MEDTECH INSIGHT
CITELINE COMMERCIAL

16 Jan 2024 | **News**

European Member States Call For Direction On Falsified Medical Devices

by Natasha Barrow

Are current regulations sufficient to address the problem of falsified medical devices? A report published by the committee investigating medical product crime uncovered conflicting views among European member states.

The recent report from the Committee of Experts on Minimising Public Health Risk Posed by Falsification of Medical Products and Similar Crimes (CD-P-PH/CMED) confirmed falsified medical devices have been identified across Europe. Yet, there are few investigations and even fewer prosecutions.

Its recently published report aims to raise awareness and encourage concrete action to address the issue, given the extreme lack of data and awareness for falsified medical devices.

When asked if the regulations were sufficient to address the problem of falsified medical devices, respondent countries gave varied and conflicting responses. While some countries simply stated it was "too early" to say, others commented that the regulations are not being used to their full potential.

The Medical Device Regulation (MDR) regulates falsified medical devices in all surveyed countries, however some countries also have additional national regulations in place.

Falsified medicines benefit from well determined requirements and enforcement across legislation, procedures, and responsibilities, specialist medical device consultant Matt Burton highlighted. But for falsified medical devices, "there is a much lower level of rigor applied" despite the same potential risk to patient, Burton concluded.

Falsified medical devices create various issues: not only can they fail to treat or prevent disease, posing significant risk to the patient, but they waste resources and lead to a loss of public

confidence in healthcare providers.

The issue of falsified medical devices is significant and requires urgent attention, as reported by the World Health Organization.

How Does The MDR Regulate Falsified Medical Devices?

Several countries surveyed by the CD-P-PH/CMED indicated that it was "too early to assess whether it [the MDR] was sufficient to address the problem of falsification." Others commented that the EU's regulations were not used to their "full potential".

Tiina Tyni, medical device regulatory specialist, highlights in a *LinkedIn post* the specific articles in the MDR which regulate falsified medical devices:

- Article 2 (9) defines falsified devices;
- Article 7 sets out prohibited false impression claims (i.e. claims that may suggest a product is a medical device when it is not);
- Article 13 and 14 give reporting obligations for importers and distributors for falsified devices, respectively'; and
- Article 93 gives competent authorities the right to take falsified devices off the market to protect public health.

The Unique Identification System (UDI system) and the forthcoming introduction of the European database on medical devices (Eudamed) have been marked as key instruments in the "fight against falsified medical devices", in the MDR and by MedTech Europe, the EU's largest trade association representing medical technology industries.

> ***"The effective functioning of EUDAMED and UDIs is pivotal in the battle against falsified devices. A robust system for identification and traceability is crucial for swiftly recognising and combating the infiltration of counterfeit medical technologies." – MedTech Europe***

Eudamed will give a living picture of the lifecycle of medtech products by integrating electronic systems to collate and process information about medical devices and their companies. The system will allow better access to relevant information by all key stakeholders, including by patients and practitioners, and it will improve coordination between member states and the EU.

Eudamed contains six modules, one of which is related to UDI and device registration.

The UDI allows for clear identification of a specific medical device product. The UDI systems will trace medical devices throughout their lifecycle, enhancing the effectiveness of post-market safety-related activities.

However, Petra Zollner, Medtech Europe's Director of Regulatory Affairs, commented on a *recent LinkedIn post*, authored by Tiina Tyni, that while "transparency and traceability through Eudamed and the UDI will certainly help," these tools cannot solve the issue of falsified devices alone.

MedTech Europe also contested the point that "it was too early" to say whether the MDR sufficiently addresses falsified medical devices, stating that "while MDR is no longer a new law, it is too early to tell if this framework will be sufficient for tackling the issue of falsified devices until we have experience with a fully operational and populated Eudamed.''

MediCrime Convention: Coordination Between European Member States

Three of the respondent countries indicated that the *MediCrime Convention* is also used to regulate falsified medical devices.

However, nine out of twenty-two respondent countries have actually ratified the MediCrime Convention. CD-P-PH/CMED reported this indicated a lack of awareness of the MediCrime Convention, that needed to be improved.

The MediCrime Convention is the first international treaty against counterfeit medical products involving threats to public health.

It lays down the framework for national and international co-operation between competent health authorities and the police, creating measures from crime prevent and prosecution.

Fragmented National Regulation For Falsified Medical Devices

A selection of the surveyed countries also had national regulations in place to support the MDR/IVDR in the regulation of falsified medical devices.

For example, the response from Sweden referred to the General Product Safety Regulation, while the UK referred to the Consumer Rights Act, Consumer Protection Act and Fraud Act. The UK commented that the Fraud Act was often used as the legal instrument to prosecute for falsified medical devices over medical devices legislation.

Notably, the national legislation mentioned by the different member states was not sectoral legislation exclusive to falsified medical devices, rather vertical legislation intended to regulate different sectors.

Even with additional regulations in place, some countries commented that their current regulations did not cover the topic of falsified devices in enough detail.

Romania commented "a chapter would be necessary" to develop the topic. While France called for more specific guidance and coordination at European level.

This lack of regulatory detail manifests itself in operational challenges. Manufacturers don't know how, and where, to report falsified medical devices, noted consultant Matt Burton.

Adding to this, Burton explained that when he approached BfArM, the German national authority, with an incident relating to falsified devices, they reverted them to Ministry of Social Affairs, Health, Integration and Consumer Protection (Ministerium für Soziales, Gesundheit, Integration und Verbraucherschutz, MSGIV), "which appears to be a more general health department" he concluded.

The CD-P-PH/CMED also noted many countries lacked systems for reporting.

They asked member states if they used EDQM (European Directorate for the Quality of Medicines & HealthCare) KnowX database, a tool for sharing knowledge on falsified medical devices. However only one out of the nineteen respondents had heard of it.

> ***"Combating the cross-border nature of falsified medical technology requires a coordinated and collaborative approach. Strengthening intelligence-sharing among stakeholders is essential to curbing the proliferation of counterfeit devices, emphasising the need for a united front against this global challenge." - MedTech Europe***