

Mr Jyrki Katainen
Vice-President
Jobs, Growth, Investment and Competitiveness
European Commission
Rue de la Loi 200
B- 1049 Brussels

Brussels, 15 April 2019

Prior via email

Re: Open letter on the implementation and readiness status of the new Medical Device Regulation 745/2017 (MDR)

Dear Vice-President Katainen,

I am writing to you regarding an issue of absolute urgency for patient care across Europe and for the internal market at large. The medical device industry in Europe confirms that without immediate action by the European Commission, the new regulatory system will not be ready on time to ensure continued access of patients and healthcare systems to life-saving and life-transforming devices.

Our industry is prepared to submit product files to comply with the new Medical Device Regulation (MDR). However, we cannot do so. The new regulatory system is not ready to function. The deadline for the system to be fully operational is not 26 May 2020, the date of MDR application as the Commission continues to suggest. The deadline for the system to be ready for our industry to comply is now.

One of the critical concerns is the designation and capacity of Notified Bodies, which the European Commission and Member States are still assessing to the new rules. It is only after being designated that Notified Bodies will be able to start re-certifying and certifying products to the MDR. Notified Bodies will typically take 3-9 months to complete a product re-certification, and it is expected that it will take them even more time for new MDR certification. Tens of thousands of medical devices will have to undergo such a process, and May 2020 is 13 months away.

Furthermore, many product categories in the market, representing additional tens of thousands of devices, will be brought for the first time into the scope of Notified Body supervision. By May 2020, they will require MDR certification before they can continue to be used. At the current pace of preparation, the new regulatory system will not be ready early enough to absorb this extra workload. As of May 2020, thousands of medical devices will become non-compliant and will not be authorized for use by surgeons, doctors, hospitals and patients.

All new medical devices needing certification to access the European market will add on to the two points above. Due to an unavailable new regulatory system (they cannot benefit from the old one), none of these products will be able to be approved to serve the EU healthcare system.

A severe consequence of this is that European start-ups and SMEs, which represent 95% of the medical device industry, are already turning to the United States, China and other regions to develop and roll-out their innovations and bring their related economic activity outside of Europe.

From the 58 existing Notified Bodies designated to operate under the Directives, only 1 has been designated to the MDR – a UK one. DG GROW expects not more than 12 Notified Bodies will be designated by the end of year, 5 months before the deadline! This is way too late, insufficient and gives no guarantee that Notified Bodies would have enough capacity to ensure continued regulatory approval of devices by May 2020.

The new Regulation attempts to provide some relief to the system through a ‘grace period’ and a ‘warehousing’ clause. Unfortunately, since these mechanisms only work for a portion of medical devices currently available, they just partially achieve their initial objective. Please refer to the Annex for details.

This situation is clearly untenable, and time has run out to build a functioning regulatory system. This set of circumstances will profoundly disrupt the medical technology internal market and create yet another significant ‘Cliff Edge’ putting patient safety, healthcare services and EU healthcare environment in a major disarray.

The industry continues to support the implementation of the new regulation as a major step to guarantee patient safety and access to innovative medical solutions to alleviate health conditions in Europe.

Considering this daunting situation, we call upon you, Mr. Vice-President, as responsible for ensuring a functioning EU internal market and temporarily also for public health, to take decisive action. I urge you with utmost speed and urgency, and before the end of this Commission’s mandate, to address this situation and safeguard the continuity of patient care in the region and the sustainability of an SME-driven medical device industry.

Considering the above, I would like to ask you for a meeting to discuss possible solutions on this matter.

Yours sincerely,



Serge Bernasconi
Chief Executive Officer, MedTech Europe

Annex: Explanatory note on the limitations of transitional measures foreseen in the Medical Device Regulations.

Cc:

- Vytenis Andriukaitis, Commissioner for Health and Food Safety via Head of Office - Arūnas Vinčiūnas, European Commission
- Elżbieta Bieńkowska, Commissioner for Internal Market, Industry, Entrepreneurship and SMEs, European Commission
- Antti Peltomäki, Deputy Director-General for Internal Market, Industry, Entrepreneurship and SMEs, European Commission

Annex: Additional Details on Why Contingencies are Needed

There are a couple mechanisms in the Medical Devices Regulation that can provide 'some' relief to the challenges laid out in our letter. This Annex explains why these mechanisms cannot be relied on to provide systemic, EU-wide solutions. Due to the limitations of the mechanisms below, it is essential that the Commission and Member States rapidly develop and communicate more substantial contingencies.

Mechanism #1: The 'grace period' till May 2024

What it is: This mechanism allows Notified Body certificates, issued in accordance with the former Directives (90/385/EEC and 93/42/EEC) prior to 26 May 2020, to remain valid until 27 May 2024. This four-year period is sometimes referred to as the 'grace period,' because it allows certain existing devices to be placed on the market in accordance with the old rules for an extended period. It thereby allows these products to be certified to the new Regulation later-on, spacing out the (re-)certification workload facing the Notified Body system over a longer timeframe.

Why it does not solve the problem: This mechanism is only available to products that already require Notified Body certification under the former Directives. Various 'up-classified' products, such as certain reusable surgical instruments of custom-made implants, are not eligible, and thus need a Notified Body certificate, issued under the new Regulation, to be able to be placed on the market after 26 May 2020. Moreover, even for products that are eligible for the grace period, existing capacity in the Notified Body system, even under the Directives, is extremely strained. On 14 February, the EU body representing Notified Bodies (NB-MED) told the Medical Devices Coordination Group that it would be 'nearly impossible' for Notified Bodies to put all existing certificates through the grace period by 26 May 2020.

Mechanism #2: The 'warehousing' provision

What it is: Under this mechanism, products placed on the market before 26 May 2020, in compliance with the former Directives, may continue to be made available or put into service until 27 May 2025. For instance, manufacturers established in the Union can do this by 'stockpiling' devices to a distributor also based in the Union, who may then legally 'sell off' the devices until 27 May 2025. It is sometimes claimed that this mechanism should be used by manufacturers who cannot find a Notified Body with the capacity to issue them with certificates under the Regulation by 26 May 2020.

Why it does not solve the problem: This mechanism may be legally sound, but it does not offer system-wide solutions, because it is only available to devices that physically exist in the Union. I.e., they were built or assembled within the Union, or they have already cleared Union customs from a third country. For devices with limited shelf lives, stockpiling is impossible due to degrading properties of materials (e.g., plastics which get brittle, medicinal products which lose their strength/efficacy, batteries which lose their capacity, etc.) and because shelf life is connected to time-consuming validation studies. Even for devices with long shelf lives, warehousing until 27 May 2025 would pose extreme practical difficulties which manufacturers could only overcome by taking excessive financial risk. To be cost-effective and competitive, the medical devices industry in general produces at or close to the capacity limit. Both device manufacturers and their component/material suppliers typically produce 'just in time' to keep the stock of finished devices low. Hence, manufacturers may not be able to stockpile more than a few weeks (or at best, months) of product without increasing their production capacity (i.e., finding additional personnel, equipment and production space). To do this, they would need to refinance both their own capacity extension and that of suppliers.