European Union

Statement

WHO

152nd Executive Board

(30 January - 7 February 2023)

_____

Item 12.1 - Strengthening WHO preparedness for and response to health emergencies: Strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination

_____

Geneva, 4 February 2023

WHO

152nd Session of the Executive Board

Item 12.1 - Strengthening WHO preparedness for and response to health emergencies: Strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination

EU Statement

Chair,

Director-General,

Excellencies,

Colleagues,

This statement is made on behalf of the EU and its Member States.

The candidate countries North Macedonia, Montenegro, Serbia, Ukraine and Bosnia and Herzegovina*, the potential candidate country Georgia as well as Armenia align themselves with this statement.

High quality of clinical trials is essential to guarantee the **safety and efficacy** of novel health technology, such as new medicinal products, medical interventions and devices, entering to clinical practice and to secure the **confidence and trust** of the population in health systems.

* North Macedonia, Montenegro, Serbia and Bosnia and Herzegovina continue to be part of the Stabilisation and Association Process.

Challenges in increasing clinical trials capacities are well described in paragraph 13 of the secretariat's report. No single or easy solution exists. The EU supports following **comprehensive approach** based on a good overview of the multiple dimensions to be addressed.

Firstly, the EU agrees that **regulatory capacity and supervision** is key, including to guarantee the safety of trial participants. A stepwise process should start from countries, which have reached WHO maturity level IV in regulatory capacity. In drafting normative guidance, **harmonization of ethics review and regulatory procedures,** necessary in novel trial modalities, should be taken into account, which is already in progress in the EU.

Secondly, through inter alia the European and Developing Countries Clinical Trials Partnership (EDCTP), the EU is will continue **supporting LMICs intensively in the development R&D capacity**. More LMICs with sufficient regulatory and other necessary capacities will not only enable trials on solutions for **neglected tropical diseases**, emerging diseases and zoonoses, which affect these countries. It will also make the world better prepared to assess in quality clinical trials **long expected innovations to come**, such as new antimicrobials and vaccines against HIV, tuberculosis or malaria.

The Agile Member State Task Force has identified the need to find new sources of income to WHO. Most medical innovations which are proven effective and safe are commercialized. We would like to propose a discussion on making the contribution by WHO to their clinical trials be made **payable to WHO to yield public benefit from public investment**.

The EU would like to ask whether the lessons learned in seeking solutions to communicable diseases through promoting R&D and clinical trials **could be extended to NCDs**.

Chair

As to public health emergencies of international concern, the EU believes that **what works in normal times works also in emergencies**. The COVID pandemic improved collaboration and made innovation faster. On the negative side, only 5 percent of the almost 3000 clinical trial arms with more than half a million participants, were appropriately randomized. Could the percentage have been higher, if systematic, easily accessible normative guidance had been available?

Finally, the EU would propose **further consultation** be organized after the EB on a possible questionnaire on clinical trials capacities.