KNOW-HOW

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HEALTHCARE AND LIFE SCIENCES

EU-WIDE SIMPLIFICATIONS IN RESPECT OF MEDICAL DEVICES, PROTECTIVE EQUIPMENT AND DISINFECTANTS

Face masks, protective coveralls, eyewear protection, surgical masks, exploration gloves – these are just a few examples of items the short-term sourcing of which is essential in the battle against the Corona virus. The EU Commission's most recent measures are intended to speed up the process of bringing these kinds of products to market. While the adage "Necessity knows no law" often quoted in crisis situations does not apply, the provision of medical devices that fall somewhat short of the conformity assessment criteria and the CE labelling requirements can be temporarily authorised. The intention is for PPE conformity assessment procedures to be conducted quickly and as a matter of priority by the notified bodies, also giving consideration to technical solutions other than harmonised standards. Lastly, regarding the prosecution of conformity violations, the market surveillance authorities are being asked to confine themselves to those that have a serious risk potential. The Federal Office for Chemicals is also issuing derogations for the manufacture and sale of hand disinfectants.

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 fully harmonised in the European Union on the basis of the Medical Devices Directive (Directive 93/42/EEC), 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. Moreover, the EU Commission plans to postpone the entry into force of the Medical Devices Regulation – which was actually to take place on 26 May 2020 – by one year. 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.

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.

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).

Conclusion

The rapid provision of sufficient medical devices and PPE is critical to the success of the fight against the Corona virus. The EU Commission is showing a remarkable level of flexibility, especially in light of the recent tightening of bureaucratic requirements at all levels in the wake of the reform of EU legislation around medical devices. It is calling upon economic operators and Member States to adjust the conformity assessment and market surveillance procedures as a way of meeting the huge rise in demand for PPE and medical devices across the entire EU as quickly as possible. The German authorities are using the derogation provision in the Biocidal Products Regulation to address shortages in supplies of disinfectants. Manufacturers and other operators involved in the supply chain for affected products are requested to avail themselves of the simplifications.

Please do not hesitate to contact us if you have any specific questions or require assistance in implementing these simplifications.

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