European Union

Statement

WHO

74th World Health Assembly
(24 May-1 June 2021)

WHA74 - Item 13.4, 13.6, 13.7: Global strategy and plan of action on public health, innovation and intellectual property, Substandard and falsified medical products, Standardization of medical devices nomenclature

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Geneva, 27 May 2021

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Draft EU Statement

Chair,

Director General,

Excellencies,

Colleagues,

I have the honour to speak on behalf of the European Union and its Member States.

The Candidate Countries the Republic of North Macedonia*, Montenegro* and Albania*, the country of the Stabilisation and Association Process and potential candidate Bosnia and Herzegovina, as well as Ukraine, the Republic of Moldova and Armenia align themselves with this statement.

The European Union and its Member States welcome the resolution on the Local Production of Medicines and other Health Technologies to Improve Access. The EU is committed to Universal Health Coverage and increasing the resilience of health systems, including the supply of medicines and other health technologies. The current crisis is demonstrating more than ever the need for medicines

* The Republic of North Macedonia, Montenegro and Albania continue to be part of the Stabilisation and Association Process.

production capacity across the world. The EU is committed to supporting those efforts – and that is why we are delighted to cosponsor this resolution!

In the response to COVID-19, it is essential to ensure timely, fair and equitable access to quality, safe and affordable diagnostics, therapeutics and vaccines as a global public good. Currently, the EU is the largest exporter of COVID-19 vaccines to the world. Further ramping up production throughout the world and along the entire supply chain will be essential to achieve worldwide immunisation.

The EU and its Member States are committed to support the establishment of sustainable manufacturing hubs for health technologies in the global south, in particular in Africa. Therefore, we call on the WTO and the WHO as well as all Member States to promote and facilitate co-operation between health technology developers, manufacturers, and investors. The European Union is committed to support the development of production capacities through an adequate environment by strengthening regulatory frameworks, supporting regional manufacturing hubs, and stimulating the voluntary transfer of technology and know-how as well as research capacity. At the same time, it is crucial to reinforce competitive markets for affordable, high-quality and safe health technologies.

The EU and its Member States value the work of the Member State mechanism on substandard and falsified medical products. The national regulatory authorities have been under substantial pressure in the context of the COVID-19 pandemic. We encourage WHO and Member States to keep an impact-driven

approach to support regulatory institutions to tackle substandard and falsified medical products and to ensure access to quality, safe, efficacious and affordable medical products.

Regarding the Standardization of medical devices nomenclature, the EU and its Member States commend the Secretariat for having responded to the need for continued discussion with key stakeholders on the outcomes of this process by organizing an information session on 12 April and by conducting a series of stakeholder meetings.

The EU has recently published the European nomenclature of medical devices, which is up for consultation and complies with all the requirements of WHO.

We encourage the Secretariat to finalize the development of an international system to harmonise medical devices nomenclature and call on all stakeholders to join forces for making this international nomenclature system as flexible, safe and user-friendly as possible.

Therefore, we strongly advocate to continue this work in a result-oriented manner and are confident that this systematic approach will lead to a solution that can be endorsed by all Member States. Building bridges to harmonise parallel medical devices nomenclature systems is in our common and mutual interest.

Thank you.