European harmonised standards: most appropriate regulatory technique in times of crisis?

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Series: EU Harmonised Standards: Behind the Scenes of Private Rule-making

'Yesterday, the Commission adopted decisions on harmonised standards which will allow manufacturers to place high performing devices on the market to protect patients, health care professionals and citizens during the Covid crisis.'

While a general framework for EU harmonised standards (ENs) was given in the first blog post of this series, we can now approach the interesting case study related to the use of ENs during the pandemic. European legislation for medical devices relies heavily on harmonisation, with numerous ENs ensuring a presumption of conformity on a variety of goods.

In March 2020, the European Commission adopted revised ENs as part of the work to assist speedier conformity assessment procedures for those selling medical devices. The implementing decisions that were released tackled, inter alia, the fast production of medical face masks, gloves, containers for intravenous injections, sterilisation devices and disinfectants, while also demanding specific requirements for emergency and transport ventilators. When the Union faced an unprecedented health crisis, it opted for ENs as a regulatory technique to respond to urgent needs and demands in the market. In the words of Stella Kyriakides, Commissioner for Health and Food Safety, 'we must not waste a second in our fight against the virus, and with the measures we adopted today we speed up the entry of safe, essential medical equipment.'

Before the pandemic, EU legislators enacted Regulation (EU) 2016/425 on personal protective equipment and the Medical Devices Directive 93/42/EEC which set the needed framework to ensure high protection of health for patients, resulting in 300 ENs. Hence, in practice, an economic operator wishing to sell face masks could apply EN 14683:2019 related to medical masks to prove compliance with Regulation (EU) 2016/425. Later on, EU authorities defended the rationale and need for new ENs for medical devices in 2020 as a guarantee of European resilience in the face of the pandemic, increasing overall health care capacity across all Member States. It did so by publishing a guidance document in April 2020, which summarised the legal requirements – including the relevant EU harmonised standards – to put medical devices on the market during the health crisis. It reinforced its position in a press conference stating that 'standards will facilitate a faster and less expensive conformity assessment procedure, playing a pivotal role in the current Covid-19 pandemic because they relate to critical devices such as medical face masks, surgical drapes, gowns and suits, washer-disinfectors and sterilisation.'

Enacting ENs in times of crisis: an effective solution in practice?

Arguably, the Covid-19 pandemic made it blatantly clear that health could no longer be treated as a sole national issue. Yet, was

enacting ENs at the EU level the most appropriate response? The answer to this question cannot be black-and-white. While the Commission made efforts to make ENs more accessible by removing market barriers for manufacturers, it was ultimately not fast enough to respond to shortages.

On the one hand, the Commission removed barriers and facilitated access to ENs by making certain ENs for personal protective equipment and medical devices free of charge. Indeed, as a reminder, ENs are rules enacted by **private** organisations, products of private intellectual production, and thus come with copyright fees even once they are published in the Official Journal of the EU. However, during the pandemic numerous ENs related to medical devices were offered freely by ESOs and the Commission. This was announced by Thierry Breton, Commissioner for the Internal Market, who stated that following contacts with the Commission, 'CEN and CENELEC have agreed to make freely available the standards needed for such companies to be able to produce masks and other protective equipment.' This resulted in 11 standards developed by CEN published with free access, covering filtering masks, medical gloves and protective clothing.

On the other hand, what was observed during the pandemic is that even ENs were not the speediest way to manufacture products. Indeed, the Commission had to show regulatory flexibility due to shortages following the Covid-19 emergency. In Recommendation (EU) 2020/403, the European Commission presented measures to significantly speed up and simplify procedures for the distribution of personal protective equipment (PPE) and medical devices. In March 2020, manufacturers could thus place their products on the market without the required CE marking. Due to unexpected high demands the completion of conformity procedures, often employing ENs, could not ensure the fast delivery of products. This meant that some were placed on the EU market even if the products[1] were not fully in line with the corresponding ENs (Articles 24 and 25, 2020/403). Hence, even though ENs were promoted as the go-to solution to respond to the crisis to the public, the Commission itself made an exception to the rule in its recommendations.

To conclude this part, it can be stated that the current compliance with ENs was not as efficient as predicted, opening the door to food for thought for new prospects in the field. Indeed, are there any other flaws related to ENs than the ones that surfaced during the pandemic? Do they have to remain within the private sphere in the future? What are the alternatives? While ENs are predicted to play a role in the EU's path towards a strong economic recovery, the blog in this series will discuss how it can better satisfy this expected responsibility.

This blog is written by Juan Diego Ramírez-Cárdenas Díaz and Pauline El Khoury.

The views expressed in this blog are those of the authors and not necessarily those of EIPA.

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[1] Note that these products were only meant for medical professionals and could not be placed on the normal distribution channels.