Cooley

Considerations for Manufacturers in Europe Switching to Production of Medical Supplies

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The extraordinary times we find ourselves in during the global COVID-19 crisis has led to extraordinary measures being taken by product manufacturers and suppliers across the globe. In an effort to do their part to counteract the lack of life-saving medical supplies, clothes manufacturers are making surgical masks and other protective clothing items for medical personnel, airplane makers and other heavy industrial manufacturers are turning their hand to produce medical devices, and alcohol distillers are now manufacturing hand sanitizers.

Regulatory bodies and governments around the world are taking equally unprecedented measures. The changing regulatory landscape, where deviations from normal course are being permitted on an almost daily basis across Europe, warrants a well-considered but flexible and fast-moving response from those seeking to benefit from it.

Below are some key considerations for companies looking to move into time-pressured medical supply production in Europe, against the backdrop of a regulatory landscape subject to daily change.

1. What regulatory regimes apply to the new products?

There are several regimes that can potentially apply to COVID-19 medical supply products, depending on many factors, including product composition, product function and claims made about the product in advertising/labelling. All of these factors will be heavily influenced by the current climate in which the product is being manufactured.

Some relevant regulatory regimes include:

- **Medical devices regime.** Medical devices are articles (including software) intended to be used to diagnose, prevent, monitor, treat or alleviate disease, injury or handicap; investigate, replace or modify anatomy or physiological process; or control conception other than primarily by pharmacological, immunological or metabolic means.
- **Personal protective equipment regime.** Personal protective equipment is equipment that will protect the user against health or safety risks at work, including gloves, eye protection and respiratory protective equipment.
- **Biocidal products regulation.** A biocidal product is one which controls harmful or unwanted organisms through chemical or biological means and includes a very diverse group of products, including disinfectants, pest control products and preservatives.
- **Human medicines regime.** A medicinal product is any substance(s) for humans that has properties of preventing or treating disease or that restores, corrects or modifies a physiological function by exerting a pharmacological, immunological or metabolic action, or by making a medical diagnosis.

Other regimes such as poisons legislation and detergents legislation may also apply.

As is often the case in the life sciences context, products can be considered 'borderline products' in straddling many of these regimes, and careful consideration needs to be given to these issues. The circumstances of production of the products may limit arguments that less medically-orientated regimes apply, such as the cosmetics regime, when in simpler times such arguments could be validly made.

The above-mentioned regimes impose different obligations and are overseen by different regulatory bodies. Expert assistance and a case-by-case assessment is required, but surveying existing products on the market makes a good starting point (and something authorities will consider). Well thought-out outreach to authorities may be considered in some contexts.

2. Do your products comply with the applicable regulatory regimes?

Given the particularly close link between human health and safety and medical supplies, these regulatory regimes tend to be particularly technical and complex.

From a practical perspective, the following are the types of issues likely to be encountered when bringing the product to market, which differ from regime to regime:

- Allowable product compositions
- Authorizations/licenses and/or approval from relevant regulatory bodies
- Testing requirements, including clinical trials
- Information-keeping requirements
- Manufacturing standards/processes
- Labelling, including specific hazard warnings and use instructions and CE marking

Whilst the goodwill efforts of the companies trying to do their part for society in these circumstances will hopefully not be overlooked, it seems product safety and quality is still paramount to authorities charged with oversight of these areas. We have seen examples of European health authorities rejecting supplied personal protective equipment on the basis of lack of CE marking or other mandatory product safety labelling. There are examples of non-compliant and/or counterfeit products being seized across Europe as well.

3. Can you team up with other manufacturers or actors in the supply chain, especially those that are experienced in the production of the specific products, to lighten the regulatory lift and speed up production times?

A technical expert may well be required in respect of the above requirements, especially for testing and resultant documentation.

Companies could consider teaming up with pre-existing manufacturers in this area, as this may often result in a reduced regulatory uplift to get new products to market. It also means companies new to the area can benefit from the extensive expertise of the more established medical supply manufacturer and their reputation and relationships with relevant stakeholders, such as regulators and suppliers.

Trade bodies are an invaluable source of information at this time for up-to-date information affecting their membership and to assist in any lobbying activities.

4. Can you benefit from any exemptions or derogations being granted by local governments and authorities to address the supply chain issues associated with COVID-19?

Several governments and local authorities are making COVID-19-specific exemptions to allow manufacturers to produce medical supplies very quickly. Currently, despite initial appearances otherwise, these derogations are often quite narrow – aimed at allowing local manufacturers, sometimes only in areas somewhat rehearsed in the manufacture of the relevant product, to produce products for the benefit of local health authorities. Companies

need to carefully assess any derogations or reliefs from regulatory compliance made and whether these are applicable to their situations.

Whilst it is positive to see governments take steps to address the COVID-19 situation, the very specific exemptions allowable would, in some ways, suggest that they might be less likely to entertain exceptions outside the scenario they have addressed specifically. It is not correct to assume that authorities will allow complete relaxation of regulatory compliance requirements given the extraordinary circumstances we find ourselves in. However, the regulatory landscape changes on a daily basis and monitoring and adapting to the same is required.

We will provide relevant updates on specific areas as they become available.

Coronavirus resource hub