POLICY & MEDICINE
COMPLIANCE UPDATE
Reprinted from
Volume 8.3 | March 2022

FEATURE

Never the Same Again

Tectonic Shifts in Global Life Sciences Regulations Opens Doors to Future Progress

By Oliver Steck, Paul J. Silver, Bill Greenrose, and Malka Fraiman[1]

Summary: While the pandemic introduced many global challenges in the life sciences industry, it also brought accelerated global scientific and regulatory collaborations and innovations. As the industrial and regulatory landscape continues to evolve, it's vital for stakeholders to have clarity on the next steps to help them prepare their people and systems for the next global crisis.

The life sciences industry impacts the most precious resource of every country—its people. Thus, governments have a vital interest in the industry, an interest evidenced in the approaches taken to regulating vaccine, drug, and medical device companies. However, even in what might be generously termed ordinary times, the global life sciences regulatory ecosystem evolves. Yet since the outbreak of the COVID-19 pandemic in early 2020, that ecosystem has experienced tectonic shifts.

According to a new Deloitte report titled "Never the same again," the COVID-19 pandemic presents a case study in the ways in which the global life science regulatory community, life sciences industry, and health care system responded to a global outbreak of a communicable disease.[2] The report explored five major economies (United States, European Union, Japan, China, and India) and their responses to the pandemic. While the United States' pandemic response at both the national and local levels has received widespread and almost constant media coverage, the same is not true of the other four major economies, which is why they are covered in depth in this article.

These non-US economies' responses varied in timing, intensity, and effectiveness in keeping with their individual regulatory structures. Also, inevitably, their responses reflected the levels of economic development, regulatory infrastructure, political integration, communication capabilities, resource allocation methods, and cultural values.

Simultaneously, actors in both the public and private sectors engaged in unprecedented levels of information sharing, collaboration, and cooperation which broadened and accelerated a wide range of regulatory, research and development (R&D), testing, production, and distribution processes. In the end, these new developments and approaches provided new possibilities on what can be accomplished in the public health arena while facing a crisis.

Declaring Health Emergencies

A declaration of a public health emergency positions a country's decision-makers to enact extraordinary measures. Those measures impact citizens' behavior as well as governmental regulatory agencies, life sciences companies, and the health care industry to transition into operating in "crisis mode."

The pandemic health emergency declarations varied in scope, timing, and impact—across the economies we examined—but every declaration ultimately positioned regulatory bodies and other government agencies and the life sciences industry to operate in a state of emergency. However, the success of the response depended heavily on a country's laws as well as on governance structures and mechanisms by which actions of agencies and institutions could be coordinated through a centralized approach.

For example, it was not until November 11, 2020, that the European Commission (EC) proposed rules that would give the European Union (EU) the power to declare a

health emergency and act more independently of the World Health Organization (WHO).[3] The proposed rules focused on enhancing the current legal framework for serious cross-border health threats and reinforcing the crisis preparedness, and defining the response role of key EU agencies, namely the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA).[4]

However, at the onset of the pandemic, this rule was not in effect; therefore, the regulatory response was fragmented and differed across the EU. This left the 27 EU member states to adopt varied approaches either alone or in combination with other member states. These varied approaches included constitutional states of emergency, statutory regimes, measures adopted under special legislative powers, and measures adopted almost exclusively under ordinary legislation (Figure 1).

In April 2020, Japan's government issued a state of emergency based on the Act on Special Measures concerning Countermeasures against Novel Influenza and Other Diseases.[5] The specific measures were left to local governments, and there was a lack of ability to enforce the measures. Thus, the effect of the declaration of a state of emergency was partial and was challenged by violators and shown to be unenforceable. Therefore, in February 2021, a revised Special Measures Law was enacted to enhance the effectiveness and enforcement of countermeasures.[6]

China's response was centralized and enforceable. China declared a public health emergency in late January 2020 in 24 provinces and cities as a Level 1 response—the highest of four—covering some 1.2 billion people.[7]

Modified Processes and Unprecedented Collaboration Between Regulators and Industry

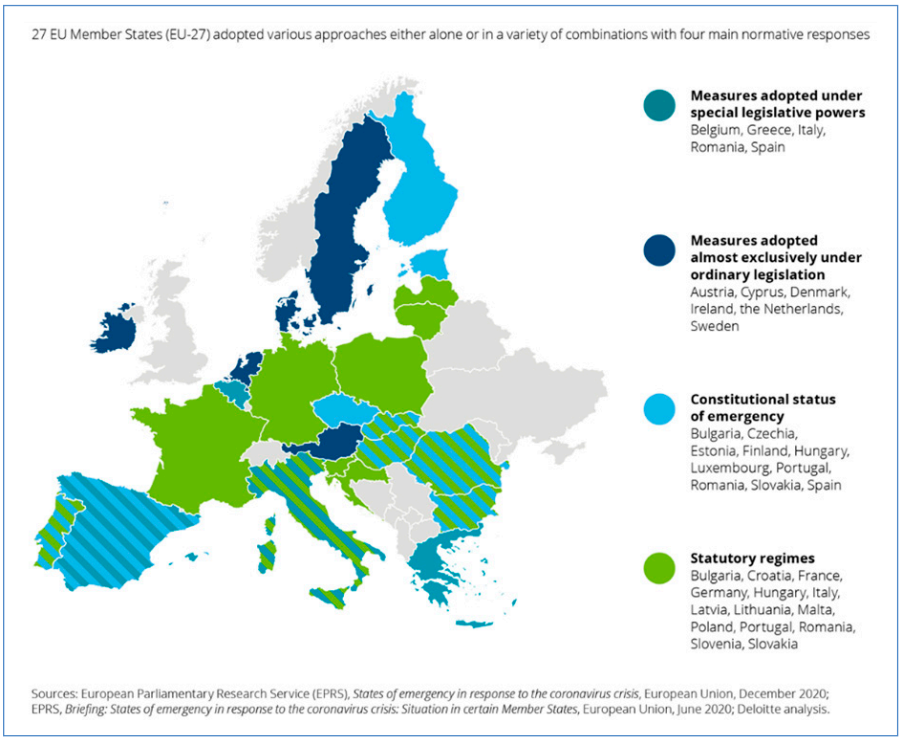
The extremely uncertain conditions generated by the pandemic prompted regulators to set priorities for diagnostics, treatments, and vaccines and for devices including diagnostic test kits, personal protective equipment (PPE), and ventilators.

The readiness and ability of regulators to relax certain requirements, lower barriers to entry, and accelerate approval processes ultimately facilitated rapid public and private sector responses. In addition, collaborations between regulators and life sciences companies reached unprecedented levels, facilitating innovation and development of products and accelerating their introduction to the market.

The relaxation of regulatory standards and heightened collaboration were evident across all five economies but, like the health emergency declarations, varied in their extent. Exercising the ability to relax regulations and to collaborate while maintaining product safety always requires a balance sought by regulators and the industry.

For example, in Japan, the Pharmaceutical and Medical Devices Agency (PMDA) generally responded within existing rules without special measures, although the PMDA did introduce several regulatory changes. However, from March to May 2020, PMDA announced temporary deregulation in several areas to ensure a

FIGURE 1: *EU Member States used various mechanisms to declare emergencies*



stable supply of existing products and to approve new COVID-19-related products. Before the pandemic, the regulatory framework for fast-track approval in emergencies was unclear.[8]

Unprecedented Collaboration Between Regulatory Authorities

Collaborative efforts to combat the pandemic not only occurred within various countries or regions or between regulators and companies but often spanned the globe and also occurred between regulatory agencies. These global, cross-border collaborations focused primarily on creating or relying on preexisting clusters of technical experts, sharing research results, leveraging inspection reports, and disseminating information. However, not unexpectedly, the results were variable.

For example, the U.S. Food and Drug Administration (FDA) and the EMA worked extensively together. However, other countries and regions took a less collaborative approach, preferring instead to rely on the WHO.

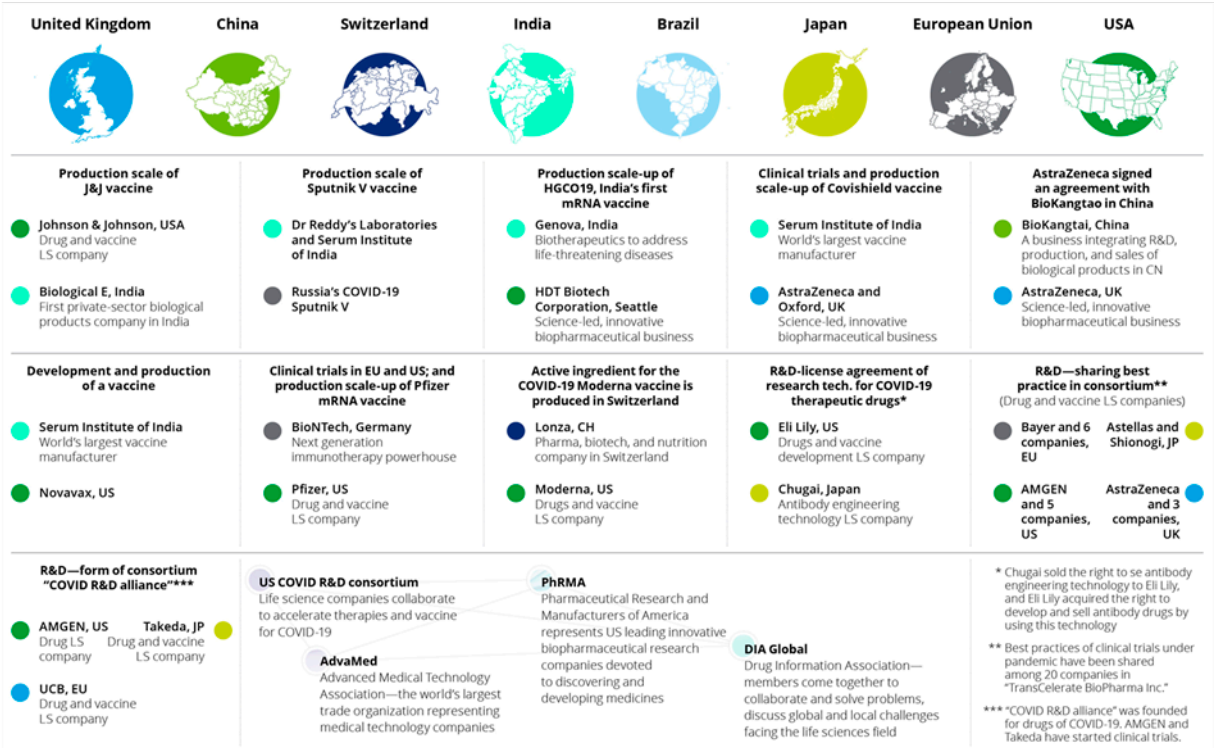
Where collaborative forums and frameworks existed among regulatory agencies prior to the pandemic, they were particularly useful because they enabled regulators to share data, exercise vigilance, and coordinate approaches within established trusted relationships. Some examples of these preexisting forms and frameworks include:

- The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH),[9]
- International Coalition of Medicines Regulatory Authorities (ICMRA),[10] and
- China's National Medical Products Administration (NMPA) which participated in the third Asian Network together with India, Indonesia, Japan, South Korea, Malaysia, the Philippines, Singapore, Vietnam, and Myanmar.[11]

Amongst Industry, Companies Joined Forces

The pandemic brought the industry, and even companies outside it, together to engage in levels of collaboration not seen in pre-pandemic times. The urgent need to develop treatments, vaccines, diagnostics, and medical devices, along with the relaxation of related regulations, allowed life sciences companies that are competitors to cooperate in developing solutions to scientific problems.

FIGURE 2: *Global collaborations among life sciences companies*



It also prompted non-life sciences companies to enter the arena, if only temporarily, to help address raw materials shortages, digitalize more of the drug development process, and enhance manufacturing capacity.[12]

The results demonstrated the power of collaboration to accelerate development by tapping core competencies of selected contributors and to supplement production by using facilities in specific locations to meet capacity and distribution needs accelerated product introduction (Figure 2).[13]

Assessing the Industry Impacts

Innovation, Efficiency, and Disruption

The pandemic's primary impacts on the life sciences industry included accelerated product innovation and improved business efficiency. It also accelerated the preexisting trends of remote work and process digitalization, often with the support of regulatory agencies.

However, these impacts came at the cost of business disruption. "Normal business" in the life sciences industry became a lower priority and experienced some setbacks. Two prominent adverse effects included disruption of clinical trials for non-COVID-19 products and reduction in regulatory inspections. (Figure 3).

Although in the short term the pandemic has affected business as usual, it may prompt most countries to consider ways to enhance their public health systems in the future and potentially adjust regulatory approaches to speed up drug registration and approval processes which may lead regulators to establish more rapid approval mechanisms.

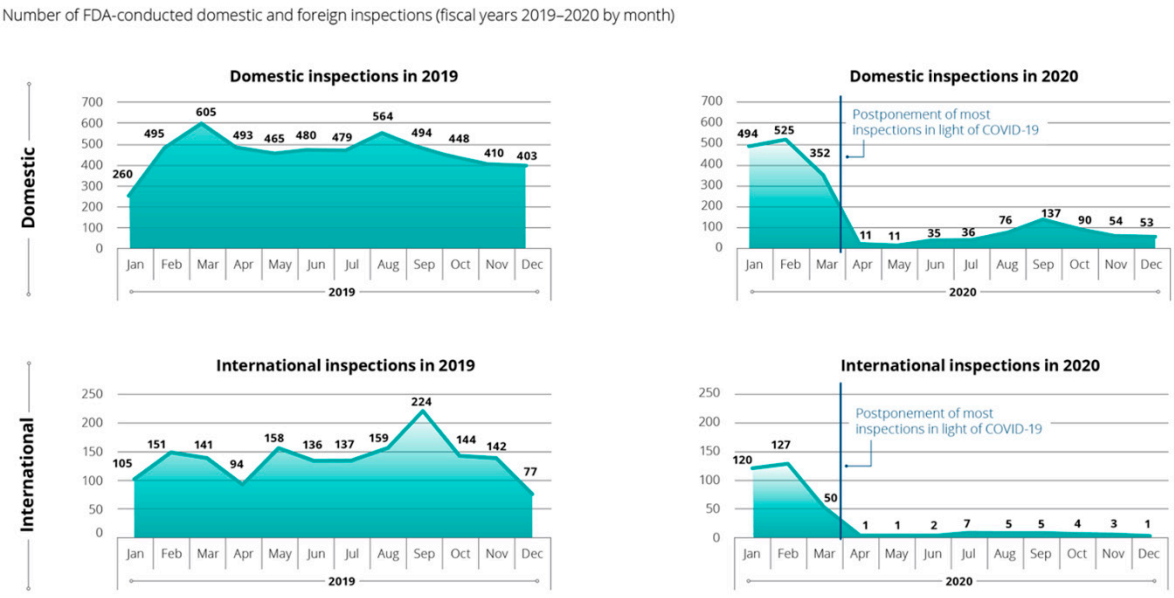
What Do These Impacts Mean for the Future?

Now is the time to assess the impacts of this health crisis, especially as governments worldwide begin discussing what the "new normal" looks like in the face of endemic coronavirus. Although the pandemic is ongoing, there is enough information to explore the strengths and vulnerabilities it has exposed and a potential direction to take going forward. For life sciences companies, regulators, and government, we believe some of the crucial lessons include:

Prepare now for the next health or other global crisis

Many responses were rapid, effective, and efficient, others less so. Specific areas to consider might include capabilities for analyzing data on infections and interventions, forecasting developments and needs, and mounting effective responses. Currently, it is a good

FIGURE 3: *FDA insinspection reduction trends*



Sources: US Government Accountability Office, "COVID-19: Critical vaccine distribution, supply chain, program integrity, and other challenges require focused federal attention," January 28, 2021; Deloitte analysis.

time to review methods of goal setting, communicating effectively, coping with change, and managing an often remote, stressed, and diminished workforce.

Take a proactive approach to regulatory agencies

For the private sector, the pandemic provides an opportunity to review the ways in which regulatory responses affected organizations and how these regulatory changes benefitted or hindered their efforts. Useful activities might include:

- Identifying potentially negative impacts of changes while operating in "crisis mode;"
- Considering changes that would benefit the organization, the larger industry, and health care ecosystem if they were institutionalized and carried forward; and
- Developing positions on these matters and presenting them to relevant regulators, either directly or in concert with other companies

Consider—and accelerate—digital transformation

Regulatory agencies in most of the major economies discussed here approved remote telehealth visits for patients, for prescriptions, and for follow-up visits. Regulators also employed remote inspections of clinical trial sites and manufacturing facilities and digital communication of clinical trial data, and similar tech-enabled interactions.

Within companies, interactions between sales representatives and health care providers have occurred through virtual meeting platforms, which can save time, money, travel, and human resources. The critical lesson is that digital transformation needs to be embraced but also planned for carefully and with all due attention to security.

Foster closer collaboration with other organizations

Many vaccine, drug, and medical device companies—as well as regulators—were able to collaborate fruitfully in the face of the pandemic. Therefore, companies should consider ways in which some heightened level of inter-organizational collaboration could be beneficial going forward.

Ask "What if?"—and ask it often

It has been said that a mind stretched to new limits resists a return to its former boundaries. It remains an open question whether this becomes true for regulators and life sciences companies because of the pandemic. Perhaps, but it will require new habits of mind as well as new ways of operating.

Develop and Implement Leading Practices

The broader health care and life sciences ecosystem would benefit from the development and promulgation of leading practices in each of the five areas outlined above, based on the needs raised by this global health crisis, especially for health care system risks and opportunities. Doing so will involve a robust analysis of the costs, benefits, and oversight considerations.

Conclusion

The COVID-19 pandemic presented a significant challenge to the life sciences industry and its stakeholders; however, it also provides for an opportunity moving forward to improve, shape, and digitize the industry's regulatory and compliance processes to be more safe, efficient, and effective. In turn, that can facilitate a faster product lifecycle and bring products to market quicker and with improved safety. Collectively, the life sciences ecosystem players can shape the future of the industry and improve public health.

References

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2 *See Terence Yifan Cal, et al., **Never the same again – How COVID-19 created seismic change in life sciences regulations**, Deloitte (2021), available for download at: https://www2.deloitte.com/us/en/pages/financial-advisory/articles/covid-19-created-change-in-global-life-sciences-regulations.html?id=us:2or:3or:awa_gritcovid:grit_covid_report.*

3 *See Francesco Guarascio, **In blow to WHO, EU seeks powers to declare health emergencies**, Reuters (Nov. 11, 2020), available at: https://www.reuters.com/article/health-coronavirus-eu-reform-int/in-blow-to-who-eu-seeks-powers-to-declare-health-emergencies-idUSKBN27R277.*

4 *See European Comm'n, Press Release, **Building a European Health Union: Stronger crisis preparedness and response for Europe** (Nov. 11, 2020), available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2041.*

5 *Government of Japan, **Declaration of emergency for new coronavirus infection, Article 32 of the Law on Special Measures for New Influenza (Act No. 31 of 2012)** (Apr. 7, 2020), available at: https://corona.go.jp/news/pdf/kinkyujitai_sengen_0407.pdf.*

6 *Government of Japan, **Summary of the Law of the New Type of Influenza Special Measures** (Feb. 2021), available at: https://corona.go.jp/news/pdf/tokuso_gaiyou_r3.pdf.*

7 *Xinhua News Agency, **Shanghai, Tianjin, Chongqing, and Anhui launch a first-level response mechanism for major public health emergencies** (Jan. 24, 2020), available at: http://www.gov.cn/xinwen/2020-01/24/content_5472050.htm.*

8 *See Pharmaceuticals & Medical Devices Agency, **PDMA's Efforts to Combat COVID-19**, https://www.pmda.go.jp/english/about-pmda/0002.html (last accessed Feb. 11, 2022).*

9 *See Int'l Council for Harmonisation of Tech. Requirements, **Welcome to the ICH Official Website** (last accessed Feb. 18, 2022), available at: https://www.ich.org/.*

10 *See Int'l Coalition of Med. Regul. Authorities, **COVID-19** (last accessed Feb. 18, 2022), available at: https://www.icmra.info/drupal/en/covid-19.*

11 *See Nat'l Medical Products Admin, **NPMA takes part in 3rd Asian Network Meeting** (updated Apr. 23, 2021), available at: http://english.nmpa.gov.cn/2021-04/23/c_613829.htm.*

12 *See, e.g., Kim Lyons, **Dyson says the UK doesn't need the ventilator it developed to treat COVID-19 patients**, The Verge (Apr. 25, 2020), available at: https://www.theverge.com/2020/4/25/21236141/dyson-ventilator-25-million-covid-19-coronavirus-ford-tesla-gm.*

13 *See Terence Yifan Cal, et al., supra n. 2 at 26. For Individual data sources see id. at 50-56.*

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