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Recommendation for a

COUNCIL DECISION

authorising the opening of negotiations on behalf of the European Union for the conclusion of an international agreement on pandemic preparedness and response as well as for the negotiations of complementary amendments to the International Health Regulations (2005)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE RECOMMENDATION

• Reasons for and objectives of the recommendation

Multilateral cooperation is essential to fighting pandemics that by definition know no borders and require collective action. The COVID-19 pandemic has however brought to light the persistent vulnerabilities of the international health system and of global cooperation.

Before the COVID-19 pandemic, the reviews and evaluations following the Severe Acute Respiratory Syndrome (SARS-CoV), the H1N1 influenza pandemics and the Ebola outbreak in West Africa had already highlighted shortcomings in the global capacity to prepare for and respond to outbreaks, and have made numerous and specific recommendations to address these shortcomings. To some extent, those recommendations have resulted in important improvements, such as the revision in 2005 of the International Health Regulations (IHR) and the establishment in 2016, after the Ebola outbreak, of the World Health Organization (WHO) Health Emergencies Programme and of the Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme (IOAC).

In the light of the enormous challenges posed by the COVID-19 pandemic, the need to be better prepared at global level to predict, prevent, detect, assess and effectively respond to pandemics has however become clear. Based on its mandate, WHO has a central role to play in this process, as the leading and coordinating authority in addressing global health challenges, including preparedness for, prevention and detection of, and response to outbreaks.

In the course of the past months, several independent review committees and panels¹ have pointed to the urgent need for a stronger international regime to confront pandemics, as well as for the strengthening of the independence, authority and financing of WHO. This creates a unique momentum to reinforce global health security in light of lessons learnt from the COVID-19 pandemic.

Since the outbreak of the COVID-19 pandemic, the European Union has made a major contribution to the global pandemic response. The Union has been a driving force in supporting the leadership role of WHO and advancing the WHO reform process. The Union's role in strengthening WHO has been reflected in various documents, including Council Conclusions² of November 2020 and a Statement³ of the Members of the European Council in February 2021.

In this vein, the Union and its Member States, for the second year in a row, spearheaded a resolution at the 74th session of the World Health Assembly in May 2021 to strengthen WHO preparedness and response to health emergencies. This resulted in the set-up of a Working Group of WHO Member States on strengthening WHO preparedness and response (hereafter referred to as “the WHO Member States Working Group”) to consider the findings and recommendations of the independent review committees and panels and to report to the World Health Assembly in May 2022.

¹ In particular, the Independent Panel for Pandemic Preparedness and Response, the Review Committee on the functioning of the International Health Regulations (2005) during the COVID-19 response and the Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme.

² <https://data.consilium.europa.eu/doc/document/ST-12276-2020-INIT/en/pdf>.

³ [Statement of the members of the European Council, 25-26 February 2021 - Consilium \(europa.eu\)](#).

In the run-up to the 74th session of the World Health Assembly, the Union and a broad-based group of supporting countries from all WHO regions have also pushed to establish a process towards an international treaty on pandemic preparedness and response. In March 2021, 25 Heads of State and Government from around the world joined the President of the European Council Charles Michel and the Director-General of the World Health Organisation, Dr. Tedros Adhanom Ghebreyesus, in an Op-ed calling for an international treaty on pandemics, drawing from the lessons learnt during the COVID-19 pandemic⁴.

On 20 May 2021, the Council adopted the position to be taken on the Union's behalf in the 74th session of the World Health Assembly⁵. This Decision clearly set out the Union support for the establishment of a WHO process for a new Framework Convention on Pandemic Preparedness and Response. It also indicated that the Union must be allowed to participate in the negotiating process, in view of the Union's possible accession to such a treaty. The Union's commitment to working towards an international treaty on pandemics within the framework of WHO has also been reflected in the Statement of the members of the European Council of February 2021 and in the European Council Conclusions of June 2021⁶.

On 21 May 2021, the European Commission and Italy, as chair of the G20, co-hosted the Global Health Summit, where the leaders of G20 and other States, in the presence of the heads of international and regional organisations, adopted the "Rome Declaration"⁷. The principles set out in this declaration provide common guidance for the prevention and preparation to future pandemics and are of particular relevance in view of the discussions on an international treaty on pandemics.

At the World Health Assembly in May 2021, the Union together with the Group of Friends (the co-signatories of the Op-ed) worked to establish a negotiating mandate for an international treaty on pandemics. This could not be achieved due to lack of consensus. As a way forward, the World Health Assembly adopted a decision asking the WHO Member States Working Group to consider the potential benefits of developing a WHO convention, agreement or other international instrument on pandemic preparedness and response. It was also decided to convene a special session of the World Health Assembly from 29 November to 1 December 2021 devoted to this issue and with a view to starting the formal negotiation process immediately thereafter.

The WHO Member States Working Group held five meetings between July and November 2021, as well as several intersessional meetings.

In the course of the discussions, the number of countries speaking in favour of an international treaty has increased. Based on the discussions held in the WHO Member States Working Group and as stated in its report adopted on 15 November⁸, a number of potential benefits of a new instrument for strengthening pandemic preparedness and response have been identified, including:

⁴ <https://www.who.int/news-room/commentaries/detail/op-ed---covid-19-shows-why-united-action-is-needed-for-more-robust-international-health-architecture>. The Op-ed was signed by Heads of State/Governments of: Fiji, Thailand, Portugal, Italy, Romania, United Kingdom, Rwanda, Kenya, France, Germany, Greece, Republic of Korea, Chile, Costa Rica, Albania, South Africa, Trinidad and Tobago, Netherlands, Tunisia, Senegal, Spain, Norway, Serbia, Indonesia, and Ukraine.

⁵ OJ L 238, 6.7.2021, p. 79.

⁶ [European Council conclusions, 24-25 June 2021 - Consilium \(europa.eu\)](https://european-council.europa.eu/media/e0000000-1000-1000-1000-100000000000_en.pdf).

⁷ https://global-health-summit.europa.eu/rome-declaration_en.

⁸ [Report of the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies to the special session of the World Health Assembly](https://www.who.int/news-room/feature-stories/detail/report-of-the-member-states-working-group-on-strengthening-who-preparedness-and-response-to-health-emergencies-to-the-special-session-of-the-world-health-assembly)

- (a) promoting high-level political commitment and whole government, whole society approach, which could strengthen cross-sectoral coherence and mobilisation;
- (b) providing an opportunity to enhance, update and strengthen the leading and coordinating role of WHO and its function to act as the directing and coordinating authority on international health work;
- (c) creating constituency support for the new instrument and its goals for pandemic preparedness and response;
- (d) fostering confidence by State Parties to mutual high-level commitments to pandemic preparedness and response;
- (e) anchoring all the principles found in the WHO Constitution (Preamble), including the principle of non-discrimination and the right to the enjoyment of the highest attainable standard of health;
- (f) addressing equitable access to countermeasures such as vaccines, therapeutics and diagnostics; a new agreement would be the most appropriate global process to consider and agree how to improve equity in the future and this could be done by including a framework for concrete measures and long-term mechanisms to develop, manufacture and scale up new countermeasures, and improve equitable access to existing countermeasures, including through increasing local production and strengthening regulatory systems;
- (g) sharing of data, samples technology and benefits; this should be included in a multilateral framework for sharing surveillance and monitoring data, genetic data and pathogens, with an agreement on how the benefits derived therefrom should be shared; this includes mechanisms to facilitate research and rapid sharing of technology to ramp up regional production and distribution of countermeasures, cognisant of ongoing discussions and negotiations in other fora;
- (h) reducing the risks posed by emerging diseases of zoonotic origin in the future and enhancing the ‘One Health’ approach, including targeted elements specifically aimed at reducing the risks posed by zoonotic diseases in future, strengthening existing platforms and surveillance, furthering multi-sectoral partnerships (human, animal and environmental health sectors), and promoting specific countermeasures in line with the ‘One Health’ approach; as well as
- (i) strengthening health systems and their resilience, through strengthening primary health care service, healthcare workers and achieving universal health coverage.

In addition, an important number of Member States have also expressed their support to strengthen the IHR, including through implementation, compliance, and potential targeted amendments without re-opening the entire instrument for negotiations.

On this basis, the WHO Member States Working Group concluded, in its report to the special session of the World Health Assembly, that “the way forward should include a process or processes for: i) developing a WHO Convention, Agreement or other international instrument on pandemic preparedness and response, and ii) strengthening IHR (2005), including implementation, compliance support for IHR core capacities and potential targeted amendments to the IHR”. The negotiation process would thus include both the negotiation of

a legally-binding agreement on pandemic preparedness and response, as well as a set of complementary amendments to the IHR.

The present recommendation is therefore addressed to the Council in connection with the special session of the World Health Assembly of 29 November to 1 December 2021.

- **Consistency with existing policy provisions in the policy area**

The proposed recommendation is in line with the existing Union legal framework on serious cross-border health threats, as currently set out under Decision No 1082/2013/EU⁹.

In addition, from the outset of the COVID-19 pandemic, the Union has put in place a set of measures and coordination to support Union Member States in tackling the pandemic and to strengthen the resilience of their health systems. The proposed recommendation is in line with the following measures taken at Union level and aims at complementing them by establishing a strong international framework for cross-border threats with pandemic potential:

- In June 2020, the Commission presented a common EU Vaccines Strategy¹⁰, which enables the support and speeding up of development and manufacturing at scale. This approach has ensured access to COVID-19 vaccines for all Union Member States, as well as exports to more than one hundred fifty countries worldwide.
- On 11 November 2020, the Commission laid the building blocks of a European Health Union by adopting a proposal for a regulation on serious cross-border threats to health, a proposal to extend the mandate of the European Medicines Agency and a proposal to extend the mandate of the European Centre for Disease Prevention and Control¹¹. Drawing on the lessons learned from the current crisis, these proposals aim to strengthen the Union's resilience to health threats and to ensure enhanced preparedness and response during the current and future health crisis.
- Adopted on 25 November 2020, the Pharmaceutical Strategy for Europe¹² also builds on the weaknesses exposed by the COVID-19 pandemic and presents appropriate actions to adapt the EU pharmaceuticals system in the years to come. It aims at creating a future proof regulatory framework and at supporting industry in promoting research and technologies that reach patients in order to fulfil their therapeutic needs while addressing market failures.
- On 6 May 2021, the Commission adopted a Union Strategy for the development and availability of COVID-19 therapeutics¹³, which complements the EU Vaccines Strategy. The Union Strategy for the development and availability of COVID-19 therapeutics covers the full lifecycle of medicines, from research, development and manufacturing to procurement and deployment. It includes clear actions and targets, including authorising at least three new therapeutics by the end of 2021.
- On 16 September 2021, the Commission launched the new European Health Emergency Preparedness and Response Authority¹⁴ to strengthen Europe's ability to prevent, detect, and rapidly respond to cross-border health emergencies, by ensuring

⁹ Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC, OJ L 293, 5.11.2013, p. 1

¹⁰ COM/2020/245 final, 17.6.2020.

¹¹ COM/2020/727 final, COM/2020/726 final, COM/2020/725 final, 11 November 2020.

¹² COM/2020/761 final, 25.11.2020.

¹³ COM/2021/355 final/2, 6.5.2021.

¹⁴ OJ C 393I, 29.9.2021, p. 3-8.

the development, manufacturing, procurement, and equitable distribution of key medical countermeasures.

In addition, the proposed recommendation is in line with the following general objectives of the EU4Health Programme, the new Programme for the Union's action in the field of health for the period 2021-2027, as set out under Article 3(b) and (c) of Regulation (EU) 2021/522 of the European Parliament and of the Council¹⁵:

- “protecting 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;
- Improving the availability, accessibility and affordability of medicinal products and medical devices, and crisis-relevant products in the Union, and supporting innovation regarding such products.”

Close synergies between EU4Health and the Neighbourhood, Development and International Cooperation Instrument¹⁶, as well as the Union Civil Protection Mechanism¹⁷ are essential in this regard.

- **Consistency with other Union policies**

The proposed recommendation is also in line with the following Union policies and actions:

- Climate and environment policies, for the prevention and management of zoonotic risks as part of a “One Health” approach;
- Development and cooperation policies:
 - The Union is providing support to Union neighbouring regions to strengthen their public health systems preparedness and resilience in case of cross-border health threats;
 - The Union worked to establish and support the tools to share vaccines with lower and middle-income countries, the Access to COVID-19 Tools¹⁸ - Accelerator (ACT-A) and COVAX, its vaccines pillar. Team Europe, which involves the European Union, its Member States and financial institutions, remains one of the biggest donors of COVAX, having committed over EUR 3 billion;
 - The Union works with its industrial partners to make vaccines available for low and middle-income countries in 2021 and 2022, and Member States are sharing their vaccines via COVAX, but also on a bilateral basis;

¹⁵ Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014, OJ L 107, 26.3.2021, p.1-29.

¹⁶ Regulation (EU) 2021/947 of the European Parliament and of the Council of 9 June 2021 establishing the Neighbourhood, Development and International Cooperation Instrument – Global Europe, amending and repealing Decision No 466/2014/EU and repealing Regulation (EU) 2017/1601 and Council Regulation (EC, Euratom) No 480/2009, OJ L 209, 14.6.2021, p. 1-78.

¹⁷ Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism, OJ L 347, 20.12.2013, p. 924.

¹⁸ <https://www.who.int/initiatives/act-accelerator>.

- The Union offers humanitarian assistance¹⁹ to populations affected by health crises, including disease outbreaks, through field operations and to countries in need of assistance under the Union Civil Protection Mechanism by bringing medical supplies to people in hard-to-reach areas. The Union also supports partners by contributing to vaccination strategies, the procurement and the distribution of supplies;
- The European Commission, in cooperation with several Member States is pursuing an initiative with African partners to develop the production and access to vaccines, medicines and health technologies in Africa²⁰.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

The procedural legal basis for the proposed decision is Article 218(3) and (4) of the Treaty on the Functioning of the European Union (TFEU).

Article 218(3) of the TFEU provides that the Commission shall submit recommendations to the Council, which shall adopt a decision authorising the opening of negotiations and nominating the Union negotiator. According to Article 218(4) of the TFEU, the Council may address directives to the negotiator and designate a special committee in consultation with which the negotiations must be concluded.

The substantive legal basis will be considered at a later stage once more information is available: i) on the scope and content of the international agreement on pandemic preparedness and response, and ii) on the scope and content of the complementary amendments to the IHR.

• Subsidiarity (for non-exclusive competence)

Although its exact scope is not yet known, the envisaged international agreement is intended to address serious cross-border health threats with pandemic potential. It will therefore have an impact on the exercise of Union competences, and on Union legislation in areas such as health, environment, trade, free movement, data protection, internal market, development cooperation, all of which might become relevant under the envisaged agreement.

Although there is no decision yet on the provisions of the IHR that may be amended, it is likely that such amendments would have an impact on the EU legal framework on cross-border health threats, as set out under Decision 1082/2013.

In view of the above and the likely affectation of the existing Union legislation in different areas of the Union's action, it is essential that the participation of the Union in the future negotiations and resulting international agreement is assured.

• Proportionality

Strengthening health systems and the international preparedness for – and response to – future pandemics is a top priority for the EU and is clearly in the interest of the Union.

¹⁹ European Consensus on Humanitarian Aid (2008/C 25/01) and Council Regulation (EC) No 1257/96 on humanitarian aid, OJ L 163, 2.7.1996, p. 1 – 6.

²⁰ Press release of 21 May 2021, “€1 billion Team Europe initiative in Africa (europa.eu)”.

A Council Decision is necessary to authorise the opening of negotiations by the Union on an international agreement on pandemic preparedness and response, as well as on complementary amendments to the IHR if so is decided.

The proposed recommendation does not go beyond what is necessary for achieving the objectives pursued, in accordance with Article 5(4) of the Treaty on European Union.

- **Choice of the instrument**

The choice of the instrument is stipulated in Article 218(3) and 218(4) of the TFEU.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

Not applicable

- **Stakeholder consultations**

Not applicable

- **Collection and use of expertise**

Not applicable

- **Impact assessment**

Not applicable

- **Regulatory fitness and simplification**

Not applicable

- **Fundamental rights**

According to Article 35 of the Charter of Fundamental Rights of the European Union, a high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.

The proposed recommendation seeks authorisation for the opening of negotiations with a view to strengthening health systems and the international preparedness for and response to future pandemics. This would positively impact the right for a high level of human health protection, as enshrined in Article 35 of the Charter of Fundamental Rights of the European Union.

4. BUDGETARY IMPLICATIONS

The opening of negotiations for an international agreement on pandemic preparedness and response and the possible complementary amendments to the IHR are not deemed to have a budgetary impact.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

Preparatory work and negotiations are expected to start soon after the special session of the World Health Assembly of 29 November to 1 December 2021. A preliminary phase may be envisaged.

- **Detailed explanation of the specific provisions of the recommendation**

The Commission recommends that:

- The Council authorise the Commission to open and conduct negotiations for the conclusion of a new international agreement on pandemic preparedness and response, as well as on complementary amendments to the IHR if so is decided;
- The Commission be nominated as Union negotiator;
- The Commission conduct the negotiations in consultation with the special committee if designated by the Council in accordance with Article 218(4) TFEU;
- The Council approve the negotiating directives annexed to this recommendation.

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THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty in the Functioning of the European Union, and in particular Article 218(3) and (4) thereof,

Having regard to the recommendation from the European Commission,

Whereas:

- (1) The special session of the World Health Assembly of 29 November to 1 December 2021 was called by the World Health Organization (WHO) Decision WHA74(16) of 31 May 2021 to consider the benefits of developing a WHO convention, agreement or other international instrument on pandemic preparedness and response with a view towards the establishment of an intergovernmental process to draft and negotiate such a convention, agreement or other international instrument on pandemic preparedness and response,
- (2) The Union, should participate in the negotiations on such convention, agreement or other international instrument, as well as on complementary amendments to the International Health Regulations (2005) (IHR),
- (3) The negotiations will take place in the context of the WHO,

HAS ADOPTED THIS DECISION:

Article 1

The Commission is hereby authorised to negotiate on behalf of the Union an international agreement on pandemic preparedness and response, as well as complementary amendments to the IHR within the framework of the decisions taken during the special session of the World Health Assembly of 29 November to 1 December 2021.

Article 2

The negotiating directives are set out in the Annex.

Article 3

The negotiations shall be conducted in consultation with the [name of the special committee to be inserted by the Council].

Article 4

This Decision is addressed to the Commission.

Done at Brussels, 1.12.2021

*For the Council
The President*



Brussels, 1.12.2021
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ANNEX

DOWNGRADED on 6.12.2021

ANNEX

to the

Recommendation for a Council Decision

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ANNEX

DIRECTIVES FOR THE NEGOTIATION OF AN INTERNATIONAL AGREEMENT ON PANDEMIC PREPAREDNESS AND RESPONSE AS WELL AS FOR THE NEGOTIATION OF COMPLEMENTARY AMENDMENTS TO THE INTERNATIONAL HEALTH REGULATIONS (2005)

Within the framework of the intergovernmental process set out in the Decision SSA2/CONF./1Rev.1 of the Special session of the World Health Assembly (WHA) of 29 November to 1 December 2021, which provides a globally inclusive negotiating forum, the Commission will aim at negotiating an international agreement on pandemic preparedness and response¹ (hereinafter “Pandemic Agreement”). The Commission, on behalf of the European Union, shall endeavour to achieve a comprehensive negotiated outcome, which encompasses the objectives and principles outlined below, drawing on the lessons learnt during the COVID-19 pandemic, and in view of preparedness for possible public health emergencies in the future.

The Pandemic Agreement, which should complement the International Health Regulations (2005) (hereafter referred as IHR), will set out substantive, legally-binding obligations for its Parties aimed primarily at:

- preventing and controlling;
- detecting and reporting; and
- preparing for, and responding to pandemic threats.

The substantive obligations should be framed, including in the Pandemic Agreement’s preamble, by a series of general objectives and principles, such as the right to enjoyment of the highest attainable standard of health, international solidarity, equitable access to pandemic countermeasures (e.g. personal protective equipment, access to vaccination, therapeutics and diagnostics, medical and social care services), “One Health” approach, the need to address the close links between human, animal and environmental health, and the centrality of multilateral cooperation and the WHO in the global health governance.

The Pandemic Agreement should also include provisions setting out:

- the institutional framework;
- rules on further rule-making;
- monitoring and accountability mechanisms;
- “whole of government”/cross sectorial preparedness approaches leading to better mobilisation of all competencies and resources and coherence in pandemic prevention and response; and
- technical assistance and capacity building for implementation.

In particular, an effective Pandemic Agreement will require significant investment in implementation support. This should include:

- Strengthening WHO’s ability to support national and regional core health system capacities for pandemic prevention, preparedness, detection and response;
- Strong technical assistance and capacity building for low and lower middle income countries aimed at:

¹ This designation denotes an agreement within the meaning of Article 2.1(a) of the Vienna Convention on the Law of Treaties and is without prejudice of the name that the agreement signatories will ultimately chose, e.g. convention, treaty or agreement.

- the effective implementation of Pandemic Agreement and related IHR commitments;
- the improvement of national and regional mechanisms for pandemic prevention, detection, preparedness, and response (including inter-agency and inter-sectoral coordination mechanisms); and
- the improvement of the health systems capabilities in the area of pandemic preparedness and response, including by increasing health and social care workforce capabilities to prevent, detect and respond to public health emergencies with pandemic potential, as well as developing and deploying digital health and social care tools.

The Pandemic Agreement should aim at laying down substantive provisions and commitments especially in the key areas indicated above, while also charting the course for future negotiations, including by means of supplementary protocols. Legally binding provisions may be complemented by non-binding provisions (such as guidelines, standards and declarations).

All United Nations Member States and regional (economic) integration organisations should be allowed to become parties of the Pandemic Agreement or any of its protocols. Specific arrangements for cooperation with relevant international organisations and non-governmental stakeholders should also be set out.

In the light of the urgency of the subject matter of the Pandemic Agreement, the possibility of its provisional application, pending ratifications, should be envisaged so as to initiate implementation of the Pandemic Agreement's provisions as early as possible.

Transitional periods for implementation by low and lower middle-income countries and related implementation support should also be provided for.

The objectives of pandemic preparedness and response pursued through the Pandemic Agreement may require complementary amendments to the IHR. Such amendments should aim at clarifying and strengthening existing IHR provisions and increasing their effective implementation, while ensuring complementarity and compatibility between such amendments and the provisions of the Pandemic Agreement.

The Commission will represent the Union in the inter-governmental negotiating body in charge of developing a Pandemic Agreement, as set out in the WHA Decision SSA2/CONF./1Rev.1, and any preparatory or related body, as well as in the work of the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies related to the development of IHR complementary amendments to strengthen the IHR, and their subsequent negotiation.

The Commission should endeavour to ensure that the Pandemic Agreement and any possible complementary amendments to the IHR are consistent with relevant Union legislation and policies, as well as the Union's commitments under other relevant multilateral agreements.

The Commission should conduct negotiations in accordance with relevant Union legislation in force.