EUCOPE
European Confederation of
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European Commission
DG SANTE
Unit B6 Medical Devices
B-1000 Brussels

IMPLEMENTATION OF MDR AND IVDR: ENSURING FAIR COMPETITION FOR SMES

Dear Ms Ampelas,

I am writing to you on behalf of the EUCOPE, the trade association representing small to medium-sized companies active in pharmaceuticals and health technologies in Europe. Several of our members are developing medical devices and diagnostics products, providing patients in Europe with the most recent and safest health innovation.

Small and medium-sized companies form the backbone of the EU's economy. New discoveries and innovative technologies often come from smaller companies, bringing new products to patients and ensuring a sustainable and competitive European internal market.

With less than four months to go before the application of the Medical Devices Regulation (2017/745) and 28 months before the In Vitro Diagnostics Medical Devices Regulation (2017/746) will fully apply, we would like to express some concerns regarding the current state of implementation of both pieces of legislation and the risk it poses to the sustainability of small and medium-sized companies and, by extension, to the stability of the internal market.

A LEVEL PLAYING FIELD FOR ALL COMPANIES

The Medical Devices Regulation and the In Vitro Diagnostics Medical Devices Regulation aim to improve patient safety with stricter rules for the assessment of devices, based on a risk classification system. Our companies thrive to develop the safest products and therefore fully agree with the guiding principle of the two Regulations.

Both texts will have a profound impact on the way medical devices and diagnostics are reviewed.

- A wide range of health technologies will need to undergo a sound assessment by designated Notified Bodies for the first time or will see their risk category up-classified with the transition to the new Regulations.

- Developers of drug-device combination products will have to follow the provisions set out by Article 117 of the Medical Devices Regulation, adding more administrative burden to their internal process and more workload to the Notified Bodies.

- The same can largely be said for the assessment of diagnostics devices. Most of them will have to undergo the review of a Notified Body for the first time. This assessment will also be accompanied by the involvement of a medicine's authority for companion diagnostics, adding an extra layer of complexity.

This does not come without some concerns for our sector.

As of today (31/01/20), only nine Notified Bodies have received the official designation from the European Commission to operate under the Medical Devices Regulation, while only three have received it for the In Vitro Diagnostics Medical Devices Regulation. These scarcely low numbers are a cause of great concern for our members and for the sector in general.

Will there be enough Notified Bodies to sustain the system? Will the designated Notified Bodies have the capacity to deal with all the requests? We have already heard of complex cases in some Member States where Notified Bodies are refusing to take in requests from new clients.

We are worried the situation leads to **unfair competition for smaller companies, endangering the sustainability of the system and generating delays in innovation, eventually impacting the safety of patients**.

We would like to receive from the European Commission the reassurance that all efforts are and will be made to create the conditions of fair competition between all players and that no company, whatever its size, will be disadvantaged following the implementation of the two Regulations.

Sincerely yours

Dr. Alexander Natz
SecretaryGeneral