EVERSHEDS SUTHERLAND

Life Sciences

Covid-19 and latest impacts on medical devices industry

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Implications of Covid-19 on the medical device industry

The current Covid-19 pandemic has numerous direct consequences for the medical device industry. A number of these consequences are already beginning to have an impact on the industry, for example, some Notified Bodies have already closed down or are restricted in their activities. They no longer conduct on-site audits, and authorities are affected similarly. Medical device companies and production sites have to adapt their ways of working due to the pandemic, with a number of suppliers shutting down production, and others are unable to meet the increase in demand.

The pandemic has also impacted the start of the upcoming **Medical Device Regulation (EU) 2017/745 (MDR)**. Scientists and engineers who have been working on the new MDR framework for the last few years have now switched their attention to coronavirus research, and combat teams, research institutions and industry players are building up additional research and production capacities to meet the increased demands.

Medical devices

Medical Device Regulation (MDR) postponed

Given these impacts, on 25 March 2020 the European Commission announced that it intends to postpone the **Medical Device Regulation (MDR)** application date for one year from May 2020 to May 2021. The decision was reached with patient health and safety as a guiding principle.

This decision at least relieves the pressure from national authorities, so-called Notified Bodies, manufacturers, and other industry players as it allows them to focus on urgent priorities related to fighting the Covid-19 pandemic.

This raises several questions:

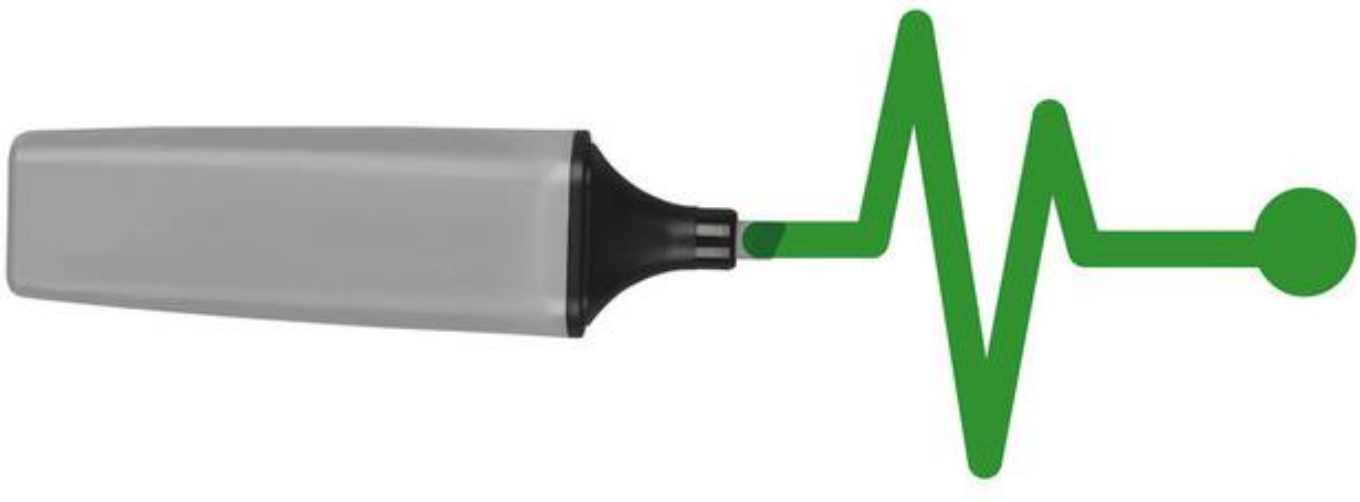
- will there be transition periods;
- what are the implications on local implementing acts; and
- do manufacturers have to adhere to the MDCG (Medical Device Coordination Group) guidelines?

The European Commission has stated that work on a proposal to postpone the application for the MDR is ongoing and it intends to submit this proposal in early April for the Parliament and the Council to adopt it quickly, as the current date of application is 26 May 2020.

In Vitro Diagnostic Regulation

There is however no similar decision for the **In Vitro Diagnostic Regulation (EU) 2017/746** (yet). Although this Regulation has a longer implementation time, diagnostic manufacturers and authorities must prepare for major changes and requirements to adapt to the new framework as well. Their current capacity is also focused on the task of keeping critical diagnostic tests available, despite the challenges the pandemic is creating for both production and distribution.

The industry has welcomed the decision to postpone the MDR and requests a similar approach for the In Vitro Diagnostic Regulation.



Medical devices and PPE

Placing on the EU market with no CE marking

Covid-19 has significantly increased the demand for protective equipment, such as face shields, mouth and nose protection masks, protective clothing and gloves.

Such products qualify as protective personal equipment (PPE) or as medical devices, dependant on the individual product's purpose. In any case however, placing such product on the EU market in general requires a lengthy conformity assessment procedure and obtaining a CE marking that demonstrates conformity with regulations based on the positive results from such procedure.

In order to adapt the availability of protective products, whether medical devices or PPE, as quickly as possible to the increasing demand, the European Commission simplifies their market access with its Recommendation (EU) 2020/403 dated 13 March 2020. The European Commission calls on the competent market surveillance authorities and so called Notified Bodies to take all measures available to ensure that healthcare professionals receive equipment with a high level of protection for the duration of the pandemic.

For the assessment of marketability of protective equipment without CE marking in connection with the spread of Covid-19 of, **for Germany**, the Federal Ministries of Labour and Social Affairs and Health recommend as follows:

In order to cope with the current situation and in view of limited production quantities of goods such as face shields, surgical masks, gloves and other protective equipment as listed in the annex to the official recommendation, it is urgently necessary to purchase these goods at the place of manufacture/provision and import them into Germany, even if they do not bear a CE marking. Such products are considered to be marketable in Germany, if they would be marketable in the US, Canada, Australia or Japan - even without CE marking, declaration of conformity and instructions for use in German language. For products that are marketable outside the aforementioned countries, the marketability in Germany must be checked by competent authorities.

According to this, PPE and medical devices may be placed on the market without CE marking temporarily and in individual cases. Medical device companies must now consider and discuss with their competent authorities and Notified Bodies whether their products may benefit from the market access simplification measures. In addition, manufacturers should ensure that the use of the equipment is understood by its users and explain the manuals, or train users on the equipment so that they are used safely.

European Standards and other technical documents available for free

In line with the above measures and upon request by the European Commission, the European Standardization Organisations CEN and CENELEC, with support by all members including the German organisation DIN (*Deutsches Institut für Normung*), decided to make a number of European standards and technical documents for medical devices and PPE such as masks, medical gloves and protective clothing available free of charge until further notice in order to support the fight against Covid-19. This measure shall help companies wanting to switch product lines to manufacture urgently needed equipment at short notice. Interested companies and organisations can download the standards online.

Export requires authorisation

In order to meet the high demand for PPE and protective medical devices in the EU, the European Commission has, by its Regulation (EU) 2020/402 dated 14 March 2020, temporarily put the export of certain products subject to authorisation.

An export authorisation is granted in individual cases only. These newly introduced export restrictions are difficult for companies contractually obliged to supply products covered by this Regulation to third countries. Exports of medical protective equipment from the EU to the EFTA states Switzerland, Liechtenstein, Norway and Iceland are exempt from the export authorisation requirement (in force in Germany 21 March 2020).

Companies are recommended to consider applying for such an export licence and, if not, what legal and/or commercial possibilities exist to deal with the export ban and existing business relations with its partners.

Protective and safety clothing - voluntary supply

In Germany, the responsible Federal Ministry of Health decided to carry out the tender of contracts in the so-called open house procedure from the end of March 2020. It accepts all supplies that meet the required specifications and are transported to the named place of delivery at a fixed price.

Details on prices, specifications etc can be found here:

https://ted.europa.eu/udl?uri=TED:NOTICE:147548-2020:TEXT:EN:HTML&src=0

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