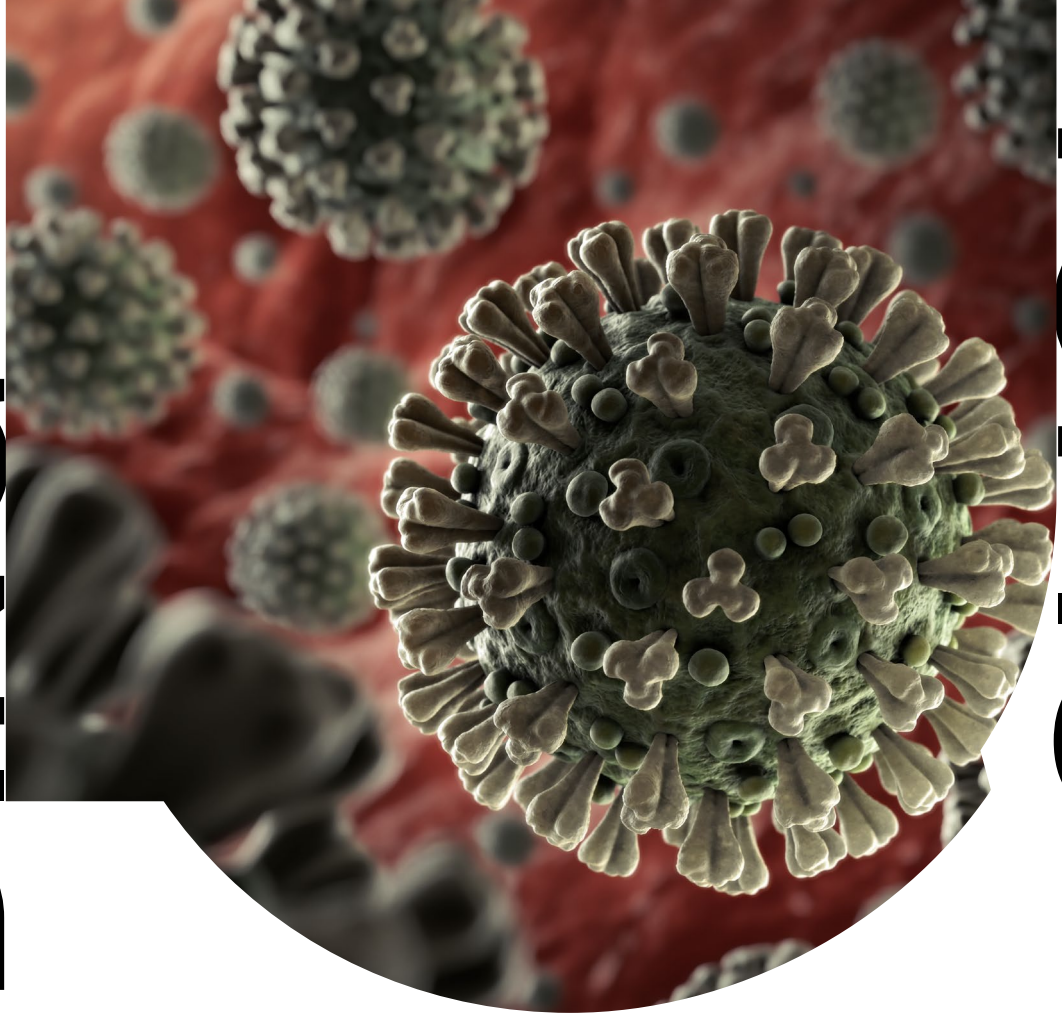
TRENDING TOPIC



22 OUT. 20

HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

Coronavirus: Exceptional rules for products to prevent the spread of the virus

The rapid spread of the new Coronavirus (SARS-CoV-2) and the COVID-19 pandemic have led to a very significant increase in demand for medical devices (MDs) and personal protective equipment (PPE), masks for social use (textile articles) and other products destined to prevent the spread of the disease. As a result, it became clear that there was insufficient supply to meet existing needs during the state of emergency and the subsequent period.

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There have already been multiple initiatives to combat the pandemic, particularly by converting production lines to manufacture personal protective equipment, medical devices and other essential products (such as biocides). In view of this and the circumstances of the pandemic, Decree-Law 14-E/2020 of 13 April [1] was published to establish exceptional and temporary arrangements for the manufacture, importation, placement and availability on the market of medical devices (MDs) and personal protective equipment (PPE). The aim of these measures is to prevent the spread of the new Coronavirus by setting out the conditions under which it is possible to derogate from or adapt the procedures to assess compliance with the legally imposed health, safety and performance requirements.

These exceptional arrangements only apply to: *(i)* single use surgical masks for use by healthcare professionals; *(ii)* masks for social use, both single use and reusable; *(iii)* respiratory protection half-masks; *(iv)* masks with integrated visor; *(v)* surgical gowns; *(vi)* full protection suits; *(vii)* hoods; *(viii)* caps; *(ix)* arm and leg covers; *(x)* protective footwear - overboots; *(xi)* protective footwear - overshoes; *(xii)* single-use gloves. *(xiii)* safety eyewear; *(xiv)* visors; and *(xv)* swabs.

As regards the importation of MDs and PPE, it is provided that:

- The MDs and PPE necessary to prevent the spread of SARS-CoV-2 can be imported even if they do not bear the CE marking. However, they must be accompanied by certificates or other documents proving they comply with the rules on health, safety and performance established by other states that are equivalent to those required by EU regulations. The items that can be imported are listed by INFARMED in relation to MDs, and by ASAE in relation to PPE.
- For MDs and PPE without CE markings that do not appear on the list drawn up by INFARMED, it is necessary to present the documentation needed to check them. These items may then only be imported subject to a prior favourable decision by ASAE or INFARMED, as appropriate. At the request of the importer, these bodies must issue their decision within four working days. This period may be extended once for an equal period, if it is necessary to consult other bodies.

MDs and PPE can be manufactured, provided the manufacturer complies with the health, safety and performance rules indicated for this purpose by INFARMED (for MDs) and by ASAE (for PPE). Manufacturers must also submit documentary proof of compliance with the essential health and safety requirements applicable to the products in question.

"The rapid spread of the new Coronavirus and the COVID-19 pandemic have led to a very significant increase in demand for medical devices and personal protective equipment, masks for social use and other products destined to prevent the spread of the disease."

1 As amended by Decree-Law 36/2020 of 15 July, which simplified the licensing procedures for industrial establishments manufacturing medical devices, personal protective equipment, ethyl alcohol and biocide disinfectant products intended to prevent the spread of the Coronavirus (SARS-CoV-2).

As regards the requirements for the manufacture, importation and marketing of masks for social use (textile articles), Decree-Law 14-E/2020 does not define specific rules, but only refers to the technical requirements that are published by the economic and health authorities.

As a result of this legislation, in April 2020, the authorities (INFARMED and ASAE) published a set of additional rules on procedures for the manufacture, import and marketing of MDs, PPE and social use masks on their websites. These rules, published by INFARMED and ASAE, essentially address the equivalence of applicable international technical rules and labelling.

As to placing and making items available on the market, when the importation or manufacture is carried out in accordance with what is set out above, and provided the other requirements for placing products on the market are met:

- The MDs, PPE and masks for social use can be made available on the Portuguese market as long as their health, safety and performance characteristics are guaranteed.

- Respiratory protection half-masks, masks for social use and single-use gloves can also be made available in vending machines.

Lastly, while the original version of Decree-Law 14-E/2020 was intended to facilitate the reorientation of companies' production structures towards the products needed for the pandemic, it did not make any changes to the industrial licensing requirements.

"MDs, PPE and masks for social use can be made available on the Portuguese market as long as their health, safety and performance characteristics are guaranteed."

In response to this problem, Decree-Law 36/2020 amended Decree-Law 14-E/2020 by establishing a simplification of procedures for industrial licensing of MDs, PPE, ethyl alcohol and other biocide disinfectant products.

The authorisations resulting from these simplified procedures, which are intended to make it easier to place on the market products to prevent the spread of the COVID-19 pandemic, are exceptional in nature and expire 30 days after the repeal of Decree-Law 14-E/2020.

Finally, both Decree-Law 14-E/2020 and the amendment introduced by Decree-Law 36/2020 have retroactive effect as from 13 March 2020 to ensure compatibility with the law containing measures to expedite the production and marketing of products necessary to prevent the spread of COVID-19. ■