What regulators must learn from COVID-19

Greater convergence between national regulators will help prepare for the next pandemic

The COVID-19 pandemic has been challenging from a public health perspective. The magnitude of the global threat from this virus was underestimated early on by many health authorities as attempts at containment and mitigation were made. As it became clear that the virus would become an established threat, achieving a balanced portfolio of antiviral agents, monoclonal antibodies and vaccines was challenging to accomplish, given competing priorities and limited resources. In addition, manufacturing capacity across the globe was not sufficient to immediately rise to the scale of production necessary for the diagnostic tools, therapeutic agents, vaccines and personal protective equipment needed to combat the pandemic. Even though these issues have now been at least partially addressed, the global deployment of vaccines that aim to bring the outbreak under control has been complicated by political and social media disinformation campaigns that work against the public health.

One positive consequence of the ongoing pandemic for the public has been a heightened external awareness of the work of regulators and the innovative regulatory pathways that can be used to facilitate the availability of crucial medical products in an emergency. There has been some apprehension about the pace of the development of medical products during the pandemic, with some voicing concerns regarding the investigational nature of vaccines and other products that were made available under Emergency Use Authorization in the United States. Therefore, it has been critical to ensure that the development, review and authorization and approval process is as open and transparent as possible. This has included: providing clear standards for product development and review in regulatory guidance documents; making review documents public; holding open, easily accessible advisory committee meetings; and having senior agency staff speak to the public whenever possible about the evidence and decision making regarding COVID-19 diagnostics, therapeutic agents and vaccines.

Throughout the pandemic, within public health agencies such as the US Food and Drug Administration, regulators have had to deal with the evaluation of unprecedented amounts of emerging scientific data and a deluge of product submissions, all under time pressures and a public health need that is unprecedented in our lifetimes. While this has strained regulatory systems, it has also led to a search for efficiencies across the spectrum of product development. The urgency to expedite the development of critical devices, therapeutic agents and vaccines led the agency to initiate conversations with product developers very early on during the product development lifecycle, and these frequent conversations often continued during clinical trials through authorization or approval. As the pandemic progressed, this informational program for therapeutic drugs and biological agents became known as the Coronavirus Treatment Acceleration Program. Although sponsors were not obligated to take the advice provided, many did so, and thereby took advantage of the agency's expert knowledge in chemistry, manufacturing and controls, as well as in both conventional and innovative clinical trial design.

Global regulators have interacted to identify and evaluate potential safety signals, such as Guillain-Barré syndrome and myocarditis, arising after the deployment of COVID-19 vaccines. Greater regulatory collaboration and convergence would help to prepare for the inevitable next pandemic. Diagnostic tests, drugs and vaccines that ultimately need to be deployed globally could be developed according to unified expectations. This would allow product developers to generate the data necessary for global deployment just once, and thereby avoid the time-consuming rework that is currently necessary to meet the specific regulatory requirements of a multitude of different regulatory jurisdictions. Major regulators across different countries could also agree upon standardized formats for emergency access, and mutual recognition agreements could allow trusted regulatory partners to share the burden of regulatory review. These actions would simplify and expedite critical decision-making, which would in turn speed up access to essential, newly developed diagnostics, drugs and vaccines.

The current breakneck pace of regulatory work has been essential to reduce the burden of disease due to COVID-19, but this intensity of work cannot continue indefinitely. Refocusing resources on COVID-19 has come at the cost of delaying the development of other crucial medical products. For example, in the United States, our ability to provide timely feedback to developers of gene therapies has been impaired.

As the world slowly moves into the post-pandemic period, regulators will need to pick and choose those aspects of regulatory process enhancements that are maintained, those that return to their pre-pandemic status, and those that should be implemented to help address the next global public health crisis better.

Choosing wisely to retain the most meaningful regulatory processes will be important to best meet the needs of industry and regulators, while maximally benefiting the public health. Increasing international convergence of regulatory requirements and continuing the enhanced dialogue between product developers and regulators are both useful lessons from COVID-19 that could be further built upon. By maintaining or amplifying the best practices that have been developed over the past two years, regulators, industry and the public can derive something of benefit from this terrible pandemic. ❐

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