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Opening the Doors: Return-to-Workplace Considerations During COVID-19

EU Regulatory

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Food, Drug, and Device

Businesses are developing plans for reopening workplaces. As they do, many employers are considering ways to determine which employees can safely return to the workplace, and what protective equipment should be provided to employees once they return. In the European Union (EU) and United Kingdom (UK), many of the products used in these strategies are regulated as medical devices or personal protective equipment. Certain products may also be regulated as biocidal products. This alert provides an overview of key EU (and UK) regulatory issues companies should consider as part of their return-to-workplace (RTW) strategies. We have published a separate alert on U.S. considerations.

The alert is part of Covington's "Opening the Doors" series, which addresses RTW considerations for employers. Previously, we released a Return to Workplace in Europe: Resource Guide, which covers an array of issues companies face as employees return to the workplace, including employment, privacy, competition, policy, environmental and regulatory considerations at the EU level. More broadly, Covington has established a COVID-19 Task Force and Toolkit for our clients, addressing the numerous legal issues associated with the COVID-19 pandemic.

Feel free to reach out to any of the Covington contacts listed at the end of this alert, or email our COVID-19 Task Force at COVID-19@cov.com with questions.

Testing at the Door: Determining Who Can Enter the Workplace

Employers implementing return-to-workplace programs potentially will employ a variety of screening mechanisms—thermometers, digital health tools, and diagnostic tests—in an effort to determine who is safe to enter the workplace, all of which can trigger important regulatory considerations.

EU Regulation of Thermometers and Temperature Scanning Products

In the EU and UK, thermometers and other temperature scanning products, are typically regulated as medical devices and must be CE-marked under the EU medical devices rules before being placed on the market in the EU (or UK).

While EU regulators generally do not regulate the *use* of medical devices by healthcare professionals, patients or other lay persons, employers wishing to implement temperature screening programmes should ensure that they source and use in the EU and U K only CE-marked products (i.e., thermometers). Employers should also use such products in a manner that is consistent with their intended use and labelling, to ensure appropriate device performance and the safety of employees.

EU Regulation of Digital Health Tools for Assessing COVID-19 Risks or Symptoms

Digital health screening tools, which ask employees about risks of exposure to COVID-19 (for example, COVID-19 status of individuals in the employee's household, COVID-19 testing history, social distancing practices) or about the individual's symptoms), could be regulated as software medical devices. This will depend on the functionality and intended use of the digital health tool. EU regulators generally do not regulate tools that match user-specific information (e.g., symptoms) to established reference information (e.g., health authority guidelines). Likewise, tools intended to help a patient document their health and communicate health information with a healthcare professional are not regulated as devices. On the other hand, EU regulators would likely regulate as a medical device a tool that provides patients recommendations on COVID-19 diagnosis if it does more than automate health authority guidelines.

Companies utilizing digital screening tools developed by third parties will generally not be subject to medical device regulation, but employers that seek to develop their own digital health tools could be subject to regulation as a device manufacturer, depending on the functionality of the product. Companies developing tools, including those contracting out certain elements of the development, should carefully consider whether EU regulators will actively regulate the tool as a medical device.

EU Regulation of COVID-19 Diagnostic Tests

While temperature screening and digital health tools may suggest which employees should be tested further, many employers are considering a more direct strategy: to use diagnostic tests to determine which employees may be infected. However, diagnostic testing implicates a number of regulatory matters, as both the tests themselves and their use may be subject to regulation.

In the EU, COVID-19 testing kits (including associated materials/equipment) are regulated as *in vitro* diagnostic (IVD) medical devices and, ordinarily, would need to be CE marked before being placed on the market or put into service. Strictly speaking, if a company wishes to start performing COVID-19 testing, with the purpose of providing diagnosis of COVID-19 in individuals, it will need to ensure that the tests comply with the EU IVD medical device rules. This will require the test to be CE marked as an IVD or subject to an applicable derogation. Derogations would need to be applied for on a Member State-by-Member State basis in each EU country where the company wished to conduct the tests. That said, regulatory policies and processes in the EU are evolving very quickly and EU regulators are becoming increasingly pragmatic. Companies wishing to perform testing activities should therefore keep abreast of current developments.

Companies should also be aware that certain EU Member States impose legal requirements on testing labs (whether clinical or otherwise) to hold a government license. Labs used for the purpose of employee screening programs may therefore be subject to national approvals, which will need to be considered on a Member State-by-Member State basis.

Other Regulatory Considerations Raised by Employee Screening Practices

In addition to the above considerations, all of the above screening/testing options raise a host of other regulatory and legal issues. These include (but are not limited to) the following:

- **Privacy Laws**. Companies will need to carefully consider privacy laws regarding the data generated and collected from employees through temperature screening, digital health, and diagnostic testing programs, including the legal basis for processing sensitive data, what employee consents may be required and what data security controls would need to be implemented. In our Return to Workplace in Europe: Resource Guide, we discuss the key employment law and data privacy considerations relating to "return-to-work" employee screening measures.
- **Practice of Medicine**. Companies performing temperature screening or administering diagnostic tests to employees will need to assess whether such practices must be conducted by a licensed healthcare professional. Likewise, companies should consider whether discussions related to test results or elevated temperatures implicate practice of medicine requirements. Many national competent authorities require notification to public or governmental authorities of positive test results.
- **Employment Law**. Companies will need to consider employment law requirements when determining the scope of information or testing that may be requested (or required) from employees. In our Return to Workplace in Europe: Resource Guide, we discuss the key regulatory considerations relating to "return-to-work" employee screening measures, such as COVID-19 testing.

Protecting Employees in the Workplace

In addition to screening employees returning to the workplace, employers will use a variety of different strategies to ensure the safety of employees in the workspace, including enhanced cleaning protocols, workplace social distancing measures (such as staggered work hours, limitations on in-person meetings, distancing of work stations, etc.), use of masks and other personal protective equipment (PPE), availability of hand sanitizers, training of employees, and procedures for reporting and responding to any positive COVID-19 cases in the workplace.

In the EU and UK, masks and gloves intended for medical use (such as to prevent the wearer from infecting a patient) will be regulated as medical devices. However, the same product could be regulated as PPE if it does not have an intended medical use, but is intended to protect the wearer from the risk of infection. PPE, like medical devices, must normally be CE-marked before being placed on the market in the EU (or UK). However, see below in respect of temporary regulatory positions in light of COVID-19. Products that are simple barrier items may be regulated as general consumer or hygiene goods in some jurisdictions and as such do not need CE marks, but they would still need to satisfy any other applicable rules including as to general product safety.

As regards disinfectant products such as hand sanitizers, in the EU and UK, these generally fall into one of three categories:

- **Cosmetics**. If the product is primarily used and intended to clean, protect, and condition skin or to provide any other cosmetic enhancement, it is likely to be regulated as a cosmetic product. Normally, these products may provide a secondary antimicrobial effect but interpretation varies at the national level.
- **Biocides**. If the products are used and intended primarily to kill pathogens, or to disinfect or sanitise using an active biocidal or antimicrobial ingredient, these are likely to be regulated as biocidal products.
- **Medicines**. If the products are specifically intended to have some medicinal purpose or if they make claims to treat and/or prevent infection associated with specifically named pathogens, these are likely to be regulated as medicines.

Many of the regulatory requirements for these products will attach to particular economic actors, and not employers (unless they are making their own products or substances) but some requirements also apply to supply and use. Employers should be aware of the regulatory requirements, and supply sufficient information to employees and visitors to allow safe use, in order to inform their employer risk assessments and satisfy duty of care obligations.

Regulatory Considerations for PPE Masks

Companies providing face masks to employees to limit the transmission of COVID-19 in the workplace should be aware of the distinctions between the different types of masks, the level of protection they provide, and the level of regulatory review they receive, and should ensure that the masks provided to employees are compliant with applicable requirements. In addition, companies who are importing masks from sources outside the EU should be aware of the regulatory framework when importing masks and PPE.

In the EU, masks provided to employees could be regulated in one of a number of ways: (1) as personal protective equipment (PPE), (2) as medical devices, or (3) general consumer or hygiene goods. The classification, and associated regulatory requirements, will be highly dependent on how the products are positioned, their intended function and effects, and any claims made in respect of the product.

These policies create a complex regulatory paradigm for PPE:

Non-surgical Face Masks

In the EU, non-surgical face masks fall outside of the medical device rules. However, they are subject to CE-marking requirements under PPE rules if they are intended to protect the wearer from infection. Alternatively, they could be viewed as "unregulated" products if they are intended to reduce the risk of the wearer passing on an infection to others, but are not intended for use in a medical context. Many Member States are issuing guidance and standards for such non-PPE and non-device "face coverings" or "barrier masks". Much will depend on the claims associated with the mask.

Surgical Masks

In the EU, surgical masks are medical devices. Such masks must be CE-marked under the device rules before being placed on the market or be subject to a national derogation.

NIOSH-approved Respirators

In the EU, NIOSH-approved respirators are regulated as PPE. Such masks must be CE-marked under the PPE rules before being placed on the market or be subject to a national derogation.

Imported Respirator Masks

EU regulators expect masks imported into the EU to be appropriately CE-marked as either PPE or a medical device, as applicable. However, the European Commission has acknowledged that PPE or medical devices not bearing the CE marking could also be assessed as part of a purchase organized by the relevant Member State authorities, provided that such products are only available for healthcare workers during the current health crisis and are not available to other users. National authorities typically expect to see evidence that the masks have been manufactured either in line with a relevant European Standard, in accordance with a standard referenced in the WHO guidelines or to an alternative technical solution that delivers adequate safety. An example of the latter is the French standards body, AFNOR, Barrier Mask Standard.

Regulatory Considerations for Sanitizers

The regulatory requirements will differ depending on which regulatory regime applies to the products, and whether any temporary regulatory positions or derogations are applicable in light of COVID-19. Typically, the process will involve some sort of authorization and approval process, including for any active substances, and the products will have to satisfy particular safety requirements and carry warnings and information to allow safe use.

For example, antimicrobial disinfectants for use on skin and surfaces are usually regulated under the EU Biocidal Product Regulations (BPR) as biocidal products. To bring products to market under the BPR, the active substances used in products must go through a review process to evaluate the potential risks. If unacceptable risks are identified, the active substance will be non-approved. If there are no unacceptable risks and the active substance is approved, products containing that substance must go through a risk and efficacy assessment, culminating in a decision to either authorize or not authorize the product - authorized products can be marketed subject to specific conditions, whereas products that are not authorized are not allowed on the market.

Companies should identify which product type applies to their particular product and use - e.g., product type 1: for use on human skin, without a medicinal claim – and that all the active substances in the product are approved and it is past the last approval date to apply for and obtain BPR product authorization. If, for the relevant product types, all the active substances are

under review, or some are under review and some are approved, or if all of the active substances are approved but it is before the last approval date, authorization is not needed. However, companies must check and satisfy national transitional rules before marketing products in a particular jurisdiction. Companies must also have evidence to substantiate any claim(s) and should ensure the claims do not contradict the BPR authorization conditions or rules around advertisements.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our EU Food, Drug, and Device practice:

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