

The Involvement of the European Commission in the Implementation of the “European Union for Health” Program for the Period 2021-2027 Relevant Union Legislative Mechanisms

Elise-Nicoleta Vâlcu

*Associate Professor, PhD, Faculty of Economic Sciences and Law, University of Pitesti, Romania
elisevalcu@yahoo.com*

ABSTRACT: The need for a new concerted approach by the member states of the European Union starting with 2020, regarding the "EU policy in the field of health" was generated by the outbreak of the crisis caused by COVID-19. On 11 March 2020, the World Health Organization (WHO) declared the epidemic caused by the new coronavirus (COVID-19) as a global pandemic, causing an unprecedented health crisis. Faced with this cross-border threat to public health, the member states have concluded that additional action at the European Union level is necessary to support cooperation and coordination between them. Therefore, the Union co-legislator adopted Regulation (EU) 2021/522 of the Parliament and of the Council on 24 March 2021, establishing a program of action of the European Union in the field of health "European Union Program for Health" for the period 2021-2027 (Regulation (EU) 2021/522 of the Parliament and of the Council of 24 March 2021 establishing an action program of the European Union in the field of health ("the "EU program for health") for the period 2021-2027 (OJ L 107, 26.3 .2021, p. 1-29) repealed Regulation (EU) no. 282/2014. This regulation is mandatory in all its elements and applies directly in all member states from January 1, 2021).

KEYWORDS: health programme, member states, financing, actions, governance

Introductory provisions regarding the context of the adoption of the “European Union for Health” Program 2021-2027

In accordance with the provisions established by Articles 9 (“In defining and implementing its policies and actions, the Union takes into account the requirements for promoting a high level of employment, guaranteeing adequate social protection, combating social exclusion, as well as the requirements for a high level of education, of professional training and protection of human health”) and 168((1) “A high level of protection of human health shall be ensured in the definition and implementation of all policies and actions of the Union. (2) The Union encourages cooperation between member states in the fields covered by this article and, if necessary, supports their action. It encourages, in particular, cooperation between Member States to improve the complementarity of their health services in cross-border regions. (3) The Union and the member states favour cooperation with third countries and with competent international organizations in the field of public health”) (ex-Article 158 TEC) of the Treaty on the Functioning of the European Union (TFEU) and Article 35 (Every person has the right to access preventive healthcare and to benefit from medical care under the conditions established by national laws and practices. A high level of protection of human health shall be ensured in the definition and implementation of all Union policies and actions. The principles contained in this article are based on articles 11 and 13 of the European Social Charter) of the Charter of Fundamental Rights of the European Union, in the definition and implementation of all Union policies and actions the prevention of the direct and collateral effects of future health crises on the citizens of the member states is ensured.

Regulation (EU) 2021/522 has as its regulatory object the establishment of an action program of the European Union in the field of health (“The EU program for health”) for the period 2021-2027, adopted in synergy with other programs of the European Union among

which we mention the InvestEU Program established by Regulation (EU) 2021/523 of the European Parliament and of the Council (Regulation (EU) 2021/523 of the European Parliament and of the Council of 24 March 2021 establishing the InvestEU Program and amending Regulation (EU) 2015/1017) and the Recovery and Resilience Mechanism established by Regulation (EU) 2021/241 of the European Parliament and of the Council (Regulation (EU) 2021/241 of the European Parliament and of the Council of 12 February 2021 establishing the Recovery and Resilience Mechanism (OJ L 57, 18.02.2021, 17)

The crisis caused by COVID-19 has highlighted many challenges, including the dependence of the European Union on third countries in terms of ensuring the health systems of the member states regarding the supply of raw materials, medicines, medical devices needed during health crises, especially pandemics.

As stipulated in Article 3 of Regulation (EU) 2021/522, “The Program has an added value for the Union and complements the policies of the Member States with a view to improving human health throughout the Union” meaning that it proposes a set of general objectives, among which we mention:

- a) supporting the promotion of health in order to prevent diseases, by reducing health inequalities, by promoting a healthy lifestyle and by promoting access to healthcare;
- b) protecting Union citizens against serious cross-border threats to health and strengthening the reaction capacity of Member States’ health systems;
- c) improving the availability and accessibility in the Union of medication and medical devices, products needed in crisis situations, as well as supporting innovation in such products;
- d) strengthening health systems by improving their resilience and resource efficiency, in particular by: (i) supporting an integrated and coordinated activity between member states; (ii) promoting the implementation of best practices and promoting data exchange; (iii) strengthening the health workforce.

In accordance with the provisions of Article 6 of the Union norm, in order to implement (In order to implement the program for the period 2021-2027, the European Union allocates a financial package of 2 446 000 000 EUR which is increased by an additional allocation of 2 900 000 000 EUR as established in accordance with the provisions of Article 5 of the Regulation (EU, Euratom) 2020/2093 of the Council of 17 December 2020 establishing the multiannual financial framework for the period 2021-2027 (OJ L I, 22.12.2020, p.11). The distribution of the amounts is done as follows: a) a minimum percentage of 20% of the total amount is reserved for health promotion and disease prevention actions; b) a maximum percentage of 12.5% of the total amount is reserved for public purchases in order to build stocks of essential products for health crisis situations; c) a maximum percentage of 12.5% of the total amount is reserved for supporting the international commitments undertaken by the European Union on behalf of the member states; d) a maximum percentage of 8% of the total amount is reserved for preparation, monitoring, control, audit and evaluation activities) the above-mentioned objectives, together with the European Union, the following may participate:

- third countries that are member states of the European Free Trade Association, members of the European Economic Area (EEA) (The member states of the EEA are: a) the member countries of the European Union (EU): Austria, St. Bartholomew Belgium, Bulgaria, Cyprus (excluding Northern Cyprus), Czech Republic, Croatia, Denmark, Estonia, Finland, France, Guadeloupe, French Guiana , Germany, Greece, Ireland, Italy, Iceland, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, St. Martin, Martinique, Mayotte, Norway, Holland, Poland, Portugal (including the Azores and Madeira islands), Romania, Reunion, Slovakia, Slovenia, Spain (including Tenerife, Balearic and Canary Islands), Sweden, Hungary; and b) Member States of the European Free Trade Association, respectively Liechtenstein, Norway and Switzerland, Iceland);

- acceding countries, candidate countries and potential candidate countries, in accordance with the general principles established by the framework agreements concluded with the European Union;
- the countries within the European neighborhood policy, in accordance with the general principles and the general clauses and conditions for the participation of the respective countries in the Union's programs.

The role of the European Commission in the implementation of the “European Union for Health” Program 2021-2027

The actions to be taken by the member states based on the provisions of this regulation will be constantly supported by the institutions of the European Union, in accordance with the principle of subsidiarity, as provided for in paragraph 3 of article 5 ("Based on the principle of subsidiarity, in areas that are not within its exclusive competence, the Union intervenes only if and to the extent that the objectives of the intended action cannot be satisfactorily achieved by the member states, neither at the central level, nor at the regional or local level, but due to the dimensions and effects of the intended action, they can be better achieved at the level of the Union") of the TEU. Also, third countries that are members of the European Economic Area (EEA) may participate in Union programs within the framework of the cooperation established under the Agreement on the European Economic Area (JO L 1, 03.01.1994, p.3) that provides for the implementation of such programs.

Specifically, from a legislative point of view, the competence of the European Commission to adopt acts based on a *delegated competence* is foreseen, in accordance with the provisions of Article 290 of the TFEU. Thus, in accordance with the provisions of paragraph (1), a Union legislative act can delegate to the European Commission the power to adopt non-legislative acts with a general scope of application, which complete or modify certain non-essential elements of the Union legislative act.

The delegated competence (In accordance with the provisions of article 19 in conjunction with the provisions of article 25 of Regulation (EU) 2021/522) of the European Commission regarding the “Health Programme” is retained in relation to the review, modification and addition of the indicators provided for in Annex II, of this regulation. Specifically, when exercising its delegated powers, the Commission (meetings of the Commission's expert groups tasked with the preparation of delegated acts) must organize appropriate consultations with the European Parliament and the Council, and consult the experts designated by each member state, those consultations being carried out in accordance with the principles established in the Interinstitutional Agreement on Better Law-Making of April 13, 2016 (JO L 123, 12.05.2016, p. 1). The competence to adopt delegated acts in the matter derived from this analysis is conferred on the European Commission for a period of seven years starting on March 26, 2021.

In the event that neither the European Parliament nor the Council have raised objections within two months of the notification of the draft program by the Commission, or in the event that, before the expiry of the aforementioned term, the European Parliament and the Council have informed the Commission that they will not raise objections, the delegated act draft will be considered adopted and will enter into force. The respective term can be extended by two months, only at the initiative of the European Parliament or the Council. Immediately after the delegated act has been adopted, the Commission notifies it simultaneously to the European Parliament and the Council.

The delegation of powers referred to in Article 19 paragraph (2) may be revoked at any time by the European Parliament or the Council. The revocation decision takes effect from the day following its publication in the Official Journal of the European Union (Boghirnea 2015, 119-124) or from a later date mentioned in the content of the decision.

Paragraph (2) of Article 291 of the TFEU regulates *the execution competence* of the European Commission, in case it is necessary to develop the necessary conditions for the

implementation of the Union regulations, directives and decisions (Niță 2016, 242-248; Militaru 2017, 117-120).

With a view to uniform application of the provisions of the regulation deduced from the analysis, one acknowledges *the execution competence* of the European Commission, in accordance with the provisions of paragraph (2) of Article 291 TFEU stated above, applying the examination procedure, in order to adopt implementing acts through which are adopted: a) annual work programs in accordance with the criteria provided in this regulation; b) rules regarding the technical and administrative provisions necessary to implement the actions of the program, as well as regarding the uniform data collection models necessary to monitor the implementation of the program (Both the delegated competence and the execution competence are exercised in accordance with Regulation (EU) no. 182/2011 of the European Parliament and of the Council of 16 February 2011 establishing the rules and general principles regarding the control mechanisms by the Member States of the exercise of enforcement powers by the Commission (OJ L 55, 28.02.2011, p.13))

Regarding the procedural mechanism appropriate to this program, we specify that Article 15 paragraph (1) of the Union norm regulates the establishment of a coordination group of the “European Union for Health” program made up of the European Commission and the member states. At the representation level, each member state appoints a member and an alternate member within the Coordination Group of the “EU for Health” program. *How can the involvement of the European Commission in the implementation of the Health Program be summarized?*

Regarding the Commission's involvement as a member of the Coordination Group of the “EU for Health” program, we retain the following competences:

(a) Consults the Steering Group of the EU Health Program on: the preparatory work of the Commission for the annual work programmes, each year at least six months before the presentation of the draft annual work programme. In this sense, the Commission meets at least once a year, during the six months preceding the presentation of the draft work program, and with relevant stakeholders, including representatives of civil society and patient organizations (See for more details Article 16(2) of Regulation (EU) 2021/522).

(b) Every year, before the last meeting of the EU Health Program Coordination Group, the Commission presents to the European Parliament the results of the work of the EU Health Program Coordination Group and the stakeholder consultation mentioned above.

(c) Adopts, through implementing acts, the annual work programs, which establish, in particular, the component actions of the program, the related allocation of financial resources; eligible shares of legal entities established under European Union law or an international organization; eligible shares of legal entities from a third country associated with the program; the actions of legal entities that are established in a third country that is not associated with the program but that can be declared eligible, under exceptional conditions “if this participation is necessary to achieve the objectives of a certain action” (See for more details, Article 13 paragraphs (1) – (3) of Regulation (EU) 2021/522).

(d) Participates in the adoption of its own rules of procedure, which contain provisions to ensure that the group meets at least three times a year, meetings that ensure a constant exchange of views between member states.

(e) Ensures coherence and complementarity between the health policies of the Member States, as well as between this program and other policies and actions of the European Union;

(f) Coordinates monitoring of program implementation and propose any necessary adjustments based on evaluations (See for more details Article 15 of Regulation (EU) 2021/522).

Conclusion

The legislation of the European Union in the field of health has an immediate and direct impact on public health, on the efficiency and resilience of the health systems of the member states and, last but not least, on the good functioning of the internal market.

Therefore, the appropriate “European Union for Health” Program for the period 2021-2027, aims to strengthen resilience at the Union level in case of cross-border threats to the health of its citizens, but also to support, develop, implement and ensure compliance with Union legislation in the field of health. Also, the Union institutions involved in the implementation of the program, especially the European Commission, propose a constant collaboration with relevant bodies such as the European Medicines Organization and ECDC, thus, they will provide data, including from real medical practice, in order to support the development of policies, including monitoring their implementation, while also developing tools to evaluate the progress made by the member states in this field.

References

- Boghirnea, Iulia. 2015. “The Importance and Utility of the Preliminary Ruling Procedure of the Court of Justice of the European Union.” In *Research and Science Today Journal* no 1 (9).
- Council Regulation (EU, Euratom) 2020/2093 of 17 December 2020 establishing the multiannual financial framework for the period 2021-2027 (OJ L I, 22.12.2020, p. 1).
- Interinstitutional Agreement on Better Law-Making of April 13, 2016.
- Militaru, Ioana Nely. 2017. *European Union Law. Chronology. Springs. Principles. Institutions. The internal market of the European Union. Fundamental Freedoms*. Third edition, revised and added. Bucharest: Universul Juridic Publishing House.
- Niță, Manuela. 2016. “Decision-Maker Action in Developing a Public Policy”. In *International Conference “Society based on knowledge. Norms, values and contemporary benchmarks”*, June 10-11, Targoviste, published in the Supplement of Valahia University Law Study. Bibliotheca Publishing House, pp. 242-248.
- Regulation (EU) 2021/522 of the Parliament and of the Council of 24 March 2021 establishing an action program of the European Union in the field of health (“The EU program for health”) for the period 2021-2027 (OJ L 107, 26.3.2021, pp. 1-29).
- Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, signed at Lisbon, 13 December 2007.