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HEALTHCARE AND LIFE SCIENCES

EU-WIDE SIMPLIFICATIONS FOR PRODUCTS RELEVANT TO THERAPY – MDR POSTPONED TO 26 MAY 2021

Medical ventilators, facemasks, protective coveralls, eyewear protection - procuring these products rapidly is vital to treating the sick and containing the coronavirus. The EU Commission has already recommended that Member States issue permits for urgently needed products that, by way of derogation, enable them to be placed on the market without a conformity assessment. On 3 April, the Commission published a draft regulation postponing the entry into force of the new Medical Devices Regulation 2017/745 by one year to 26 May 2021: for the medical technology industry, this regulation is complex. The notified bodies and the market surveillance authorities are to use all measures available to them to meet the increased demand for personal protective equipment (PPE) and medical devices throughout the EU market. Germany's Federal Office for Chemicals has also issued derogations for the manufacture and sale of hand disinfectants. Nevertheless, the adage "Necessity knows no law" – often quoted in crisis situations – does not apply here. According to the new provisions, no corners are to be cut when it comes to product safety and quality. Customs duties will also be dropped on imports of these products into the EU by State bodies or aid agencies.

High level of protection for PPE and medical devices

The regulatory requirements around the design, manufacture and placing on the market of medical devices and personal protective equipment ("PPE") are largely harmonised in the European Union on the basis of provisions including the Medical Devices Directive (Directive 93/42/EEC), replaced by the Medical Devices Regulation (Regulation (EU) 2017/745), and the PPE Regulation (Regulation (EU) 2016/425), all of which go to ensure that the same basic health protection, safety and performance standards apply across the European internal market.

Generally speaking, before placing medical devices and PPE on the market manufacturers carry out the conformity assessment procedures stipulated by EU law – either themselves or together with the notified body – and, if the products meet the basic safety, health protection and performance requirements, they affix the CE marking. Where the manufacturers resort to specific technical solutions that are part of the harmonised standards published in the Official Journal of the European Union, conformity of the medical devices and PPE is presumed.

Medical devices and PPE without CE marking are frequently the subject of market surveillance procedures conducted by the competent market surveillance authorities. If they conclude in the course of their assessment that the EU requirements are not met, then they request the economic operator concerned in a manner commensurate with the nature of the risk to take corrective action to bring the PPE into conformity with said regulations or to withdraw or recall it.

Simplifications for conformity assessment and market surveillance procedures

In an attempt to remedy the shortages in supplies of PPE and medical devices in the current Corona crisis, on 13 March 2020 the EU Commission issued a recommendation that was published in the Official Journal of the European Union on 16 March 2020. On 3 April, moreover, the EU Commission published a draft regulation postponing the entry into force of the Medical Devices Regulation – originally planned for 26 May 2020 – by one year to 26 May 2021. This is meant to avoid supply shortages and disruptions. As a further short-term measure to ensure that the acute need for medical devices is met, the EU Commission took additional decisions on 24 March 2020 on the adoption of harmonised standards for medical devices, which manufacturers can use as a

reference point.

In its recommendation the EU Commission invites all the relevant economic operators and public authorities to deploy all the measures at their disposal in the context of conformity assessment and market surveillance procedures to support the efforts to match the growing demand. The general health and safety requirements continue to apply, however. Specifically, it covers the following measures:

Expedited conformity assessment procedures

Conformity assessment procedures for **PPE** are to be prioritised and swiftly conducted by the notified bodies. The following efforts are being put in place to expedite the procedures:

- **WHO recommendations** can be used as a source of reference for technical solutions other than harmonised standards provided that an adequate level of protection is guaranteed.
- Where notified bodies accept other technical solutions, they should immediately inform the notifying authority and other notified bodies about this possibility in order to secure EU-wide acceptance.

Conformity assessment procedures for **medical devices** should be carried out more quickly and at a lower price:

- It will be possible to authorise a **derogation from conformity assessment procedures** on application by a manufacturer because the use of the urgently needed medical devices is in the interest of public health. In this way the products can already be placed on the market before the conformity assessment procedure is completed if they meet the basic health and safety requirements laid down in the Medical Devices Directive and the Medical Devices Regulation.
- For products that play a key role in combatting the pandemic, the EU Commission has adopted **additional harmonised standards**. By way of exception, these are here available free of charge. They include, for example, medical facemasks and disinfection devices. Once published in the Official Journal of the European Union, the conformity of these products with the regulatory requirements for medical devices will be presumed if these standards are applied.
- The MDR's entry into force is being postponed to 26 May 2021 to enable all market players to concentrate on making the urgently needed medical devices available. Introduction of the MDR will be complex, involving various implementing acts, and would overstretch manufacturers, supervisory authorities and notified bodies during the current crisis (see here).

Adjusted market surveillance procedures

The competent market surveillance authorities in the various Member States are also being involved in order to secure the availability of PPE and medical devices for appropriate protection against the Corona virus:

- Capacities are to be freed up at the **market surveillance authorities** by having them focus as a matter of priority on non-compliant PPE or medical devices raising **serious risks as to the health and safety** of their users.
- Even if the conformity assessment procedures, including the affixing of CE marking, have **not been fully finalised according to the harmonised rules**, the market surveillance authorities may authorise the making available of these products on the European internal market **for a limited period of time**.
- The EU Commission and the other Member States are to be informed immediately by the market surveillance authorities about the authorisation of these kinds of temporary arrangements.
- **Non-CE-marked** PPE and medical devices can also be placed on the market, provided that they have been assessed and are only being sourced by the competent Member State authorities in order to make them **available to healthcare** workers for the duration of the Corona pandemic. One important caveat here is that measures must be taken to ensure that PPE and medical devices of this kind cannot be made available to other users via the regular distribution channels.

Use of existing EU derogations

At national level, too, the authorities are making use of existing opportunities in EU law to respond to shortages in supplies during the Corona crisis: In view of the increased demand for disinfectants, the Federal Office for Chemicals has issued two general rulings with derogations for hand disinfectants in accordance with Article 55(1) Biocidal Products Regulation (Regulation (EU) No. 528/2012). The general orders of 4 March 2020 and 20 March

2020 extend the circle of manufacturers on the one hand and the range of permissible formulations for hand disinfectants on the other, subject to a precise definition of the group of customers (the general public or professional users).

Customs duties on imports from third countries to be dropped

On 7 April 2020, the EU Commission created the requirements for relief from customs duty for disaster victims under Council Regulation (EC) No. 1186/2009 setting up a Community system of reliefs from customs duty and Council Directive 2006/112/EC on the common system of value added tax. To reduce the costs of medical devices and PPE urgently needed in the coronavirus crisis, the Commission has decided that no customs duties or value added tax will be incurred on imports of these products from third countries between 30 January and 31 July 2020. A requirement for this, however, is that the importer is an aid agency or State body (or acting on such agency or body's behalf) for the purpose of distributing or making available these products free of charge to persons who have contracted or are at risk of contracting COVID-19 or are involved in combatting the outbreak.

Conclusion

Managing the coronavirus crisis will depend on making medical devices and PPE rapidly available in order to meet demand. The EU Commission and the national authorities are doing their best to simplify the legal framework. All the same, manufacturing protective equipment that is epidemiologically safe as well as complex medical devices such as medical ventilators remains a demanding task in terms of the technology used and the quality needed. Another major challenge for those involved is the conversion of other branches of production to these products. This has already occurred in the cases of the automotive and clothing industries, for example. The EU Commission's contribution to this is welcome, however. The Commission is simplifying legal requirements and postponing the entry into force of the new Medical Devices Regulation to 26 May 2021. This frees the medical technology industry from the burden of having to modify its plants and products to meet the new Medical Devices Regulation's stricter requirements while making available the urgently needed products.

Please do not hesitate to contact us if you have any specific questions or require assistance in applying these new rules.

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