total budget allocated to the programme shall amount to EUR 10 397 614 000 (in current prices) for the period 2021-2027:

- EUR 1 946 614 000 shall derive from heading 5 'Resilience, Security and Defence' of the MFF for the period 2021-2027;

- EUR 8 451 000 000 shall derive from proceeds of the EU Recovery Instrument, constituting external assigned revenues.

Programme for the Union's action in the field of health for the period 2021-2027 ("EU4Health Programme")

2020/0102(COD) - 20/10/2020 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety adopted a report by Cristian-Silviu BUŞOI (EPP, RO) on 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).

The severity of the COVID-19 pandemic pushed several health systems to breaking point within and outside of the Union. While the Union´s action in the field of health is limited, a separate and robust Programme shall have the capacity to deliver on future pandemics and health threats, and very importantly, make EU health systems more resilient, able to face current weaknesses, such as medicine shortages, antimicrobial resistance, health inequalities and support health sector in the digital transition.

The committee recommended that the European Parliament's position, adopted at first reading under the ordinary legislative procedure, should amend the Commission proposal as follows.

Budget

The proposed financial envelope for the implementation of the Programme for the period 2021-27 shall be ***EUR 10 398 000 000*** in current prices (EUR 9 370 000 000 in constant prices). This budget shall be frontloaded, meaning that there is a need for clear and focused objectives. The administrative expenses related to indirect actions shall not exceed 5% of the total amount under the Programme.

General objectives

Members stressed that a holistic approach is needed to improve health outcomes, and EU policy-makers should ensure that the principle of 'health in all policies' is applied in all policy-making. In this regard, the proposed Programme shall pursue, *inter alia*, the following general objectives, in keeping with this principle:

- improve and foster health in the Union, by supporting health promotion and disease prevention, reducing health inequalities and ensuring equal and full access to health;

- protect people in the Union from any serious cross-border threats to health;

- support the development and implementation of better preparedness and coordination within and between Member States as regards health emergencies;

- support existing and future Union legislation and policies to restore pharmaceutical independence and address shortages;

- strengthen the Union fight against cancer in synergy with the Europe's Beating Cancer Plan, including by supporting actions for the surveillance, prevention, early diagnosis and treatment and care of cancer, including paediatric cancer;

- address vaccine hesitancy, and support action for the elimination of vaccine preventable diseases, including cancers.

Enhance European Reference Networks (ERNs)

Adequate funding shall be ensured to consolidate and expand the ERN model of cross-border healthcare by securing the provision of a range of clinical services through different channels, including online second opinions and specialist advice for patients on treatment and management and 'online out-patient' clinics. These networks shall be extended in the form of Excellence Networks in the field of communicable and noncommunicable diseases.

Communication portal

The report proposed the setting up of a communication portal for the public which would allow the Union to share validated information, send alerts to European citizens and fight against disinformation. This portal may also be used to promote, in cooperation with the European Centre for Disease Control ('ECDC'), a strong immunisation coverage at European level.

Synergies

A EU4Health Steering Board shall be created with a focus on creating synergies between the Programme and other programmes where a health dimension is integrated, through coordination and cooperation, promoting patients and society engagement, and providing scientific advice and recommendations.

The Commission shall propose a new Union strategic framework on occupational safety and health for the period 2021-2027 and continue updating the directive on the protection of workers from the risks related to carcinogens or mutagens at work.

Programme for the Union's action in the field of health for the period 2021-2027 ("EU4Health Programme")

2020/0102(COD) - 09/03/2021 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 631 votes to 32, with 34 abstentions, a legislative resolution on 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).

The European Parliament's position adopted at first reading under the ordinary legislative procedure amends the Commission's proposal as follows:

Programme's objectives

The programme would be established for the period of the multiannual financial framework 2021-2027 and would complement Member States' policies, with a view to improving human health throughout the Union and ensuring a high level of human health protection in all EU policies and activities. It should promote actions in areas where there is EU added value.

In line with the 'One Health' approach, the programme should:

- improve and foster health in the Union to reduce the burden of communicable and non-communicable diseases, by supporting health promotion and disease prevention, by reducing health inequalities, by fostering healthy lifestyles and by promoting access to healthcare;

- protect people in the Union from serious cross-border threats to health and strengthening the responsiveness of health systems and coordination among the Member States in order to cope with serious cross-border threats to health;

- improve the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, and support innovation regarding such products;

- strengthen health systems by improving their resilience and resource efficiency, in particular through: (i) supporting integrated and coordinated work between Member States; (ii) promoting the implementation of best practices and promoting data sharing; (iii) reinforcing the healthcare workforce; (iv) tackling the implications of demographic challenges; and (v) advancing digital transformation.

Supporting actions

In order to achieve these objectives, Parliament insisted, *inter alia*, on:

- supporting actions to: (i) prevent disease, including reducing health damage from illicit drug use and addiction, (ii) end health inequalities, (iii) improve surveillance, diagnosis and treatment of communicable and non-communicable diseases, in particular cancer and paediatric cancer, and (v) improve mental health;

- improving health crisis management, in particular through the coordination, provision and deployment of emergency health resources, information exchange, surveillance and coordination of voluntary testing of national health care systems

- encouraging sustainable production and supply chains and innovation in the EU;

- promoting the safe use of medicines, in particular antimicrobials, and actions to support the development of environmentally friendly medicines;

- the establishment, in synergy with other EU instruments, of a structure and training resources for a reserve of medical, nursing and support staff assigned voluntarily by Member States and ready to be mobilised in the event of a health crisis;

- support for the creation of a European Health Data Space;

- support for global commitments and health initiatives.

Budget

It is proposed that the financial envelope for the implementation of the programme for the period 2021-2027 be set at **EUR 2 446 000 000** in current prices. This amount would be increased by an additional allocation of EUR 2 900 000 000 in 2018 prices.

The distribution of the amounts should respect the following criteria:

- a minimum of 20 % for health promotion and disease prevention actions;

- a maximum of 12.5 % for procurement complementing national stockpiling of essential crisis-relevant products at EU level;

- a maximum of 12.5 % to support global commitments and health initiatives;

- a maximum of 8 % to cover administrative expenses.

Grants

Grants paid by the Union should not exceed 60 % of eligible costs for an action relating to an objective of the Programme or for the functioning of a non-governmental body. In cases of exceptional utility, the contribution by the Union may be up to 80 % of eligible costs.

Actions with a clear EU added value should be considered to have exceptional utility, in particular, where at least 30 % of the budget of the proposed action is allocated to Member States whose GNI per inhabitant is less than 90 % of the Union average.

Governance

To achieve coherent implementation of the programme's actions, an EU Health Steering Group would be established.

The Commission should consult relevant stakeholders, including representatives of civil society and patient organisations, to seek their views on the priorities and strategic orientations of the annual work programme.

Each year, the Commission should present to the European Parliament the results of the work of the EU Health Steering Group and the stakeholder consultations.

Programme for the Union's action in the field of health for the period 2021-2027 (“EU4Health Programme”)

2020/0102(COD) - 13/11/2020 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted by 612 votes to 41, with 36 abstentions, amendments 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).

The matter was referred back to the committee responsible for inter-institutional negotiations.

The main amendments adopted in plenary concern the following points:

Programme’s objectives

In keeping with the ‘One Health’ and ‘Health in all policies’ approaches, the programme would:

- improve and foster health in the EU, by supporting health promotion and disease prevention, reducing health inequalities and ensuring equal and full access to health;

- protect people in the EU from any serious cross-border threats to health;

- support the development and implementation of better preparedness and coordination within and between Member States as regards health emergencies;

- support existing and future EU legislation and policies restore pharmaceutical independence and address shortages, improve the availability, accessibility and affordability of health care and services in the EU;

- share comparable and interoperable data, with the aim of increasing the general level of public health, health literacy and make health systems more resilient and responsive.

To achieve these objectives, Parliament insisted, *inter alia*, on:

- the coordination of stress testing of national healthcare systems;

- supporting actions contributing to the availability in the EU, during a crisis, of health crisis relevant products such as essential medicines, vaccines and medical devices;

- strengthening the European medicines market;

- creating and implementing a European Health Data Space;

- strengthening EU innovation to ensure the development and uptake of the next generation of medicines, vaccines and medical devices;

- EU action against cancer and support for the early diagnosis of neurodegenerative and other brain diseases;

- addressing vaccination hesitancy;

- the development of medicines that are less harmful to the environment.

Budget

Parliament proposed that the financial framework for the implementation of the programme for the period 2021-2027 be set at EUR 10 398 000 000 in current prices (i.e. EUR 9 370 000 000 in constant prices). The administrative expenditure related to indirect actions should not exceed 5% of the total amount of the programme.

Implementation and forms of EU funding

The Commission should facilitate the consistent implementation of the programme while seeking maximal administrative simplification and fostering synergies between the programme and other EU programmes and funds. A reliable and efficient mechanism would be created to avoid any duplication of funding.

The award criteria would be defined in the programmes and calls for proposals, taking into account, as far as applicable, a number of elements such as the cross-border dimension, the contribution to digital transformation, the social impact (benefits and costs), the contribution to the prevention of diseases, in particular cancer, and the contribution to access to medicines.

To achieve a coherent implementation of the Programme's actions, an EU Health Steering Group should be established.