



**Proposal for a**

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF  
THE COUNCIL**

**on the establishment of a Framework for the Union's unified action in times of  
health crisis (pandemic/epidemic)**

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## 1. EXPLANATORY MEMORANDUM CONTEXT OF THE PROPOSAL

### ***Context of the Proposal:***

This proposal provides for a date of application as of 19th of April 2021 and is presented for a Union of 27 Member States.

### ***Reasons and objectives:***

The Covid-19 crisis is the biggest challenge for Europe since World War 2. In light of cross-border health threats, the EU is only as strong as its weakest link. We need to build strength in unity to prevent and prepare for the next health crisis. Cooperation among member states during a health crisis is crucial.

Without further improvements in the EU-wide preparedness, the Union will be vulnerable as it is faced with an aging population and rising incidence of noncommunicable diseases.

### ***Consistency with other Union policies:***

The proposed Framework is an extension of the EU4Health proposal. It builds up on the policies related to the Covid-19 Pandemic.

It is in line with the Treaty of Functioning of the European Union (TFEU), the Treaty of the European Union, Charter of Fundamental Rights of the European Union, and the Social Pillar of the European Union.

## 2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

The policy is based on Article 168(5) TFEU, which allows for the introduction of incentive measures to safeguard and promote human health, including measures to address and ensure early warning of significant cross-border health threats, monitoring measures, and measures that aim to ensure public health.

## 3. RESULTS OF RETROSPECTIVE EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

The measures derive from thorough ex-post analysis of EU's and member states' steps during the Covid-19 Pandemic.

## 4. BUDGETARY IMPACT

The framework provides the financial and structural basis to formulate a crisis response. The commission aims for a similar Interinstitutional Agreement between the European Parliament, the Council and the Commission on budgetary discipline on cooperation in budgetary matters and on sound financial management for the proposed Framework, as adopted the EU4Health Proposal.

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(5) thereof,

*Having regard to the proposal from the European Commission,*

*After transmission of the draft legislative act to the national parliaments,*

*Having regard to the opinion of the European Economic and Social Committee,*

*Acting in accordance with the ordinary legislative procedure,*

*Whereas:*

**FOUNDATION**

- (1) Article 3(1) of the Treaty on the European Union (TEU) clarifies the Union's priority to improve the well-being of its citizens.
- (2) In accordance with Articles 9 and 168 of the Treaty on the Functioning of the European Union (TFEU) and Article 35 of the Charter of Fundamental Rights of the European Union, a high degree of human health care is to be guaranteed in the design and application of every Union policy.
- (3) According to Article 168 TFEU, the Union's function is to supplement and promote national health policies encourage cross-national cooperation and promote program coordination, fully acknowledging the member states sovereignty of their health policies and the organization and delivery of usual health services and medical care.
- (4) A joint approach in the times of health crises will support unity, strength and equality within the European Union.
- (5) The global Covid-19 pandemic has emphasized the importance of a well-coordinated crisis response to disconnected cross-border health challenges in order to ensure strength, resilience, and prescientity.

- (6) Consequently, it is appropriate to install a Framework for unified action in times of health crises, in accordance with competences in the field of public health and serious cross-border health threats (as determined by EU4Health regulation and Decision No 2119/98/EC).
- (7) Learning from past experience, the framework builds upon two pillars: a unified health crisis prevention strategy and unified crisis response.
- (8) **Crisis Prevention: Increasing Resilience of National Health Systems**
  - a. Fortifying national health systems by promoting health equity within the member states and health equality among them as well as encouraging digitalization to increase resilience.
  - b. Following the European Pillar of Social Rights, Principles 16 and 18 Chapter III, explicitly states the right to affordable, high-quality healthcare and long-term care. The commission advises the member states that invest less percentage of their GDP in public health than the EU's average to increase their health care expenditures; thus, converging their healthcare expenditure to the Union's average.
- (9) **Crisis Prevention: Building European infrastructure**
  - a. To ensure autonomy during crises the European Union has to cooperate with European local production facilities that produce medical equipment, machinery, and pharmaceuticals.
  - b. Vaccine, medical and protective equipment purchases during any Pandemic should be coordinated and follow a Joint Procurement Scheme in the future, modeled after the Joint Procurement of medical countermeasures: ensuring proper preparedness.
  - c. Union-driven R&D projects (i.a. Horizon2020) shall continuously foster innovation that strengthens European society, increases resilience, and is advantageous for crisis response. The Commission will be directly investing in portfolios of biotechnology-oriented venture capital funds.
- (10) Ensuring operationality of the single market in times of health crisis to prevent severe economic consequences is one of Union's priorities.
- (11) Protecting the consequential freedom of movement of goods (Article 26, 28-37 TFEU), of capital (Article 63-66 TFEU), freedom to establish and provide services (Article 26, 49-55, 56-62 TFEU) and the freedom of movement for people (Article 3(2) TEU and Article 21 TFEU). It is essential to include appropriate and sustainable short-, mid- and long-term solutions to protect European and National interests.
- (12) Member states should implement measures/instruments from the Pandemic Response Scheme - a catalogue of instruments evaluated as efficiency during the past, i.a. the Covid-19 Pandemic.
- (13) **Crisis Response: Short-term measures**
  - a. In case an external threat to public health emerges, immediate restrictions of movement across EU's external borders are crucial. Further, it might be necessary

to introduce nondiscriminatory restrictions on intra-EU travel. Prior to installing restrictive measures affecting multiple member states, the Commission shall be consulted and can advise against it upon European Centre for Disease Prevention and Control (ECDC) evaluation.

- b. Enabling trade within the Union (in case of restricted/closed borders) is essential to sustaining a stable economy. A possible step is implementing “green lanes”, following the practical guidance to ensure continuous flow of goods.
- c. Complete border closures are considered a last resort short-term measure, as they have severe political, economic and social impact.
- d. The Commission is authorized by the member states to negotiate on their behalf in acquisition of relevant protective equipment and medical material with reference to the Joint Procurement Scheme.

#### **(14) Crisis Response: Mid-term measures**

- a. As soon as vaccines reach late stages of development, the Commission shall negotiate their Advanced Purchase Agreements on behalf of the member states, referring to the Joint Procurement Scheme.
- b. The EMA shall become solely responsible for conditional approval of curatives and vaccines on EU territory. However, member states shall retain the right to issue Emergency Use Authorization based on their internal processes for emergency resolution.
- c. Distribution of vaccines, curatives and medical equipment in accordance with the equity in health and solidarity principle. 70% of the resources (i.a. vaccines) will be distributed per capita, while 30% of the resources are reserved as crisis response for areas that were severely affected.
- d. “Digital Green Certificate” presented a sufficient intermediate solution in the Covid-19 Pandemic to restore the freedom of movement, and the EU shall utilize this experience for future pandemics. Such a certificate shall be issued to people vaccinated with EMA-approved vaccines or their generic versions, as well as people proven healthy. In the first case, the certificate shall be valid for the entire length of the vaccine-induced immunity. In the latter, the recommendations of the ECDC should be followed.

#### **(15) Crisis Response: Long-term Measures**

- a. The Commission shall be entitled to negotiate about “travel bubbles” with non-member states. The negotiations shall commence as soon as ECDC ranks them as low risk countries. The resulting “travel bubble” could allow free movement between these non-member states and the EU independent of a vaccine certificate or a proof of health.
- b. Lifting of specific containment measures shall occur as soon as the epidemiological situation allows upon recommendation of the ECDC.

## **CONDITIONALITY AGREEMENT**

- (16) The distribution of material resources in non-crisis times, as well as distribution of any financial resources, will be tied to rule of law in each specific member state. Such conditionality ensures proper distribution of common resources without undue influence.
- (17) Therefore, in case of a significant, systematic violation of the rule-of-law principle in a member state, it shall notify the member state government and demand appropriate alternative lines of action. If the member state disagrees with the notification, it shall initiate negotiations with the Commission. If the member state is willing but unable to remedy the issue, the Commission will offer all necessary assistance.
- (18) As a last-resort, standard legal remedies are possible.