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From:	General Secretariat of the Council
To:	Council
Subject:	**Employment, Social Policy, Health and Consumer Affairs Council session on 14 June 2019** Medical devices: Implementation of Regulation (EU) 2017/745 on medical devices (MDR) *- Information from the Irish and German delegations*

Delegations will find in the Annex a note from the Irish and German delegations on the implementation of Regulation (EU) 2017/745 on medical devices (MDR). This note has been prepared to provide information under "Any Other Business" at the session of the Council (EPSCO) on 14 June 2019.

Paper from the Irish and German Delegations

Medical devices: Implementation of Regulation (EU) 2017/745 on medical devices (MDR)

Introduction

The new EU Regulation on medical devices (2017/745/EU) is due to become fully applicable in May 2020. While the Regulation represents a significant overhaul of the existing regulatory framework which has been in place since the early 1990s, it maintains the fundamental "New Approach" principles for the regulation of medical devices.

The new Regulations are essential to improve and strengthen the regulatory system and ensure that patients and public health is protected while at the same time enabling safe access to the newest, most innovative technologies to offer new diagnostic and therapeutic possibilities. Implementation should not be delayed, unless absolutely necessary, but it should also be achieved in an effective, consistent and clear manner.

The Regulation was proposed as a response to:

(i) the Council Conclusions on innovation in the medical device sector from June 2011 and

(ii) the European Parliament Resolution on defective silicone breast implants in June 2012.

This framework aimed to foster the development of safe, effective and innovative medical devices and *in vitro* diagnostic medical devices, for the benefit of European patients, consumers and healthcare professionals. It was considered that new legislation would:

- give patients, consumers and healthcare professionals confidence in the devices they might use every day;
- enable a regulatory environment to bring safe, effective and innovative products to market quickly, safely and efficiently;
- increase the consistency, efficiency and predictability of the EU system for all stakeholders;
- for industry stakeholders, provide greater certainty and confidence to the industry in terms of their continued investment in Europe.

Current Scenario

With full application of the Regulation less than a year away, it seems appropriate, together, to check on our status of preparedness and readiness to implement these new requirements both at Member State and at European level.

Across the EU, an increasing number of discussions are highlighting concern about the challenges facing each stakeholder in the sector (manufacturers, notified bodies, authorised representatives, distributors, competent authorities, European Commission) in implementing these Regulations on time and effectively. Effective implementation serves European patients and health systems and ensures they have access to safe, effective and clinically beneficial medical devices.

Notified Bodies and Capacity Issues

Much of the concern raised to date relates to the availability and capacity of notified bodies for medical devices under the new Regulation. There is undoubtedly huge dedication and commitment from the European Commission and Member States to progress the work on designation. However, based on the number of notified bodies which are expected to be available on time, there will still be significantly fewer notified bodies than currently exist. In addition, data is not available on the capacity these designated bodies will afford the system.

Devices which are certified under the existing legislation can continue to be placed on the EU market under their existing certification up until 2024, however this does not apply for all devices. Specific concerns on the impact of a lack of notified body capacity have frequently been raised in relation to existing devices, which are up-classified or subject to additional regulatory assessments as a result of the new Regulation, for example surgical instruments which are intended to be re-used. The concerns expressed are that these products cannot continue to be placed on the market under their existing Directive certificate up until 2024, like most other existing medical devices and that this will lead to market shortages.

It should also be considered that while the new Regulation on *in-vitro* diagnostic devices (2017/746/EU) has a longer transition timeframe and does not become fully applicable until May 2022 the Regulation represents a more profound change when compared to the existing Directive. In particular, it is anticipated that under the new Regulation over 80% of *in-vitro* diagnostic devices will require assessment and certification by a notified body before being placed on the EU market while today over 80% of such devices are self-declared by the manufacturer and do not require notified body certification.

While notified body capacity is the most imminent and high profile challenge, there are many other challenges across the Regulations. These challenges, at national and EU level, are numerous and often highly technical but include

(i) system requirements,

(ii) infrastructure and

(iii) secondary legislation.

Fundamentally however there is currently a lack of clarity and available guidance on many requirements of the regulation and what the expectations of the regulatory system will be.

Conclusion

It is undoubtedly the case that Member States and the European Commission are fully committed and are dedicating significant work to implementing these Regulations. It is nevertheless important to step back and carry out checks on progress and readiness.

Both Regulations place significant obligations on every party within the sector to ensure there is appropriate levels of expert resource in place to undertake the many activities required of them. In particular, the Regulations significantly increase the expectations on Member State authorities as well as and on the EU Commission to ensuring there is appropriate resource and capabilities available to undertake the required tasks effectively, consistently and in a coordinated manner across Europe.

It is imperative that appropriate levels of resource and infrastructure are put in place in each Member State and at EU level to ensure effective implementation, operation and coordination of the regulatory system. However, the state of preparedness of the regulatory system to implement the new Medical Device Regulation is difficult to appraise without further information from national and European levels.

Suggested Next Steps

1. Member States should immediately consider their state of preparedness for implementation of the new Regulations both at each national level and, along with the European Commission, at European level.
2. Specific and particular challenges should be identified and discussed along with options for solutions to these challenges.
3. Further discussion of this topic should take place between Member States, the European Commission and, if necessary, the European Parliament before the end of 2019.