To the Council of the European Union

The Spanish Presidency of the Council of the European Union The Member States of the European Union

To the European Commission

Stella Kyriakides, Commissioner "Health"

30th of November 2023

Open letter: EU negotiating position on the WHO Pandemic Agreement

As Members of the European Parliament, we call on the EU to ensure that the Pandemic Agreement currently being negotiated at the World Health Organization (WHO) includes concrete, binding and enforceable equity measures to realize the right to health for all.

While the EU is recovering from the COVID-19 pandemic, it is increasingly likely that similarly extreme health crises will occur more frequently in the future. We have taken various actions under the European Health Union to better prevent, prepare for and respond to them. Further initiatives are underway to effectively protect the health and lives of EU citizens, such as the revision of the pharmaceutical and patent framework, based on the principles of availability, accessibility and affordability, which aims to increase member states equitable access to medicines.

Commissioner Kyriakides stressed the importance of equity, saying: "Where you live should not determine whether you live, or whether you die". ⁵ This, however, cannot be true only within the EU. All lives matter equally, and viruses know no borders. Therefore, it would be counterproductive and hypocritical for the EU to protect the right to health in its own borders while failing to support the means to realise it elsewhere.

In this spirit, we are writing to express our concerns about the EU's negotiating position on the WHO Pandemic Agreement. These negotiations offer a key opportunity to agree on a pathway to effectively and equitably address future pandemics. However, while the EU claims that "the lessons

¹ https://www.gavi.org/vaccineswork/new-study-suggests-risk-extreme-pandemics-covid-19-could-increase-threefold-coming

² https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union/health-crisis-preparedness en

³ https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation en and https://ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe/reform-eu-pharmaceutical-legislation en and https://ec.europa.eu/commission/presscorner/detail/en/ip 23 2454

⁴ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0761

⁵ https://ec.europa.eu/commission/presscorner/detail/en/SPEECH 23 2465

from the COVID-19 pandemic (...) point to the need for a renewed approach to global health...", 6 its position does not go beyond existing structures and policies perpetuating global inequalities.

It proposes to continue relying solely on voluntary measures in the deployment of key public health interventions, such as the transfer of technology, know-how and "trade secrets", or the removal of intellectual property barriers. In the meantime, the EU avoids specific commitments for equitable access to pandemic products. It also does not include the key recommendations of the European Parliament's report on the COVID-19 pandemic, adopted in June 2023 such as attaching conditions to public funding for research and development (R&D).⁷

After nearly two years of negotiations, the new draft of the WHO Pandemic Agreement released by the Bureau of the Intergovernmental Negotiating Body (INB) on 16 October 2023, fails to include critical equity measures by using ambiguous language, suggesting that decisions on their final form should be delayed or omitting them altogether.⁸

The EU's stated principle of equity cannot be merely aspirational and for the Pandemic Agreement to fulfil its ambitions, it must comprehensively address all relevant issues. In the rationale for its position, the EU cautioned against including provisions in the Pandemic Agreement that will "merely be beautiful words on paper." It is time to move beyond the rhetoric.

As the negotiations progress, we call on you to constructively engage with all WHO Parties to significantly improve the draft negotiating text by supporting the measures outlined in the annex below.

Yours sincerely,
Tilly METZ MEP
Michèle Rivasi MEP
Rosa D'amato MEP
Sarah Matthieu MEP
Margrete Auken MEP
Ville Niinistö MEP
Jutta Paulus MEP
François Alfonsi MEP
Benoît Biteau MEP

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https://www.eeas.europa.eu/sites/default/files/documents/2023/EU%20proposals%20integrated%20into%20the%20ZD% 2020%20April.pdf

⁷ https://www.europarl.europa.eu/doceo/document/A-9-2023-0217_EN.html

⁸ https://apps.who.int/gb/inb/pdf files/inb7/A INB7 3-en.pdf

Damien Carême MEP

David Cormand MEP

Gwendoline Delbos-Corfield MEP

Karima Delli MEP

Claude Grufat MEP

Caroline Roose MEP

Mounir Satouri MEP

Marie Toussaint MEP

Lydie Massart MEP

1. Enforceable measures, concrete mechanisms and clear commitments and obligations

The draft negotiating text of the WHO Pandemic Agreement addresses various critical areas to ensure equity in preventing, preparing for, and responding to future pandemics. However, due to the weak language of the proposed provisions, it is unlikely to bring about a significant change in the status quo.

For example, while the need to develop multilateral mechanisms for technology and know-how transfer or even the importance of sharing "trade secrets" to scale up production are recognised in Article 11, the language calling for the "promotion" of such measures and limiting them to "mutually agreed terms as appropriate" makes them merely aspirational, and their practical application highly uncertain. Similarly, while the draft text includes a provision on the waiver of intellectual property, it leaves its adoption dependent on each Party's discretionary decision as to whether it is "necessary", effectively making no change to the current system. What is more, limiting such a waiver only to pandemic times is detrimental to building equitable prevention and preparedness capacity, and enabling rapid and effective response.

The obligations in the draft text are mostly limited to vague cooperation or support commitments, which in practice are "best endeavour" clauses. Meanwhile, specific measures are accompanied by qualifiers and other limiting language. Their use should be minimised, and "encouragements" to adopt equity provisions transformed into obligations.

2. Public health interventions not dependent on the goodwill of pharmaceutical companies

The draft text proposes that key public health interventions such as those listed in Article 10, including licensing intellectual property rights, sharing technology and know-how or limiting royalties for their use, should be based on pharmaceutical companies' willingness to engage in them.

Relying on voluntary agreements – which are often very limited, ad hoc and late – leave decision-making power in the hands of rights holders. This is not a sound public health policy. It also contradicts the Pandemic Agreement's objective to ensure that people in the global South never again have to rely on the goodwill or charitable acts of the private sector to access life-saving products.

In this light, the EU's stance that any transfer of technology and know-how or removal of intellectual property barriers should take place solely on voluntary and/or mutually agreed terms should be reversed.

3. Fair and equitable access and benefit-sharing system

The draft text includes provisions for access and benefit sharing on an equal footing but fails to oblige companies developing pandemic products based on information received under the proposed system to anything beyond allocating 20% of their production on a need base and monetary contributions to an undetermined extent.

Medical technologies related to pathogens with pandemic potential must be treated as global common goods and the PABS System should ensure that they are allocated to all who need them at the same time, equitably in sufficient quantity, rather than limiting this to a small percentage.

The Pandemic Agreement should also oblige, and not just "encourage" as is currently the case, companies that develop pandemic products under the PABS System to transfer technology and know-how (along with "trade secrets") to all capable manufacturers in order to maximise global production and supply.

Here, too, however, the EU's position takes the opposite direction. While committing countries to surveillance and rapid information sharing, it limits their obligations related to benefits by suggesting that they "make all possible efforts to ensure" that companies reserve a percentage of their production for sale to low- and middle-income countries. In this way, the EU avoids any commitments to equitable access and protects the ability of pharmaceutical companies to maintain control over technologies and ultimately the global supply of medicines and vaccines in future pandemics.

4. Agreeing on specific measures under the Pandemic Agreement

The draft text suggests delaying agreement on some important but potentially controversial measures after the adoption of the Pandemic Agreement. This is unnecessary risk that can undermine its effectiveness as a tool for equitable preventing, preparing for and responding to future pandemics. Negotiations should aim to resolve difficult issues, not avoid them.

The delayed topics include shaping the details of the standard material transfer agreement (SMTA) under the PABS System and a mechanism for fair and equitable allocation of pandemic products in Article 12. Similarly, the draft text proposes leaving mechanisms for technology and know-how transfer under Article 11 to be worked out by the Conference of the Parties at an undetermined time.

Delaying agreement on such key practical aspects carries a high risk that they will not be developed in a timely and adequate manner to be ready for the next pandemic.

5. Strict conditions on public funding for research and development

Attaching conditionalities to public funding of research and development (R&D) is essential to ensure the transfer of technology, know-how and "trade secrets" and removing intellectual property barriers – three essential ingredients enabling local production. Conditionalities should also include the important issues of transparency on the availability of pandemic products, allocation and pricing. It is therefore of great concern that the draft text leaves out many of such provisions that were included in the zero draft.

Importantly, the EU proposal, despite the substantial investment by the Union and member states in medical innovation, is silent on access conditions.

In order to operationalise the equity principle, the EU should support the obligation to attach to all public funding agreements strict conditions on fair allocation of products globally, affordable pricing with full transparency on R&D costs, transfer of technology, know-how and "trade secrets", and sharing of intellectual property rights, where applicable.

Moreover, although Article 9.4 of the draft text includes an obligation to publish their terms, it is limited by leaving it to the governments' discretion to determine whether the "extent of public funding" justifies such action.

To increase trust, accountability and equitable access, and to improve Parties' negotiating position, transparency requirements should be maintained at a high level, regardless of the extent of public funding.

6. Expanding manufacturing capacity in the global South

Diversified global manufacturing is one of the key elements to ensure equitable access to affordable pandemic products. However, this objective will not be achieved if expanding production capacity is limited to private-sector cooperation and the construction of satellite facilities of pharmaceutical companies that continue to determine products' production, price and allocation.

For example, while the Team Europe Initiative on manufacturing and access to vaccines, medicines and health technologies in Africa (MAV+) entails supporting industrial development, market shaping and technology transfer, it remains unclear whether these measures will effectively empower African countries or merely expand the market for EU industry.

Sustainable production and supply require investing in independent national or regional capacity and the Pandemic Agreement should include measures guaranteeing that global South governments have the freedom to control the technology, are able to adapt it to local needs, and are in charge of distributing the end products. The issue of decision-making power should therefore be explicitly addressed in Article 10 to ensure that financial support and cooperation contribute to increasing publicly controlled manufacturing capacity.

7. Supporting developing countries through common but differentiated responsibilities

EU member states, along with other developed countries, should commit to adequately supporting developing countries in meeting their obligations under the Pandemic Agreement. This should be done in recognition of differences in levels of economic development, capacity and resources among countries.

While the draft text in Article 3 replaced the reference to common but differentiated responsibilities with the principle of "recognition of different levels of capacity", it failed to sufficiently operationalise it in subsequent provisions.

Language on greater responsibilities of better-resourced governments towards developing countries should be strengthened to include their specific, binding commitments on issues such as financing, technology transfer, R&D cooperation or establishing and improving diversified production.

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