

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)

EXPLANATORY MEMORANDUM CONTEXT

- Consistency with the Treaty of the European Union, Charter of Fundamental Rights of the European Union, and the Social Pillar of the European Union

LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- Article 168(5) TFEU: incentive measures to monitor, combat and assure early warning of the major cross-border health scourges
- Article 6(a) TFEU: the EU shall support, coordinate or supplement the actions of the Member States, especially regarding the definition of their health policy and the delivery of health services

STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- Introduction of ex-post evaluations/fitness checks

BUDGETARY IMPLICATIONS

- Similar **Interinstitutional Agreement** between the European Parliament, the Council and the Commission

FOUNDATION

- Article 3(1): improvement of well being of citizen
- Articles 9 and 168 TEUF, Article 35 CFR: ensuring healthcare in times of crisis
- **Supplement and promote** national health policies encourage cross-national
- Ensure **solidarity** in times of crisis
- Necessity for a **well-coordinated crisis response**
- Install a **Framework for unified action in times of health crisis**
 - unified health crisis prevention strategy
 - unified crisis response.

CRISIS PREVENTION

Increasing Resilience of National Health Systems

- Fortifying national Health Systems through **aligning** health care **expenditures**
 - increase health care expenditures
 - **digitalization** of health systems
 - modernization of health systemsand therefore promoting **health equity within the member states**
- **Health equality among member states** to increase EU resilience

CRISIS PREVENTION

Building a European infrastructure

- **Joint Procurement Scheme for medication, vaccines and protective equipment**
 - based on Joint Procurement of medical countermeasures: ensuring proper preparedness
 - reducing the problem of alleged unequal distribution
- **Cooperation agreements** with vital production facilities for times of crisis
- **Common R&D measures** and industry partnerships (e.g. Horizon 2020)
 - foster innovation, strengthens european society, increases resilience and crisis responsiveness
 - direct investments biotechnology-oriented venture capital fund

It is necessary to ensure **operationality of the single market** and **freedom of movement for people**, protecting the **freedom of movement of goods** and **freedom to establish and provide services** in times of crisis!



SHORT-TERM MEASURES

- Immediate restrictions of movement across EU's external borders in case of threat to public health → consultation with the **IPIDE**
- Enablement of trade through **green lanes** within the Union in case of restricted/closed borders
- Consideration of complete border closures as a last resort

MID-TERM MEASURES

- **Budget and coordination** of EU-wide research into medical treatment and vaccines → member states shall finance prospective projects
- Joint Procurement Scheme: negotiation of **Advanced Purchase Agreements** as soon as vaccines reach late stages of development
- **EMA** responsibility to approve vaccines on EU territory → member States can issue the **Emergency Use Authorization**
- **Equity and solidarity** principles on the distribution of medications and medical equipment → 70% per capita, 30% for the most affected
- **Digital Green Certificate** as a sufficient intermediate solution



LONG-TERM MEASURES

- Low risk non-member States shall form “**travel bubbles**”
- **Lifting** of containment measures following ECDC recommendations



CONDITIONALITY AGREEMENT

- **Rule of law** will determine the allocation of resources
- If systematic violation, notification is sent → provision of assistance if needed
- Standard legal retaliations as last resource

THANK YOU!

