European Commission - Speech
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Opening Remarks by Commissioner Stella Kyriakides at the EPSCO Council-Implementation of the Medical Devices Regulation

Brussels, 9 December 2022

Ministers,

The Medical Devices Regulation, adopted by the European Parliament and the Council in 2017 and after more than 4 years of hard negotiations, followed a series of severe scandals that put patient safety at risk and in some cases, caused the loss of lives.

The reasons we had to act as EU back then remain every bit as valid now.

We all knew the transition to the new rules would be challenging, both for Member States and for industry.

Patient safety is always paramount.

The transition to the new rules has been slower than we anticipated. The pandemic, shortages of raw materials caused by Russian war against Ukraine and low notified body capacity has put a strain on market readiness.

Since our discussion in June, with the Member State experts in the Medical Device Coordination Group, we have closely monitored the situation.

The number of notified bodies has increased from 30 in June to 36 today for medical devices and 8 bodies are designated for in vitro devices, one more than in June.

The Medical Device Coordination Group adopted a list of 19 mitigating actions to increase notified body capacity and boost preparedness among manufacturers, without lowering the requirements.

However, all of us here today know that more needs to be done.

Devices covered by around 23 000 certificates issued under the previous Directives have not yet transitioned to that Regulation and will expire by 26 May 2024 at the latest.

Over recent weeks and months, we have listened carefully to national experts, Members of the European Parliament and stakeholders.

We saw the non-paper prepared by France, Germany and Ireland, which was supported by many other Member States.

We are facing a risk of shortages of life-saving medical devices for patients. This this is a risk we cannot take.

I therefore propose to you today that we extend the transition period of the Regulation to mitigate any short-term risk.

This targeted amendment would include staggered deadlines, depending on the risk of each device.

High risk devices would get a new deadline of 2027; medium and low risk devices would be valid until 2028.

Secondly, the extension should be subject to certain conditions. Only devices that are safe should benefit.

Thirdly, we suggest removing the so-called sell-off date of May 2025 to prevent safe medical devices already on the market from having to be discarded.

Provided you agree, this targeted amendment will be on your table beginning of next year.

I believe that this targeted amendment would allow to address the short-term difficulties we face.

I also believe that this must be accompanied by additional measures to address the structural problems of the Regulation we are now seeing.

As a priority, we should develop together solutions on orphan devices, to ensure patients with rare diseases continue to have access to those devices. Together with the dedicated Medical Device Coordination Group taskforce we will continue the work to identify medium and long term solutions.

We must also shape a regulatory environment that fosters innovation and ensures that notified bodies are enabled to focus on the key task at hand, patient safety and less bureaucracy.

In order to promote innovation, a pilot project will be launched early next year to offer scientific advice from the expert panels on medical devices to manufacturers. This will be targeted to manufacturers of orphan and breakthrough devices.

More support to SMEs is also something we will be working on.

I look to you for support to make the co-decision process run swiftly, as any delay would jeopardise the effectiveness of the action.

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