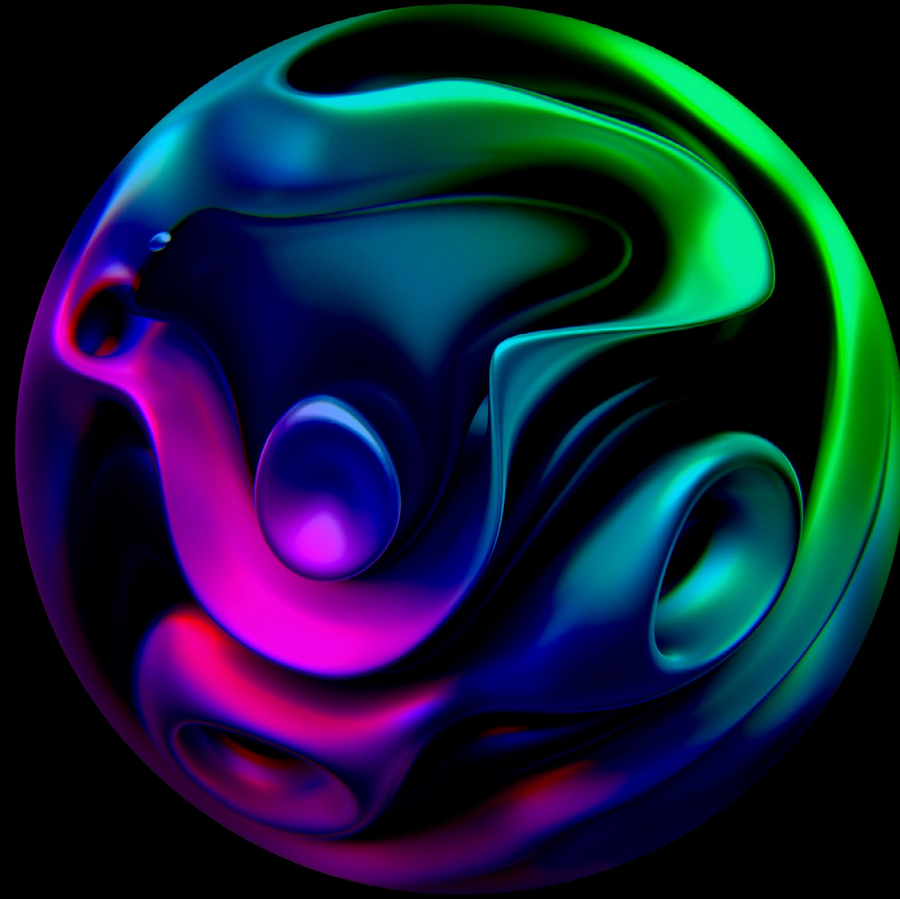


Deloitte.



Never the same again

How COVID-19 created seismic change
in life sciences regulations

**A report for executives, regulators,
and other stakeholders in the industry**



Foreword

The life sciences industry impacts the most precious resource of every country—its people—in terms of physical and mental health and matters of life and death. In light of this, every government has a vital interest in the industry, an interest evidenced in the approaches taken to regulating vaccine, drug, and medical device companies.

Even in what might be generously termed ordinary times, the regulatory ecosystem evolves. Yet since the outbreak of the COVID-19 pandemic in early 2020, we have lived in extraordinary times with the global regulatory landscape undergoing tectonic shifts that may well be, and perhaps in some cases should be, lasting.

This report aims to assist industry executives, regulators, and other stakeholders in assessing the past and likely future impact of the COVID-19 pandemic on the global life sciences regulatory ecosystem and the industry. Toward that end, we explore the regulatory and industry response to the pandemic in five of the world's largest economies and markets: the United States, China, the European Union, Japan, and India.

We have undertaken this initiative to give leaders a cogent overview of what has occurred between the industry and its regulators, what has been accomplished, and what might be done going forward during both ordinary and extraordinary times. Therefore, we report on significant—as well as less significant but interesting—actions taken by regulators and life sciences companies in the first year of the pandemic. To lend further context, we also provide observations as well as steps for regulators and companies to consider.

Although the life sciences regulatory ecosystem is increasingly global and intertwined, readers in various geographic locations and stakeholder groups will have varying levels of interest in specific parts of this report. In that sense, this report serves as a reference for organizations and individuals seeking to understand general as well as specific actions taken by key regulators and companies during the pandemic.

In addition, we trust that this review will promote clarity regarding:

- Decisions and actions that regulators, supranational organizations, and private-sector participants took, when they were taken, and the impact they had on the life sciences industry
- Levels and modes of communication and coordination between regulatory regimes and life sciences companies, within and across locations

- Ways in which life sciences companies and regulators cooperated and collaborated to address this pandemic—and produced lifesaving vaccines—in an astonishingly short time frame
- Steps that life sciences companies, regulators, and other stakeholders might consider as the pandemic continues and the risks of future health crises loom

In the global environment of relatively unencumbered movement of people, goods, and services, we see gaining clarity around these points as in the interests of everyone with a stake in the life sciences industry. Promoting that clarity is a foundational purpose of the Global Regulatory Intelligence Team (GRIT) at Deloitte. The strengths of this team include the public- and private-sector experience and knowledge base of its specialists across the Deloitte network around the globe. It also includes the team's ability to assist industry and regulatory professionals in sharing information, experiences, and leading practices—particularly in times like these.

The life sciences regulatory and industry landscape will continue to evolve, and GRIT is committed to monitoring and periodically reporting on that evolution.

It is in that spirit that we offer this report.

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The COVID-19 pandemic presents a case study in the ways in which the regulatory community, life sciences industry, and health care system responded to a global outbreak of a highly communicable and deadly disease. In keeping with each country's distinct regulatory system, those responses varied in their approach, timing, intensity, and effectiveness. Inevitably, those responses also reflected levels of economic development, regulatory infrastructure, political integration, communication capabilities, resource allocation methods, and cultural values.

This report explores the responses that regulators and the industry mounted during the first year of the pandemic to assist with answering questions like these:

- In what ways did the regulatory community and life sciences industry change their practices and stretch themselves to new limits during this crisis? Which of those new limits were the most impactful in this crisis, and which might also be beneficial in non-crisis times?
- Given what has been learned, how might regulatory processes and industry practices change moving forward in "normal" times and crisis times? Which processes and practices might usefully revert to status quo ante?
- How can participants in the industry influence a departure from the past to prepare organizations and the larger system for the next global health crisis?

Responses by regulators and the industry were generally, but by no means uniformly, rapidly and vigorously deployed. Public- and private-sector actors engaged in unprecedented levels of information sharing, collaboration, and cooperation. As a result, a wide range of regulatory, research and development (R&D), testing, production, and distribution processes were broadened and accelerated. In the course of these developments, new possibilities emerged with regard to what can be accomplished in the public health arena.

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Structure of this report

This report covers specific areas in which these efforts occurred, as follows:

Part 1. And just like that, everything changed: Governments declared 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 regulatory governmental agencies, life sciences companies, and the health care industry. One common effect was enabling governments to deploy a whole-of-government approach (to various degrees) to enact public health measures as well as steps that impacted life sciences industry supply chains and working arrangements. Regulatory agencies and industry responses soon followed, shaping the transition to operating in "crisis mode."

Although health emergency declarations varied in scope, timing, and impact, they positioned regulatory bodies and other government agencies and the life sciences industry to inform citizens, provide treatments and diagnostic tools, accelerate vaccine development, and support health care institutions and workers. Yet the success of responses depended heavily on countries' laws as well as on governance structures and mechanisms by which actions of agencies and institutions could be coordinated through a centralized approach.

Part 2. Underregulating for the common good: Regulators modified processes and collaborated with the industry at unprecedented levels.

Under the extremely uncertain conditions fostered by COVID-19, regulators set priorities for diagnostics, treatments, and vaccines, and for devices ranging from diagnostic test kits to personal protective equipment (PPE) to ventilators. The readiness and ability of regulators to relax certain requirements, lower barriers to entry, and accelerate approval processes 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.

Such measures were evident in all five locations reported on in this document. Exercising the ability to relax regulations and to collaborate while maintaining product safety always requires a balance sought by regulators and the industry. This section describes those measures.

Part 3. Allied for a common cause: Regulatory agencies collaborated across borders. To help manage the pandemic, regulators in most of the locations we studied collaborated at levels rarely, if ever, seen in the past. These collaborations focused mainly on areas such as creating clusters of technical experts, sharing research results, leveraging inspection reports, and disseminating information on how to help health care workers treat patients and stay safe. Of course, some regulators—particularly the US Food and Drug Administration (FDA) and the EU European Medicines Agency (EMA)—collaborated quite closely, while some in other regions took less collaborative approaches.

Regulators in the United States and the European Union brought those in other countries into their forums, although those in other countries relied more on the World Health Organization (WHO) and other institutions and engaged in more limited collaboration. Preexisting forums and frameworks for collaboration among agencies were particularly useful in that they enabled regulators to share data, exercise vigilance, and coordinate approaches within ongoing relationships, which foster trust.

Part 4. Pulling in the same direction: Life sciences companies reached new levels of collaboration.

Companies within the industry—and even outside it—engaged in heretofore unseen levels of collaboration. The urgent need to develop treatments, vaccines, diagnostics, and medical devices, along with the relaxation of related regulations, led life sciences companies that had been competitors to cooperate in developing solutions to scientific problems. 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.

The many instances cited in this part of the report evidence 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.

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Part 5. Mixed blessings and hard lessons: How the life sciences industry was impacted.

Key impacts on the life sciences industry included accelerated product innovation and improved supply chain in some areas of the business efficiency. The pandemic also accelerated the preexisting trends of remote work and process digitalization, the latter often with the support of regulatory agencies. However, “normal business” in the life sciences industry became a lower priority and experienced some setbacks. Prominent adverse effects included disruption of clinical trials for non-COVID-19 products and reduction in regulatory inspections.

Although in the short term COVID-19 has affected business as usual and reduced the speed of development in some areas, the pandemic has prompted most countries to consider ways to enhance their public health systems, optimize resources, and adjust regulatory approaches. Also, while some product approvals were delayed, in the longer run this crisis should speed up drug registration and approval processes and may lead regulators to establish more emergency and rapid approval mechanisms.

Within these five parts, we provide observations as well as suggestions for regulators and companies to consider as we move forward. We also separately point out how technology supported responses to the COVID-19 pandemic. In addition, Appendix A provides concise visual compendiums of key regulatory agencies in the five locales studied, and Appendix B presents timelines for significant actions and activities by key players.

The fact that responses did not occur uniformly across geographic locations and regulatory regimes is the source of many of the lessons to be drawn from the first year of the pandemic. Equally important, the more detailed effects and outcomes within locations and regimes—as reported here—warrant scrutiny, particularly by decision-makers whose roles and responsibilities impact public health.

Methodology underlying this report

In spring of 2021, members of Deloitte’s Global Regulatory Intelligence Team (GRIT) who are closely involved in the life sciences industry gathered data and information regarding steps taken by governments; regulators; and vaccine, drug, and medical device companies in the year after the outbreak in their respective countries. Select GRIT team members from around the globe contributed detailed information on the government and regulatory responses in their countries, impacts on the country’s regulatory framework, and life sciences companies’ actions as well as information on global collaboration among regulators and among life sciences companies.

These in-country professionals conducted secondary research, interviewed colleagues and contacts in the industry and regulatory community, and applied their own knowledge and

experience gained in working with companies and regulators before and during the pandemic. The information presented in this report represents the knowledge that existed in August 2021.

While we believe this report provides a good source of information on regulatory and industry responses in the first year of the COVID-19 pandemic, it does not cover nor does it aim to cover every event of significance to every stakeholder in the five locations reported upon. We have, however, exercised our best efforts to cover the most significant actions on the part of regulators and companies in the selected areas.

In this report, we focus on five of the world’s largest and most populous economies—the United States, China, the European Union, Japan, and India—and thus the largest markets for life sciences products.

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Governments declared health emergencies

On January 30, 2020, the World Health Organization (WHO) declared a global health emergency related to the novel coronavirus outbreak. A Public Health Emergency of International Concern (PHEIC) was issued, which is the highest level of alarm.¹ In turn, that prompted many countries to issue their own public health emergency declarations.

A declaration of a public health emergency positions a country's legislative and executive decision-makers to enact extraordinary measures that impact citizens' behavior as well as life sciences companies and the health care industry. One common effect was the ability of governments to deploy a whole-of-government approach to various degrees to enact public health measures as well as actions that impacted the life sciences industry, supply chains, and travel. (See Appendix B for whole-of-government approaches enacted by regulators in each location.) Regulatory and industry responses also followed and shaped the transition into operating under "crisis" mode. As with most responses to the pandemic, these declarations varied globally in their scope, timing, and effects.

United States

On January 31, 2020, the US Secretary of Health and Human Services (HHS), under section 319 of the Public Health Service Act, declared a public health emergency retroactively to January 27, 2020, nationwide.² Under this act, the FDA is now able to issue measures such as Emergency Use Authorizations (EUAs). Therefore, on February 4, 2020, the HHS Secretary determined that under section 564 of the Food, Drug, and Cosmetic (FD&C) Act there was a public health emergency with circumstances justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus (2019-nCoV).³ That, in turn, triggered the FDA's ability to issue EUAs.

In addition, on March 17, 2020, the HHS issued a declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) to provide immunity from liability to certain entities and individuals. The declaration was retroactive to February 4, 2020.⁴ Seven subsequent amendments were issued under the PREP Act in the months to come.

The COVID-19 health emergency declaration was followed by several key regulatory steps, with the following among the most significant:

- The FDA issued EUA declarations,⁵ which allow unapproved medical products or unapproved uses of approved medical products to be used for preventions and treatment of COVID on an emergency basis.
- On March 31, 2020, the FDA established a special emergency program—the Coronavirus Treatment Acceleration Program (CTAP)⁶—for fast-tracking medicinal coronavirus treatments.
- On April 3, 2020, the FDA leveraged the expanded access "compassionate use" program⁷ through the Emergency Investigational New Drug (EIND) application process. This provides a potential pathway for patients with an immediately life-threatening disease to gain access to investigational medical products. A notable example is the FDA authorized emergency use of convalescent plasma through the national Expanded Access Program (EAP) for convalescent plasma led by Mayo Clinic to treat COVID-19 patients.

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- On April 17, 2020, the National Institutes of Health (NIH) and its Foundation (FNIH) created the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) program. This consortium brought together more than a dozen leading biopharmaceutical companies, the Health and Human Services Office of the Assistant Secretary for Preparedness and Response, the Centers for Disease Control and Prevention (CDC), the FDA, and the European Medicines Agency (EMA) to develop an international strategy for a coordinated research response to the COVID-19 pandemic.⁸
- On May 11, 2020, to improve regulatory efficiency, the FDA also issued two new guidance documents that improve pathway efficiency for pre-clinical and clinical studies for COVID-19 therapies and diagnostic tests.⁹ Many other guidance documents would follow for medical devices, drugs, and therapeutics, among other matters.
- On May 15, 2020, the White House announced the creation of Operation Warp Speed (OWS).¹⁰ The aim of OWS has been to provide strong government financial and logistical support to accelerate vaccine development and distribution. OWS invested an estimated US\$18 billion for the development and early manufacturing of COVID-19 vaccines.¹¹ OWS is the largest of the global efforts for development of COVID-19 vaccines.
- During the pandemic, the US Congress¹² assisted in funding the response to the pandemic. In this role, it enacted several public laws providing funding to help government agencies, states, localities, businesses, and individuals respond to the coronavirus including the:
 - Coronavirus Aid, Relief, and Economic Security (CARES) Act (Pub. L. No. 116-136)
 - Families First Coronavirus Response Act (FFCRA) (Pub. L. No. 116-127)
 - Coronavirus Preparedness and Response Supplemental Appropriations Act (Pub. L. No. 116-123)

This whole-of-government approach facilitated a comprehensive response to the pandemic at the federal level.

China

China declared a public health emergency in late January 2020. On January 25, 2020, 24 provinces and cities launched a Level 1 response—the highest of four—covering some 1.2 billion people.¹³ The main measures of a Level 1 response include:

- **Governments** coordinating relevant departments to manage public health emergencies and control the spread of a pandemic
- **Health administrations** organizing medical institutions and centers for disease control and prevention to carry out investigation, research, and treatment during public health emergencies
- **Medical institutions** carrying out the directions of government and health administration departments through hospitals and health institutions to treat patients and contain the spread

The National Medical Products Administration (NMPA), China's life sciences industry regulator, also regulates several affiliated institutions in the areas of medical devices, vaccines, and drugs, as follows:

- **Medical devices** are regulated by the Center for Medical Device Evaluation (CMDE).¹⁴
- **Vaccines** are regulated by the National Health Commission, the Center for Drug Evaluation (CDE) and the Chinese CDC, which are responsible for public health management and disease control and prevention, as well as distribution of vaccines.
- **Drugs** are regulated by the CDE.¹⁵

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Early in the pandemic, steps taken by these regulators in specific areas included the following:

- 1. Medical devices:** The CMDE issued a series of guidance at the onset of the pandemic. These included Key Points of Technical Review for the Registration of COVID-19 Nucleic Acid Testing Reagents 2019 (Trial),¹⁶ developed by the Center for Medical Device Technology Review, National Drug Administration on February 12, 2020. This document has been serving as a standard to regulate the market of nucleic acid testing reagents.
- 2. Vaccines:** On August 14, 2020, the CDE issued five documents, including Technical Guidelines for Vaccine Development for COVID-19 Prophylaxis (Trial),¹⁷ provided criteria for evaluating COVID-19 vaccines in terms of clinical needs, safety, and efficacy, and addressed other matters.
- 3. Drugs:** On September 9, 2020, the CDE issued Guiding Principles for the Declaration of Clinical Pharmacy Research and Technical Data Requirements for Drugs of the COVID-19 Neutralizing Antibody Class (Trial).¹⁸ This is applicable to the development and clinical declaration of COVID-19 neutralizing antibody drugs, including antibody fragments, Fc-fusion proteins, bispecific antibodies, and more. Such antibody drugs have the potential to be used alone or in combination for the treatment and prevention of COVID-19.

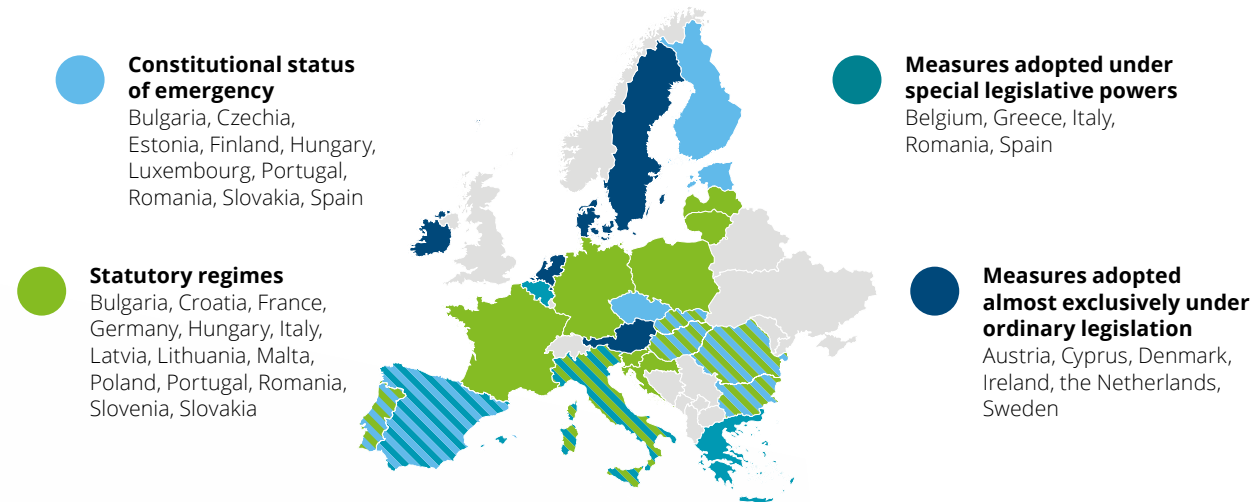
European Union

It was not until November 11, 2020, that the European Commission (EC) proposed rules that would give the European Union the power to declare a health emergency and act more independently of the WHO.¹⁹ These proposals focused on enhancing the current legal framework for serious cross-border threats to health and reinforcing the crisis preparedness and response role of key EU agencies, namely the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA).²⁰ However, at the onset of the pandemic, this rule was not in effect; therefore, the regulatory response across the European Union was fragmented.

As a result, responses to the pandemic differed across the European Union. Twenty-seven EU Member States (MS) (EU-27) adopted various approaches either alone or in various combinations. These included constitutional states of emergency, statutory regimes, measures adopted under special legislative powers, and measures adopted almost exclusively under ordinary legislation (figure 1).

Figure 1. EU Member States used various mechanisms to declare emergencies

27 EU Member States (EU-27) adopted various approaches either alone or in a variety of combinations with four main normative responses



Sources: European Parliamentary Research Service (EPRS), *States of emergency in response to the coronavirus crisis*, European Union, December 2020; EPRS, *Briefing: States of emergency in response to the coronavirus crisis: Situation in certain Member States*, European Union, June 2020; Deloitte analysis.

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The majority of MS (19) implemented a constitutional state of emergency, a statutory emergency regime (regimes provided by statute), or both; the remaining MS (8) enabled governments to adopt measures through legislation. Among the 24 MS that have a constitutional state of emergency clause, 17 have requirements that could—in principle—apply in a pandemic situation. Out of those 17, only 10 chose to activate those requirements during the first peak of the pandemic in Europe (Bulgaria, Czechia, Estonia, Finland, Hungary, Luxembourg, Portugal, Romania, Slovakia, and Spain). The remaining MS (Croatia, Germany, Lithuania, Malta, the Netherlands, Poland, and Slovenia) chose not to declare a state of emergency due to legal uncertainty, historical reasons, or both.

Some other MS (France, Italy, Latvia, and Lithuania) initiated a statutory emergency regime as their constitutional state of emergency powers could not be applied to a pandemic and activated the only possible comprehensive mechanisms. For example, on March 23, 2020, the French Parliament adopted a law on urgent measures (Law No. 2020-290) and declared a public health emergency for the first time ever.²¹

Concerns around the accepted measures among the MS centered on the extent of the measures and the legitimacy, duration, and the degree of parliamentary oversight.²²

The actions by the 27 EU governments evidenced some inconsistency in EU preparedness and crisis response for cross-border threats and somewhat insufficiently effective and targeted public health emergency governance. In response to the inconsistencies, the EC has adopted various plans and proposals to ensure better preparedness and response to future pandemics.

On February 4, 2020, the EMA activated a health threat management plan covering operations and communications with MS.²³ EMA also established a Task Force (COVID-ETF) to assist the Committee for Medicinal Products for Human Use (CHMP), a Pharmacovigilance Risk Assessment Committee (PRAC), and a Pediatric Committee (PDCO)—all to support development, authorization, and safety monitoring of treatments and vaccines.²⁴

The Task Force focused primarily on:

- Rapid scientific advice
- Rapid agreement of a pediatric investigation plan and rapid compliance check
- Rolling review
- Expedited marketing authorization
- Extension of marketing authorization
- Compassionate use
- Enhanced support for the development of treatments or vaccines

The EMA, together with other competent authorities as determined by MS, also supported the approval of medical devices during the pandemic (those authorities are defined as “notified bodies”). The EMA supported distribution of equipment such as ventilators, face masks and shields, protective gloves, and clothing for health care workers, which were in short supply in many countries.

In addition, the EMA introduced a business continuity plan. This plan describes the principles for addressing non-COVID-19–related assessments and overcoming obstacles caused by pandemics, as well as procedures related to COVID-19 medicines, treatment, and vaccines.

Japan

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.²⁵ A state of emergency allows Japan’s government to build temporary medical facilities without the land or building owner’s consent and to allocate drugs and medical devices as it deems appropriate. The state of emergency also allows public health directives to be issued for matters such as social distancing and masking. Although the national government issued a state of emergency, 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.²⁶ For example, if a business fails to cooperate with a measure, the local government can order it to do so, perform onsite inspections, and/or impose fines.

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As it relates to the development; manufacture; and supply of drugs, vaccines, and medical devices, the Ministry of Health, Labour and Welfare (MHLW) collaborated with industry groups such as Japan Pharmaceutical Manufacturers Association (JPMA), Pharmaceutical Research and Manufacturers of America (PhRMA), and the European Federation of Pharmaceutical Industries and Associations (EFPIA) to stabilize supplies of those items in response to the declaration of a state of emergency.²⁷

The regulatory authority for medical devices, vaccines, and drugs in Japan—Pharmaceuticals and Medical Devices Agency (PMDA)—also announced temporary deregulation and other regulatory changes, effective mainly from March to May 2020, to ensure a stable supply of existing products and to approve new products for prevention and treatment of COVID-19.

India

On March 11, 2020, the Indian government requested state governments to invoke the Epidemic Diseases Act (EDA) of 1897 and powers under the Disaster Management Act (DMA) of 2005. The latter authorized the Prime Minister to enact special measures and provide relief for victims. Chief Ministers in states may also invoke special powers under the law. However, the EDA is not comprehensive and leaves state governments to devise their own public health laws.²⁸

Central Drugs Standard Control Organization (CDSCO) is India's main regulatory body for pharmaceuticals and medical devices. The Drug Controller General of India (DCGI) is the key official within the CDSCO. These regulators initiated emergency measures to aid the response to the pandemic including the followings steps:

- In March 2020, the Department of Biotechnology (DBT) and CDSCO came together to set up a rapid regulatory framework to fast-track regulatory approvals for vaccines, diagnostics, prophylactics, and therapeutics designed to prevent or treat COVID-19.²⁹

- The Indian government issued directives under the wide powers vested under the Drugs and Cosmetic Act of 1940 to regulate the manufacturing, sale, or distribution of a drug as may be necessary for the public interest.³⁰
- Regulators enacted new measures to expedite access to devices intended to prevent or treat COVID-19 and to safeguard the supply of critical in vitro diagnostics (IVDs).³¹
- Regulators permitted the use of drugs, vaccines, and diagnostics under EUA.³²

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Observations

The United States, Japan, India, and EU nations initiated their emergency health measures after the WHO issued its health emergency declaration. The reliance on the WHO has prompted the European Union to change that condition in their new revision of the emergency laws for Europe in November 2020.

Although all countries issued their health emergency measures, the extent of their impact varied. Some were initially deemed ineffective and had to be revised or enhanced, while in other countries or regions the emergency measures were well thought out and initiated a coordinated government response, which enhanced outcomes.

The ability to apply a successful whole-of-government response depended not only on the predefined laws governing the emergency measures in a given location but also on the country's or region's governance substructure, authority under the law, and the ability of government institutions to be coordinated through a centralized approach.

Moving forward

Moving onto an emergency footing enables a government to prioritize public funding as well as private-sector resources toward relieving suffering and resolving the crisis. While no entity can sustain operations on an indefinite state of emergency—and crises do eventually end—certain steps related to public health emergencies may be worth institutionalizing. Indeed, in some cases this may be essential to achieve preparedness for the next public health emergency, even if it takes a different form.

From a public health and risk management perspective, steps to consider might include:

- Clarifying lines of authority:** Countries and regions with clearly defined lines of authority and communication were generally able to mount faster and more coordinated responses. While national agencies need to be sensitive to the roles of state, provincial, and local governments, they must also be positioned to mount nationwide—and international—initiatives during public health emergencies. Fragmented approaches generally slowed decision-making and deployment of countermeasures.
- Establishing robust data analytics:** Declaring a health emergency and assessing its impact are judgment calls best supported by data and analytics. Data gathering and reporting, impact monitoring, data analytics, and scenario modeling have strong records of assisting planners and decision-makers. Accurate and timely data positions authorities to improve their decision-making processes to more clearly explain their decisions, and to keep relevant parties more fully informed.
- Establishing contingency plans and processes:** Not all the reported-on countries that enacted emergency declarations had well-prepared plans and processes to provide flexibility to regulators to expedite their activities. Governments should consider reviewing and enhancing the full range of plans and processes to be enacted when a health emergency is declared. Moreover, those plans and processes should be made public and shared with the life sciences and other relevant industries, which in turn can also be well prepared for future crises.

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Regulators modified processes and collaborated with the industry at unprecedented levels

Regulators had to respond swiftly to changing needs, typically on the basis of limited and evolving information. Early efforts focused on slowing the spread of infections, diagnosing and treating patients, and developing safe and effective treatments and vaccines.

Under extremely uncertain conditions, regulators set priorities for diagnostics, treatments, vaccines, and devices ranging from diagnostic test kits to PPE to ventilators, with generally good effect. Moreover, and quite significantly, the readiness and ability of regulators to relax certain requirements, lower barriers to entry, and accelerate certain approval processes undoubtedly facilitated rapid public- and private-sector responses. A timeline depicting the major actions taken by regulators and private industry as well as milestones for some of the covered countries can be found in Appendix B.

In addition, collaborations between regulators and life sciences companies, which reached unprecedented levels during the COVID-19 crisis, facilitated innovation of diagnostics, drugs, vaccines, and medical devices and accelerated their introduction to the market.

Sample cases of regulatory flexibility and collaborative measures between regulators and the private sector are included in the following sections.

United States

Numerous regulatory modifications by US regulators enabled enhanced responses to the pandemic. Increased collaboration between regulators and the private sector accelerated the introduction of urgently needed products to the market. Regulatory modifications, enhancements, and collaborations with life sciences companies in the United States include:

• Relaxing requirements

- Relaxing requirements for good manufacturing practices (GMP) for non-life sciences companies, especially for ventilators and PPE, to supplement supply of these products early in the pandemic
- Using EUA procedures for PPE products, IVDs, medical devices, drugs, and vaccines³³ to accelerate introduction of these products

- Conducting parallel processing of activities usually done sequentially to fund production before clinical trials were approved and allowing phases of clinical trials to proceed before prior steps are approved, as was done in OWS
- Overnight review of COVID-19 protocols, and waiving the 30-day Investigational New Drug (IND) application waiting period³⁴
- Modifying IND provisions, for example:
 - Relaxing clinical trial application (CTA) provisions to accelerate the administrative process
 - Providing dedicated FDA staff accessibility to life sciences companies, and delivering scientific advice nearly in real time
 - Holding virtual meetings between sponsors and regulators as well as using telemedicine in clinical trials

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- Offering FDA assistance in creating and submitting data on behalf of companies manufacturing drugs to expedite registering their manufacturing facilities, and listing their products to enable faster production and distribution³⁵

• Issuing guidance to industry

- Regulators issued guidance to assist and clarify new or relaxed requirements under the emergency provisions for IVDs, medical devices, drugs, and vaccines and to help accelerate their development
- Regulators also issued guidance for researchers and developers on how to efficiently engage with the FDA and expedite clinical trial initiation for COVID-19 therapeutics³⁶
- The FDA, under the direction of the CARES Act, issued guidance to assist manufacturers in providing the FDA with timely notifications of changes in the production of certain medical devices that will help the agency to prevent or mitigate shortages of devices during the public health emergency³⁷

• Improving engagement and communication pathways

- Accelerated communication through the Center for Drug Evaluation and Research (CDER) by providing a specific inbox for sponsors to use with the FDA for COVID-19-related submissions and questions
 - Pre-IND meeting requests for CDER-regulated drugs submitted through these portals were routed to the mailbox staff in ways that facilitate tracking and rapid identification of division and office assignment, and expedited trial initiation

- Enhanced accessibility of dedicated FDA staff to life sciences companies and near real-time delivery of scientific advice, as in the following instances:

- CDER's Office of New Drugs (OND) has established a COVID-19 scientific/technical triage team to ensure completeness and sufficiency of information provided by sponsors for expedited review
- FDA produced multiple resources to provide general advice regarding pre-IND meeting request content³⁸ and clinical development of COVID-19 drugs for sponsors³⁹
- Virtual meetings between sponsors and regulators as well as use of telemedicine in clinical trials
- Events and conferences⁴⁰ such as virtual town hall meetings for SARS-CoV-2 test developers⁴¹

- Improved workflow management through implementation of processes and tools to more efficiently handle the heavier workload associated with EUA requests and IND applications submitted to the medical product centers

• Postponing inspections

- March 2020, the FDA postponed many routine domestic and foreign facility inspections and reserved inspections for mission-critical matters.⁴² Steps included reviewing information requested from facilities in advance or in lieu of certain inspections, using remote assessments to evaluate facility records, and leveraging information shared by trusted regulatory partners.

On March 31, 2020, the FDA established the CTAP⁴³ in which the FDA worked with agencies, academics, and private industry on developing promising countermeasures. The countermeasures aimed to facilitate expedited approval of products during the pandemic and unprecedented regulatory flexibility. The FDA stressed that these efforts would not compromise drug safety and efficacy.⁴⁴

To assess supply chain vulnerabilities and minimize disruptions, the CDRH reached out to more than 1,000 manufacturing sites in 12 countries.⁴⁵ Meanwhile, the FDA issued more than 70 guidance documents⁴⁶ to provide updated policies, transparency, and regulatory flexibility to address food supply, medical products, and public health issues. Among these was the Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act During the COVID-19 Public Health Emergency⁴⁷ to bolster the supply chain. This guidance announced the FDA's policy regarding its discretion in enforcing authorized trading partner requirements.

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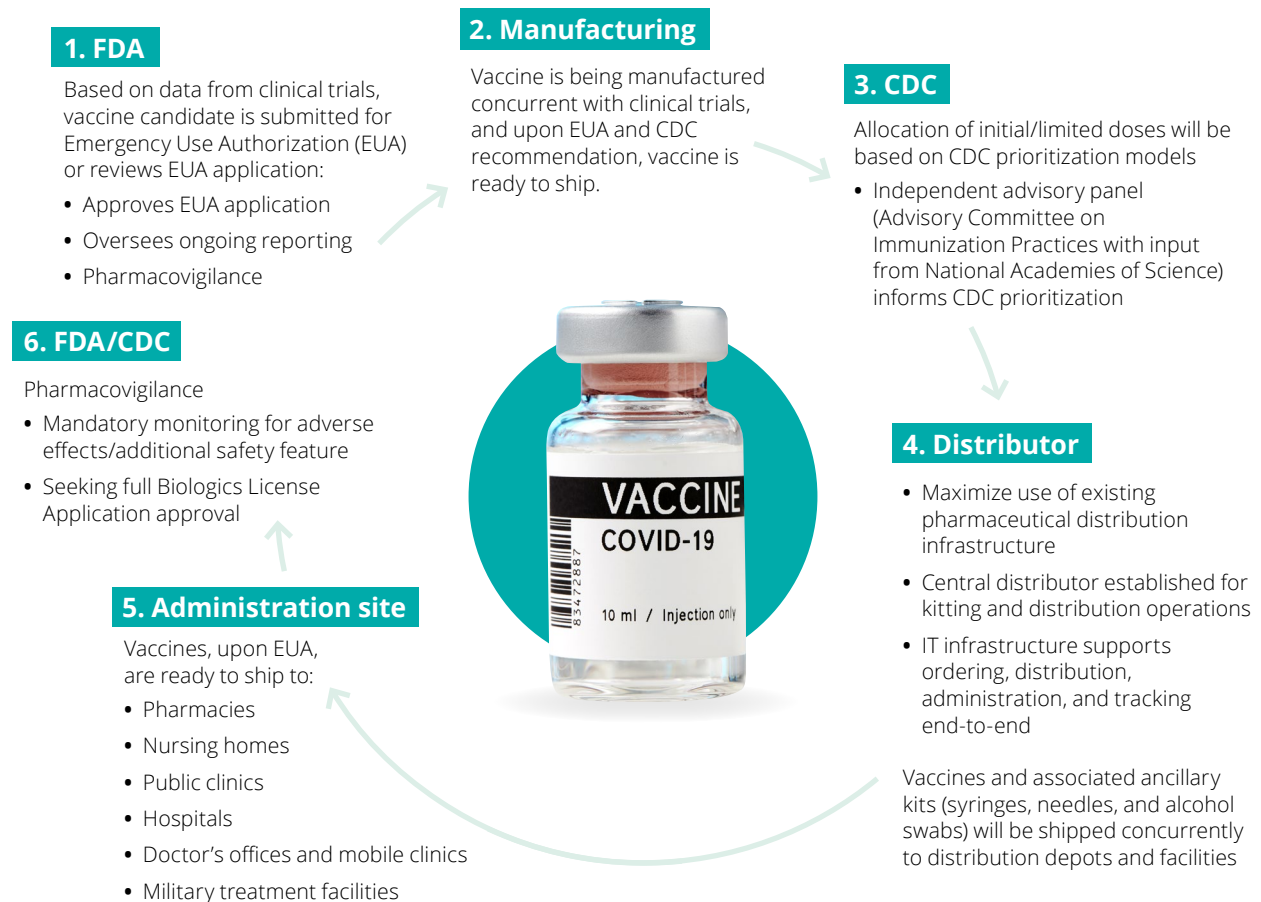
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OWS and other steps

Other steps taken include the following:

- On May 15, 2020,⁴⁸ to accelerate vaccine development the White House announced OWS (figure 2). Eight vaccines were funded through OWS and four were approved for use by the FDA and EMA. Indemnification of companies against liability claims was a key feature of this initiative.

Figure 2. COVID-19 vaccine development: Operation Warp Speed (OWS)—a USA collaborative Initiative



- In March 2020, under the PREP Act, the US government provided immunity from liability to certain entities, retroactive to February 4, 2020, for COVID-19.⁴⁹ Seven subsequent amendments were issued under the PREP Act in the months to come. These provided protection from liabilities arising from development of vaccines, medicines, and medical devices to enable companies to develop, test, produce, and distribute products quickly, with the government assuming liability.
- In April 2020, the NIH created the ACTIV program, which brought together life sciences companies, US regulators, and the EMA to develop an international research response. ACTIV streamlined development and approvals for vaccines and drugs.⁵⁰ It also standardized and shared pre-clinical evaluations, prioritized evaluations to test the most promising candidates, and optimized trial utilization.
- In June 2020, the FDA hosted virtual meetings for life sciences companies on activities related to high-priority issues. These activities included public- and private-sector entities exploring strategic partnerships to develop and manufacture COVID-19 vaccines and therapeutics.⁵¹

Also, the FDA entered a Memorandum of Understanding (MoU) with the Department of Veterans Affairs (VA) Innovation Ecosystem and the NIH 3D Print Exchange⁵² to share data and coordinate development of open-source medical products. These agencies are working with America Makes to connect health care providers and 3D printing organizations.

Source: Deloitte analysis.

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The CARES Act⁵³ expanded drug listing requirements to help quantify for regulators the volume of finished drug products and active pharmaceutical ingredients (APIs) manufactured domestically and abroad for the US market. More broadly, the CARES Act requires the National Academies of Science, Engineering, and Medicine (NASEM) to examine the security of the US medical product supply chain, including US dependence on other countries.

China

The government set ambitious goals to achieve herd immunity with its policy of ensuring that all those in need are vaccinated. As of March 31, 2021, COVID-19 vaccinations reached 120 million. Supporting this initiative, the Chinese government worked with life sciences companies in the following ways:

- **For vaccines and drugs**, the regulatory measures for the administration of drug registration specified procedures for accelerating the process. These included priority conditional approval and priority review and approval, with the medical affairs department quickly generating clinical evidence after launch.⁵⁴ The inactivated COVID-19 vaccines developed by Sinopharm and Beijing Kexing were granted conditional approval, which significantly shortened their approval process.

- **For medical devices**, the Chinese government implemented two “green channels”—innovative special approval and priority approval. For innovative special approval, NMPA performed evaluation and approval for category II and III medical devices that met certain criteria, such as lawful ownership of the core patent in China, completed preliminary research, and traceable supporting data. For priority approval, NMPA provided preference to domestic category III and imported category II and III medical devices that were urgently needed but have no Chinese substitutes.⁵⁵
- Specific instances of accelerated domestic development and deployment of products include:
 - **Vaccines:** On April 12, 2020, the Sinopharm Wuhan Institute obtained approval for clinical trials of inactivated COVID-19 vaccine; on April 13, 2020, Beijing Kexing obtained similar approval. Both organizations were granted conditional approval of vaccines in December 2020 and February 2021, respectively.
 - **Drugs:** Multiple clinical trials were approved for treatment and prevention of COVID-19, including remdesivir and favipiravir.
 - **Testing kits:** In addition to nucleic acid diagnostic reagents, approved testing kits included a colloidal gold antibody detection reagent and a thermostatic amplification chip nucleic acid detection reagent.
 - **Medical devices:** Steps were taken to accelerate approval for registration, production license, inspection, and testing of medical devices such as masks and PPE.

The pandemic also prompted increased collaboration between regulators, government agencies, and private life sciences companies. Examples include the following:

- In August 2020, Sinopharm signed an agreement on deepening strategic cooperation with the Hubei provincial government.⁵⁶
- In April 2021, Dalian Municipal Health Commission and Kexing holding Biotechnology Co., Ltd. signed a memorandum of understanding on strategic cooperation. The Municipal Health Commission will cooperate with Kexing in vaccine R&D and clinical research.

Also, the establishment of the National Bureau of Disease Control and Prevention marks a significant change in government policy. This bureau elevates the status of public health and the importance of disease prevention, which may contribute to future market development.⁵⁷

European Union

On February 4, 2020, the EMA activated a plan for managing emerging health threats, which covered operational aspects and communication with EU MS.⁵⁸ Based on experience from the 2009 influenza H1N1 pandemic and the 2014–2016 Ebola outbreak in Western Africa,⁵⁹ the plan addresses cross-border health threats necessitating coordinated action at the Union level.

The EMA also established a pandemic Task Force (COVID-ETF) to assist the Committee for Medicinal Products for Human Use (CHMP), Pharmacovigilance Risk Assessment Committee (PRAC), and Pediatric Committee (PDCO) to coherently support the development, authorization, and monitoring of COVID-19 treatments and vaccines.

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The Task Force focused primarily on:⁶⁰

- **Rapid scientific advice:** A free-of-charge procedure reducing review time to a maximum of 20 days (from 40–70 days) with no pre-specified submission deadlines. Flexibility can be arranged based on the type and extent of the briefing dossier.
- **Rapid agreement of a pediatric investigation plan and rapid compliance check:** Expedited revision of applications for agreement of pediatric investigation plans (PIPs), deferrals or waivers for treatments and vaccines (including no pre-specified submission deadlines), and review of the PIP reduced to 20 days minimum (from 120 days). EMA decision following a review was reduced to 2 days from 10 days. Developers can provide focused scientific documentation, on a case-by-case basis, and compliance checks, if required, can be reduced to 4 days.
- **Rolling reviews:** An ad hoc procedure to allow EMA to continuously assess data for highly promising new product applications as the data becomes available.
- **Marketing authorization:** Accelerated marketing authorization applications for products intended for prevention or treatment of COVID-19. Extended marketing authorization also applies to already authorized products being developed or repurposed for treatment or prevention of COVID-19.
- **Compassionate use:** Specified unauthorized medicines can be made available at national levels through compassionate use programs, through CHMP recommendations.

- **Other considerations:** Enhanced support for development of COVID-19 treatments or vaccines can be considered by the “Priority medicines (PRIME) scheme,” specifically designed by EMA.⁶¹

The EMA and “notified bodies” also supported approval of medical devices during the pandemic. Medical devices in the European Union must pass a conformity assessment to ensure they meet requirements. Depending on the device category, assessment can be done by EMA or other authorities determined by MS. Those authorities are defined as “notified bodies.”⁶² PPE and ventilators were secured by governments, with the EMA supporting supplies of this equipment.

Beyond onsite, centralized, and offsite monitoring, the EMA expanded the types of trials that may use remote source data verification (rSDV).⁶³ In addition, the EMA introduced a business continuity plan. This plan describes principles for addressing non-COVID-19–related assessments and other challenges amid pandemics, as well as procedures related to COVID-19 medicines, treatment, and vaccines.

The EMA issued guidance on temporary labeling flexibility for COVID-19 vaccines and treatments. For example, new vaccines are temporarily exempt from national language rules in their packaging. In December 2020, some countries also allowed for English-language materials and further exemptions.⁶⁴ There are also exemptions for medicinal products. The EMA emphasizes that these exemptions are temporary and apply only to essential pandemic-related vaccines and medicines.⁶⁵

During the first year of the pandemic (the period under review in this report), increased interactions between regulators and life sciences companies, specifically pharmaceutical companies, were observed. This was specifically seen regarding monitoring of the supply of essential medicines. For example, the EU Executive Steering Group on Shortages of Medicines Caused by Major Events set up a Single Point of Contact (SPOC) Network together with the pharmaceutical industry to ensure the exchange of information between national authorities and industry. Each pharmaceutical company directly reports to the EMA on any shortages or potential shortages of critical medicines for COVID-19.

Japan

In general, the PMDA responded within existing rules without special measures; however, to support the life sciences industry, PMDA introduced several changes in regulation. For example, under the normal approval review system, drugs that meet specific conditions, such as orphan drugs or drugs for high severity diseases, are subject to priority review.⁶⁶ In April 2020, PMDA announced that drugs targeting symptoms related to COVID-19 would be prioritized for review. In March 2020, PMDA abolished the 30-day waiting period after the start of clinical trials. In May 2020, PMDA announced that clinical trials may proceed if the efficacy and safety of the results of public research projects have been confirmed.⁶⁷

From March to May 2020, PMDA announced temporary deregulation in several areas to ensure a stable supply of existing products and to approve new COVID-19-related products. The regulatory framework for fast-track approval in emergencies has been tentative, and new rulemaking will be considered in the future.

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PMDA announced in April 2020 that it would prioritize regulatory procedures for disinfectants until supply and demand stabilize.⁶⁸ Also, given the tight supply of single-use parts for respirators, in April 2020, PMDA approved re-use of single-use parts after sterilization and other procedures until supply issues are resolved.⁶⁹

Moreover, in order to carry out clinical trials without delay, the following regulatory requirements were relaxed in April 2020:⁷⁰

- Medical institutions were given the ability to conduct online clinical trial review with committees.⁷¹
- Regulators accepted digital clinical trial signatures.
- Companies were able to submit a copy rather than the original of documents, such as informed consent.
- PMDA also applied special approval measures for drug products that meet three requirements: 1) urgent use is required to prevent the spread of the disease, 2) there is no appropriate method other than the applied drug, and 3) sales overseas are approved. In addition, the procedure for special approval was simplified. For instance, application materials other than clinical trials were waived and could be submitted after approval. That, in turn, accelerated special approval to days or months rather than 9–12 months.

Japan's regulators and life sciences companies collaborated more closely than in pre-pandemic times in several ways:

- Ordinarily, the PMDA regularly accepts consultations on drug applications only from specific companies and organizations. However, during the pandemic any company can consult anytime in order to realize prompt application and approval of a COVID-19 vaccine.
- For life sciences companies developing new testing methods, National Institute of Infectious Diseases (NIID) has provided reagents to 18 private testing companies, 89 university (and other) hospitals, and 33 health centers to support PCR testing.⁷²

India

A regulatory framework was quickly established for rapid COVID-19 response, including fast-tracking the approval process for vaccines, diagnostics, prophylactics, and therapeutics.⁷³ In March 2020, the Central Drug Standards Control Organization (CDSCO) and the Department of Biotechnology (DBT) established a rapid regulatory framework to fast-track approvals for clinical trials as well as importation or manufacture of a vaccine.⁷⁴

In May 2020, the Ministry of Health and Family Welfare set up an approval system permitting applicants to manufacture and stock COVID-19 vaccines under clinical trial. Once clinical trials conclude, the vaccine can be sold and distributed after obtaining permission under the New Drugs and Clinical Trial Rules, 2019.⁷⁵

The Subject Expert Committee (SEC), a CDSCO committee of eight experts, developed recommendations to relax regulations on clinical trials, drugs, vaccines, and medical devices, which included:

- **Expedited approval processes for COVID-19 vaccines**, allowing use of pre-clinical data gathered outside India and providing faster and more direct communication with CDSCO. Per the vaccine notice dated March 19, 2020,⁷⁶ companies seeking expedited approval of vaccine or needing help related to regulatory guidelines could approach the DCGI through its public relations office. This helped to establish an expedited approval system for clinical trials, manufacturing, and import of the vaccines.
- **Expedited approval processes for medical devices**, allowing any company with an IVD kit to contact the DCGI directly, and handling of priority applications within seven days.
- **Delayed inclusion of medical devices under the Medical Device Rule, 2017 (MDR)**, postponing the effective date under which 13 new categories of medical devices were to be regulated under the MDR.
- **Relaxed import requirements**, enabling importers of medical devices to submit self-attestation documents for licenses, with a four-month window for submission of notarized documents.
- **Amended clinical trial requirements**, allowing the hospitals and medical institute to import and use urgently needed but unapproved drugs on the condition that those drugs will undergo phase 3 clinical trials in India or another country, will not be sold on the open market, and will be carefully inventoried—steps that helped India to obtain remdesivir.

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- **Relaxed GMP requirements**, extending the validity of a Certificate of Pharmaceutical Product (CoPP) by six months over and above its usual three years;⁷⁷ this was issued by CDSCO through a public notice dated May 1, 2020.

Also, in consultation with DCGI, CDSCO published a memorandum on a Rapid Response Regulatory framework for COVID-19 detailing the decision to fast-track the regulatory approval process for developing vaccines, diagnostics, prophylactics, and therapeutics.

Regulatory agencies introduced numerous measures to support pharmaceutical companies to maintain uninterrupted manufacturing and distribution of drugs. Expedited approval processes by CRDCO helped drug manufacturers to get fast approvals during drug manufacturing. A draft clinical amendment was introduced to allow hospitals and medical institutions to import or manufacture unapproved drugs needed to treat life-threatening disease. A sales license exemption for sanitizers helped sellers to enter the market quickly. Import relaxation, GMP relaxation, and drug import notification were introduced to help companies to continue operations.

To further help manufacturers, the SUGAM portal,⁷⁸ a consolidated drug regulatory framework, was launched by CDSCO. SUGAM offers an online platform for submitting applications for approvals for clinical trials, medical devices, drugs, cosmetics, and vaccines. The portal enables tracking of applications through the SUGAM dashboard and enables countrywide monitoring of regulatory clearances.

Launched on January 16, 2021, COVID Vaccine Intelligence Network (CoWIN) is an Indian government application developed for vaccine management and has documented more than 1 billion vaccinations in India.⁷⁹ This application collects real-time feedback and monitors vaccine utilization, wastage, and coverage. After drawing global interest, an open-source version of the application has been distributed to nearly 50 countries in Asia, Africa, and Latin America.⁸⁰

Observations

A widespread, let alone global, public health crisis presents a broad range of challenges, particularly when the virus is new; its effects are unclear; and R&D, production, distribution, and health care capacities are geared to business as usual. In those circumstances, setting priorities and relaxing requirements become paramount. The global regulatory community is to be applauded for the alacrity with which it responded to threats presented by the pandemic and the need to reorder priorities. Rightly—and with excellent results—regulators continued to prioritize product safety and efficacy in R&D, production, and distribution efforts.

Such measures were evident in all five reported-on locations. The flexibility that regulators provided regarding site inspections; clinical trials; marketing materials; and authorized uses of previously unauthorized drugs, medicines, and devices expedited approvals and to address shortages and market needs. Although regulatory institutions responded differently at the onset of the pandemic, all adjusted their responses to address this public health crisis.

That said, the extent of relaxation and collaboration between industry and regulators varied. The ability to relax regulation and to collaborate while maintaining product safety is a fine balance sought by both regulators and industry. The risk/benefit calculation during a crisis differs from that of normal times, and thus regulatory relaxation was justified. In addition, innovative collaboration tools and forums created during the pandemic provided a break from common practices while introducing a few new risks.

Moving forward

Participants in the life sciences industry and its regulatory ecosystem should, when possible, aim to sustain the type and levels of communication attained during the pandemic. Such communication can build stronger, wider bridges between the industry and its regulators, prepare them for future crises, and enhance trust and improve relationships in ordinary times. Indeed, regulators and life sciences companies should examine all measures as well as collaborative tools, forums, and channels pursued during the pandemic and—going forward—consider ways to:

- **Identify areas where flexibility helped:** As part of the foregoing suggested approach, regulators and life sciences companies might review, separately and collaboratively, areas in which requirements were relaxed and ask: Where did relaxing requirements present no—or perhaps very limited—new risks? Where might it make sense to permanently modify requirements? How might industry participants develop a framework that sets forth areas where requirements might be more flexible in the future, in ordinary times and times of crisis?

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- **Learn where collaboration streamlined regulatory approval:** Regulators might review all areas where collaboration occurred and ask: How can collaborative measures and tools be employed in normal times? What other measures and tools can be employed? Which collaborative forums should be kept? How can collaboration address other pressing health needs such as cancer or chronic or degenerative diseases? To the extent that collaboration practices yielded benefits, the regulatory community and the industry should consider ways to institutionalize them and make them permanent. While this may be accomplished through industry associations, the value of regulator-to-company practices might be considered more deeply.

- **Revisit regulatory costs and benefits:** Development and production of COVID-19 vaccines, treatments, and medical devices provides a case study of costs and benefits of regulations that focus on R&D efforts, such as clinical trials, as well as those concerning site inspections, data development and sharing, and registration and launch of products. Reviewing these cases may help to quantify the costs and benefits of regulatory processes and ways in which they may be cost-benefit sensitive.

- **Broaden collaboration to more parties:** The pandemic impacted hospitals and caregivers, as well as supply chain and other relationships, in ways that life sciences companies and regulators rarely see. As stakeholders in the industry and regulatory system, those parties have points of view that could be worth understanding in greater depth, particularly given current and expected stresses on the health care systems. Bringing those stakeholders into the fold might well enrich the knowledge base and real-world dimensions of decisions that life sciences companies and regulators make.
- **Modify approaches to compliance:** While regulators clearly have a weighty duty of care in exercising oversight of the life sciences industry, regulators and companies might learn from actions taken during this period through further inquiry. For example, how can information about products and their components and effects be communicated better by companies? Where might providing greater transparency by parties yield benefits? How can processes be streamlined and made more efficient?

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Spotlight on Switzerland

On March 16, 2020, the Swiss Federal Council declared an “extraordinary situation” under the Epidemics Act.¹ Life sciences companies experienced little impact in development and distribution of drugs, vaccines, and medical devices, apart from ensuring that all employees followed hygiene and distancing measures.

In March 2020, the Federal Council also created the Coronavirus Crisis Unit to coordinate efforts of government departments, the Federal Chancellery, the cantons, and crisis units.² The federal government and the cantons have coordinated assessments, reconciled measures, and defined processes related to COVID-19.³ The Swiss National COVID-19 Science Task Force was created in March 2020 as an advisory body to the Federal Council, and other Swiss offices.⁴

The Federal Office of Public Health (FOPH) initiated measures according to the Swiss Influenza Pandemic Plan, which, although specific to influenza, formed the basis for operational and

emergency plans at cantonal, regional, and local levels.⁵ FOPH also created the FOPH COVID-19 Task Force to monitor the coronavirus in Switzerland.⁶ It also crafted control measures on behalf of the Swiss Federal Council and coordinated with international organizations and the Swiss National COVID-19 Science Task Force.

On April 3, 2020, the Federal Council approved various measures designed to guarantee the supply of products for preventing and combating the COVID-19⁷ disease. There were no measures taken to ensure development of drugs or vaccines.

In Switzerland, Swissmedic is the regulator responsible for overseeing drugs, vaccines, and medical devices. Interactions between life sciences companies and Swissmedic appeared basically unchanged, except for inquiries regarding onsite inspections and similar requests. Swissmedic announced that GMP decisions would be case by case, based on a risk analysis,⁸ and that GMP certificates based on routine inspections in 2017 or

2018 would remain valid until the end of 2021, provided the scope of activities remained substantially unchanged.⁹ The regulator also announced that inspections would occur only if protective measures were met, or inspections could be done remotely. Scheduled, for-cause, or non-scheduled safety assessments will generally take place onsite.

In Switzerland there is no legal basis for EUA of COVID-19 vaccines while the applications are being processed.¹⁰ Parliament and the Federal Council decided that Swissmedic should review submitted documentation carefully according to scientific criteria. Swissmedic fast-tracked all applications while ensuring that checks were not compromised. With rolling submission, Swissmedic has created a process to be used for immediate review of data submitted by companies on an ongoing basis.

1. Switzerland Federal Council (FC), “Coronavirus: Federal Council declares ‘extraordinary situation’ and introduces more stringent measures;” press release, March 16, 2020.
2. Federal Office of Public Health (FOPH), “Coronavirus: Situation in Switzerland;” accessed November 12, 2021.
3. COVID-19 Health System Response Monitor, *Switzerland: Policy responses for Switzerland*, accessed November 12, 2021.
4. State Secretariat for Education, Research and Innovation, “Swiss National COVID-19 Science Task Force: Adapted mandate and new chair;” press release, July 20, 2020.
5. FOPH, *Swiss Influenza Pandemic Plan, 5th ed.*, 2018.

6. FOPH, “FOPH COVID-19 Task Force;” June 14, 2021.
7. Swissmedic, “Placing on the market of important non-conforming medical devices for combating the COVID-19 pandemic;” June 29, 2020.
8. Swissmedic, “Inspections during the COVID-19 pandemic—additional change;” November 3, 2020.
9. Swissmedic, “Validity of GMP certificates during the COVID-19 pandemic;” November 20, 2020.
10. Swissmedic, “Benefits and risks of COVID-19 vaccines: Rapid authorisations are possible, but premature vaccinations are not the answer for Switzerland;” December 11, 2020.

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Regulatory agencies collaborated across borders

To help address this global health threat, regulators in most of the locations studied engaged in collaboration with other regulators at levels rarely, if ever, seen in the past. Collaborations focused mainly on areas such as creating clusters of technical experts, sharing research results, leveraging inspection reports, and disseminating information on how to help health care workers treat patients and stay safe.

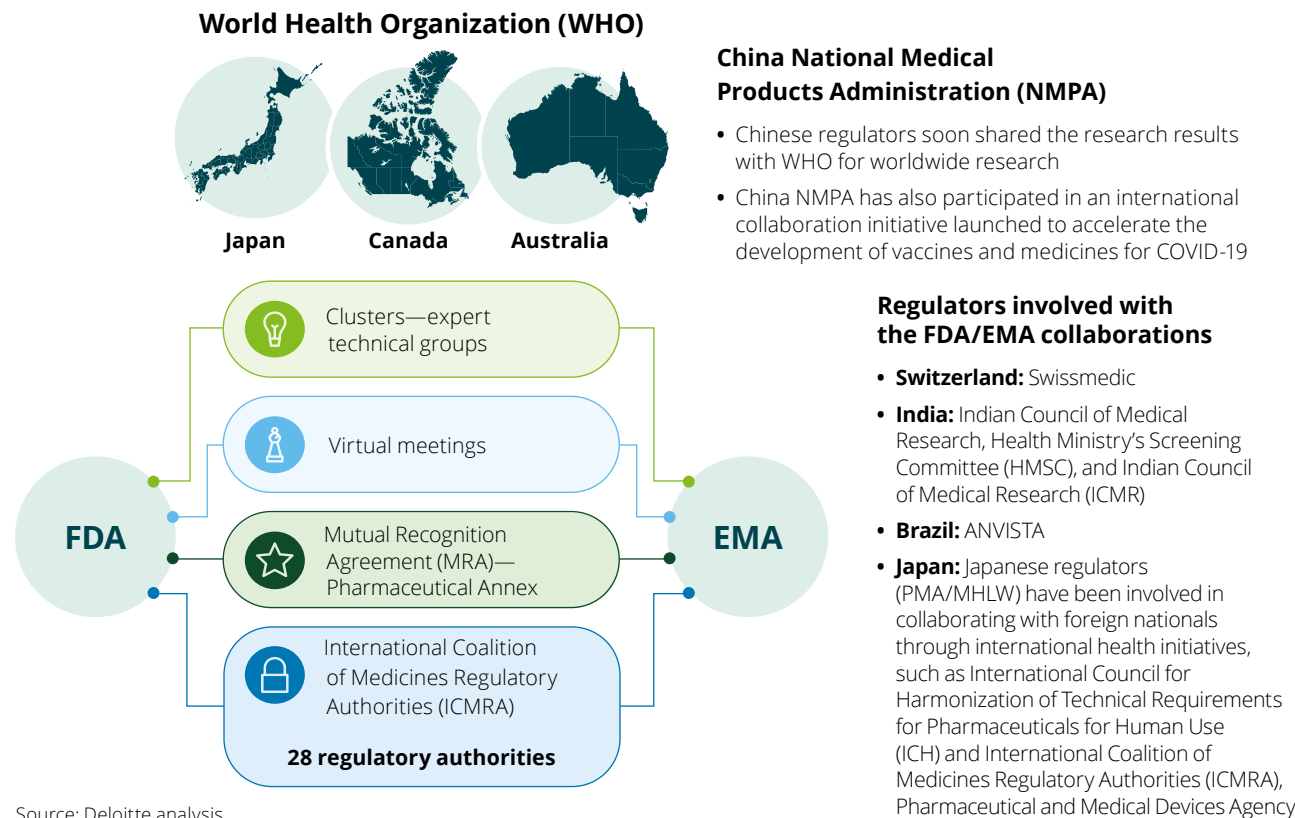
The following pages detail notable instances of international collaboration among regulatory agencies.

United States and the European Union

The FDA and EMA are key collaborators in tackling public health challenges.⁸¹ This collaboration encompasses 30 technical expert groups, or clusters, that the FDA and EMA have established since 2003 and which meet regularly for regulatory discussions held under confidentiality commitments. These preexisting relationships positioned those clusters to pivot quickly to COVID-19 and to collaborate more efficiently. Many of these groups, which often include regulators from Japan, Canada, Australia, and other countries, shifted their attention to COVID-19 (figure 3).

Figure 3. Regulators' global collaborations

Examples of how global regulators collaborated across the globe



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For example, the group on vaccines expanded to a multilateral forum to discuss regulatory issues related to SARS-CoV-2 vaccines; similarly, the pharmacovigilance group focused on observational studies related to COVID-19's natural history and interventions. The FDA's standing meetings on blood products shifted their focus to COVID-19 convalescent plasma. Similarly, drug shortage discussions focused on strategies for relieving COVID-19 medicine supply disruptions.

In addition:

- The FDA and EMA have been exchanging information on the evolving scientific landscape of products and clinical trials and jointly interpreting data supporting regulatory decisions.
- The FDA and the European Union are promoting engagement with global regulators under the International Coalition of Medicines Regulatory Authorities (ICMRA) forum,⁸² which includes 28 regulatory authorities worldwide. In March 2020, the FDA and the EMA jointly chaired the first global regulators' meeting to discuss regulatory strategies to facilitate development of SARS-CoV-2 vaccines.⁸³
- Subsequent ICMRA workshops focused on treatment development, observational studies, and real-world data as well as policy approaches to align guidance. Such efforts are reflected in the ICMRA joint statement, issued in April 2020, with global regulatory authorities expressing their collective support for countering COVID-19.⁸⁴

- COVID-19 Vaccines Global Access (COVAX) is a worldwide initiative consisting of 184 countries that has drawn support from the WHO. This initiative relieves global COVID-19 vaccine imbalance by leveraging donor-funded doses to provide equitable access of vaccines to lower-income countries.⁸⁵

The FDA is also leveraging EU and UK inspection reports under the Pharmaceutical Annex to the US-EU Mutual Recognition Agreement (MRA). The MRA enables the FDA and European Union to rely on inspections done by each other's regulatory authorities to inform decisions, such as approving drugs and addressing shortages.⁸⁶ The FDA and global collaborators also exchange information on medical device regulatory issues. These relationships have been critical to supplying PPE, ventilators, and testing supplies.⁸⁷

China

In January 2020, the genome sequence of the virus was isolated in China, and Chinese regulators soon shared the research results with the WHO for global research purposes.⁸⁸ China's NMPA also participated in an international collaboration launched by the WHO to accelerate vaccine and medicine development. In addition, China and the United States, with the United Kingdom, continued their roles as the largest contributors to coronavirus-related research.⁸⁹

The NMPA also participated in the third Asian Network Meeting, which included India, Indonesia, Japan, South Korea, Malaysia, the Philippines, Singapore, Vietnam, and Myanmar. There, the NMPA exchanged experiences in combating the pandemic and improving the availability of innovative drugs, thus setting the stage for further collaboration.⁹⁰

Japan

Prior to COVID-19, the PMDA and MHLW had been collaborating with foreign nations through initiatives such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and ICMRA. Within those initiatives, Japanese regulators continually examined regulatory issues and formulated guidelines in collaboration with each country.

In terms of COVID-19, Japanese regulators coordinated requirements for clinical trials; audits; and approvals of drugs, vaccines, and medical devices and collaborated with foreign entities to expedite these products. As a result, Japanese regulators have reached consensus with each country on the endpoints in clinical trials of COVID-19 drugs.

India

Indian regulatory authorities such as the Health Ministry's Screening Committee (HMSC) and Indian Council of Medical Research (ICMR) have collaborated with the WHO and regulators from the United States, Australia, Denmark, Brazil, and other countries and with NGOs such as the Bill & Melinda Gates Foundation (BMGF).⁹¹ Such collaborations have affirmed the impact of various drugs on the SARS-CoV-2 virus and supported the initial response to the pandemic.

Also, the WHO helped India to develop a national vaccination plan and guidelines on emergency regulatory procedures for expedited assessment of data, regulatory approval of vaccines (using a risk-based approach), and provisioning of import permits.⁹²

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In April 2021, the CDSCO issued guidance for vaccine approvals in India for emergency use. This guidance cited a statement from the National Expert Group of Vaccine Administration for COVID-19 (NEGVAC) that foreign-produced vaccines that had been granted EUA by the FDA, EMA, the United Kingdom’s Medicines and Healthcare products Regulatory Agency (MHRA), or Japan’s PMDA, or are in the WHO Emergency Use Listing, are granted emergency approval in India.⁹³

In September 2020, the Indo-US Molecular Biomarker Knowledge Network for COVID-19 was established. In addition, the WHO played a vital role in issuing COVID-19-related guidance throughout the pandemic via its weekly dashboard of updates and online courses to assist Indian health care professionals.⁹⁴

Observations

The emergency footing prompted regulators to collaborate in order to consolidate their efforts, gain insight into new discoveries, and develop new methods of operating efficiently. However, in the locations we are reporting on, some regulators collaborated more closely with their foreign counterparts than others.

In general, collaborative initiatives among regulators in the locations studied took three forms:

1. Collaborations with global institutions such as the WHO, the BMGF, and the ICH.
2. Technical expert groups, which were collaborative efforts established pre-pandemic and then expanded to a multilateral forum and transitioned to working groups focused on COVID-19 matters, with ICMRA being a good example.

3. Newly created pandemic-focused working groups such as the ACTIV program, a consortium that brought together more than a dozen leading biopharmaceutical companies, the FDA, and the EMA to develop international strategies for coordinated research responses to the pandemic.

While the United States and the European Union experienced strong collaborations and brought other countries into those forums, other regions of the world mostly relied on the WHO and on global institutions and engaged in relatively limited regional collaborations.

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Moving forward

Given that public health concerns across borders and regulatory professionals engage in certain levels of international collaboration as a matter of course, most were well positioned to communicate from the start of the pandemic. Further, the pandemic prompted regulators to take a more holistic view of the life sciences landscape and toward its regulation—a view that it may well be worth integrating into future regulatory approaches.

One lesson learned is to develop collaborative frameworks and forums during normal times so they can be readily leveraged in times of crisis. Another lesson would be to establish contingency measures during ordinary times that could be put into effect during times of crisis. It would also be useful to establish databases and technology solutions for aggregating and sharing data to facilitate collaboration.

Other steps to consider would include examining ways to:

- Review and expand forums and frameworks:** Existing forums and frameworks for collaboration among regulatory agencies enabled them to share data and information, exercise broader vigilance, and coordinate regulatory approaches within existing relationships, which foster trust. If those forums and frameworks can be expanded to include new participants and issues as the pandemic continues *and* after it recedes, they should become even more robust and effective. Establishing collaborative forums before they are needed enables regulators to act quickly when collaboration is truly needed.
- Reposition the regulatory system for speed:** As noted, no entity—including regulatory agencies—can operate on a permanent emergency footing; however, since emergencies demand speedy responses, regulators might take steps to position the regulatory infrastructure for even faster action in the event of another public health crisis. Benefits might also flow through to regulatory matters taken up during ordinary times. For example, lengthy drug and device development times can add significant human, health, and economic costs to R&D efforts. By working to reduce those times through international interagency collaboration, regulators can perhaps mitigate those costs.
- Evaluate opportunities (and risks) of harmonizing approaches:** While regulatory regimes need to consider their countries' economic, political, and cultural interests and industry issues, they may also benefit their countries' economies, companies, and public health by harmonizing regulatory approaches. This might start with considering ways to modify and institutionalize the more flexible approaches taken to date in the pandemic, as well as approaches to data sharing, compliance, and risk monitoring.

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Life sciences companies reached new levels of collaboration

“We can emerge from this emergency only by working together,” said then-Commissioner of the FDA Stephen M. Hahn, M.D. in an address on August 10, 2020.⁹⁵ Cooperation occurred not only among regulators and companies, but also among companies within the life sciences industry.

Indeed, companies engaged in heretofore unseen levels of collaboration. The urgency to develop treatments, vaccines, diagnostics, and medical devices—along with relaxation of regulations—led life sciences companies that had been competitors to cooperate in developing solutions to scientific problems. It also prompted non-life sciences companies to enter the arena, if only temporarily, to address raw materials shortages, digitalize more of the drug development process, and enhance manufacturing at high capacities and at different locations worldwide.⁹⁶

The following are some examples of cooperation and collaboration among life sciences companies.

United States

In March 2020, several large pharmaceutical companies, including Eli Lilly, Novartis, Gilead, and AstraZeneca, formed a group called COVID R&D to share knowledge and resources to accelerate development of vaccines and treatments. Also, the BMGF, the Wellcome Trust, and Mastercard launched the COVID-19 Therapeutics Accelerator to bring researchers in industry and academia together to identify treatments.⁹⁷

In addition:

- **Pfizer** announced a collaboration with the German company **BioNTech** to develop a vaccine. A few months later, they launched clinical trials of their vaccine candidates in Germany and the United States.⁹⁸
- **Atomo Diagnostics**, an Australian startup that developed a rapid blood test for HIV, shifted to developing a platform for COVID-19 after being contacted by several diagnostics companies regarding the ability of their platform to support a high-throughput test for COVID-19.⁹⁹

- **Eli Lilly** joined efforts with **AbCellera**, a Vancouver-based biotech company with a platform to rapidly develop medicines. AbCellera quickly screened a COVID sample for potential therapeutic antibodies using high-throughput imaging, genomics, and AI. AbCellera identified more than 500 potential therapeutic molecules, and the two companies launched a phase 1 clinical trial of one in June 2020.¹⁰⁰
- **AdvaMed** set up a COVID-19 resource center¹⁰¹ and released COVID-19 principles for medical device companies.¹⁰² These included scaling up manufacturing capacity, supporting initiatives to ensure patient access to critical technologies, and partnering with manufacturers inside and outside the life sciences industry.
- **PhRMA** worked with pharmaceutical companies as they navigated the complexities of COVID-19. PhRMA also supports global, innovative, cross-stakeholder partnerships and supports scientists pursuing new ways to stimulate the immune system, which could be leveraged to help combat future viruses.¹⁰³

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China

Life sciences companies quickly initiated collaborative efforts to develop vaccines in China, as shown by the following two cases:

- In August 2020, **AstraZeneca** announced an exclusive license cooperation agreement with **Shenzhen Kangtai Biological Products (BioKangtai)**¹⁰⁴ to accelerate R&D, production, and commercialization of AZD1222, a new adenovirus vector COVID-19 vaccine, through technology transfer. The agreement stated that BioKangtai, as technology transferee, will ensure annual production capacity of at least 100 million doses of AZD1222 by the end of 2020, and expand annual capacity to at least 200 million doses by the end of 2021, to meet demand in the Chinese market. The two entities will also continue to explore opportunities to cooperate in other markets and regions.
- On March 15, 2020, Shanghai Fosun Pharmaceutical (Group) Co., Ltd. announced that its subsidiary, **Shanghai Fosun Pharmaceutical Industry Development Co., Ltd. (Fosun)**, formed a strategic alliance with **BioNTech** to obtain the license to exclusively develop and commercialize its COVID-19 vaccine products in China.¹⁰⁵ For the BNT162 vaccine candidate, Fosun medical plans to conduct global clinical trials covering China and the United States. On November 12, 2020, Fosun announced that BNT162 was accepted by the China's NMPA for its registration application.

European Union

Widespread collaborative efforts occurred in the European Union, as shown by the following examples:

- **Novartis** is involved in the COVID-19 Therapeutics Accelerator and in a COVID-19-focused partnership organized by the Innovative Medicines Initiative. Novartis is also working closely with molecular partners to develop two antiviral treatments based on a new class of protein therapeutics.¹⁰⁶
- **Roche** initiated multiple COVID-related clinical trials, and compiled data from other, independently led clinical trials from around the world, and has partnered with other companies and research organizations.¹⁰⁷
- **BioNTech**¹⁰⁸ and **Pfizer** saw an unprecedented scale-up of their Comirnaty vaccine with global production projected at 3 billion doses in 2021 and 4 billion doses in 2022. BioNTech is building its presence in Southeast Asia, including a manufacturing facility. In addition, the company is collaborating with Fosun Pharma to serve China, Hong Kong, Macau, and Taiwan. Fosun Pharma intends to provide manufacturing capabilities of up to 1 billion doses a year after the vaccine gains approval in China.¹⁰⁹
- **CureVac**¹¹⁰ has been building a widespread network of partnerships. To manufacture a first-generation CureVac vaccine it partnered with Wacker, Celonic, and Bayer (later to part ways due to discontinuation of the first-generation vaccine effort). For its second-generation CureVac vaccine it is collaborating with GSK.¹¹¹ Novartis and Rentschler are also contributing to scaling up manufacturing of the second-generation vaccine.
- **Sanofi Pasteur**,¹¹² Sanofi's vaccine business unit, is collaborating with Translate Bio and GSK to develop two COVID-19 vaccines. Phase 3 results for their adjuvanted recombinant protein-based vaccine candidate are expected in 2021, which could lead to a regulatory submission thereafter. For the mRNA candidate, a phase 1/2 study started in March 2021. Sanofi is also facilitating manufacture of the BioNTech COVID-19 vaccine and provides BioNTech access to its expertise and infrastructure to produce with a goal of more than 125 million doses. They also entered agreements to support manufacturing steps of the Johnson & Johnson vaccine from a French site and of the Moderna vaccine from a US site starting in Q3 2021.
- **Accumulus Synergy's** cloud-based platform is bringing together 10 major biopharmaceutical companies to support interactions between industry and health authorities worldwide. The platform enables real-time collaboration and data exchange, as well as data submission.¹¹³
- **Boehringer Ingelheim (BI)**¹¹⁴ is part of the CARE (Corona Accelerated R&D in Europe) consortium and is leading work on antibodies capable of deactivating the COVID-19 virus via its unique spike protein. The antibody is planned to be administered via inhalation, which allows the therapy to reach the affected areas of the body faster and uses the active ingredient more efficiently.

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- **Johnson & Johnson (J&J)** also made marketed antivirals available to test together with other industry partners as potential treatments.¹¹⁵ In addition, the company worked through governments; for example, J&J worked with Belgium to ensure that the laboratories at Janssen in Beerse could be used for COVID-19 testing and to produce a disinfectant in Geel.
- **Dompé**, the Italian pharmaceutical company, coordinates the Exscalate4CoV (E4C) coalition among public and private partners across seven European countries to combat the spread of the coronavirus. This includes 18 institutions in addition to several pharmaceutical companies.¹¹⁶
- **The Ventilator Training Alliance (VTA)** brought together 10 ventilator manufacturers to ensure health care workers receive proper training on the use of ventilators.¹¹⁷ A VTA app was created to contain all training resources, including videos and user manuals.

Japan

Life sciences companies in Japan conducted joint research and development of new COVID-19 vaccines and drugs, with the following as examples:

- **Shionogi & Co., Ltd.** and **NIID/UMN Pharma** have developed a recombinant protein vaccine and started Phase 1/2 trials in December 2020.
- **Daiichi Sankyo Co., Ltd.** and the University of Tokyo's Institute of Medical Science (IMS) have developed an mRNA vaccine and started phase 1/2 trials in March 2021.
- **KM Biologics Co., Ltd.**, the IMS, NIID, and National Institutes of Biomedical Innovation, Health, and Nutrition have developed an inactivated vaccine and initiated phase 1/2 trials in March 2021.
- **AnGes, Inc.**, Osaka University, and Takara Bio Inc. have developed a DNA vaccine and are conducting small-scale phase 2/3 trials with the goal of launching a large phase 3 trial by the end of 2021.

All of the foregoing joint initiatives have been supported by MHLW for emergency purposes such as vaccine research and production to provide the vaccine in Japan.¹¹⁸

In addition, other companies have developed products not within their usual remit:

- **Sharp Corporation**, at the government's request, produced masks at its factory that usually produces liquid crystal displays.¹¹⁹ Sharp had an unused clean room and started production about one month after the request without affecting production of any existing products. The goal was to increase production from 150,000 to 500,000 masks per day.¹²⁰
- **Sony Global Manufacturing & Operations Co., Ltd.** commissioned and manufactured respirators developed and designed by Acoma Medical Industry Co., Ltd., which also contributed to an increase in the production of respirators.¹²¹

India

Collaborative efforts among life sciences companies in India include the following:

- **Jubilant Generics Ltd.** has entered into a non-exclusive licensing agreement with Gilead Sciences, Inc. for the manufacture and sale of potential remdesivir in 127 countries, including India.
- **The Serum Institute** of India and the United Kingdom's AstraZeneca undertook mass production of Covishield, a vaccine developed by the University of Oxford.
- **Gennova**, based in Pune, in collaboration with Seattle-based HDT Biotech Corporation, developed HGCO19, India's first mRNA vaccine.
- **Bharat Biotech** developed Covaxin in collaboration with ICMR and National Institute of Virology (NIV).¹²² Covaxin also received EUA approval by DCGI-CDSCO after that body's approval of Serum Institute's Covishield.¹²³
- **Biological E. Limited**, based in Hyderabad, in collaboration with US-based Dynavax and Baylor College of Medicine, is developing a vaccine.

In addition, figure 4 depicts a range of collaborations that occurred worldwide among life sciences companies.

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Figure 4. Global collaborations among life sciences companies



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Observations

Many life sciences companies' collaborations were global in nature, with a range of initiatives aiming to:

- **Take a divide-and-conquer approach** to accelerate development by using core competencies of selected partners rather than developing these competencies in-house.
- **Accelerate production** of potential drugs, therapeutics, and diagnostics by using existing manufacturing facilities in targeted locations to assist in meeting capacity needs and providing geographical proximity to distribution.
- **Leverage the experience** of manufacturing and distribution companies to meet regulatory requirements that those partners were familiar with and were already accustomed to addressing in their respective countries or regions.
- **Use innovative approaches** to research, production, and distribution possessed by other companies to achieve improved outcomes within compressed time frames.

Moving forward

Stepping up life sciences industry collaborations can be justified in the long run as well as during a crisis. In an increasingly competitive and technology-driven marketplace, joint initiatives between companies with various strategies, technologies, and markets can accelerate innovation, manufacturing, and distribution of products. No company can develop and maintain superior resources in all disciplines, so it behooves them to gain knowledge, technologies, and market access by collaborating with companies that complement their visions and goals, to the greater benefit of all.

Toward these ends, life sciences companies might consider:

- **Intensifying efforts to identify collaboration opportunities:** A company's efforts to identify potential collaboration opportunities and candidates can sometimes become rigid or stale. Whatever companies are doing in this area, consider updating the approach to keep pace with evolving market and technological realities. For example, add new posts from which to scan the horizon. Broaden the choice set of companies being considered to work with. Step up efforts to systematically review patent filings and citations. Update the scientific and industry sources that are monitored and the criteria used to monitor them.

- **Developing new ways of collaborating:** The reliance on third parties and the extended enterprise have become enduring facts of business life. This pandemic should prompt an understanding of where an organization could perform better through enhanced forms of collaboration, from both negative and positive lessons. Where did current R&D, supply chain, production, or marketing relationships come up short? Where were the bottlenecks? Where did risks rise without commensurate upside potential? Similarly, where did they perform well? Where did the history and structure of relationships enable achievement of pandemic-related goals? How did collaboration enable better management of risks? How can companies strengthen their collaborative efforts going forward?
- **Clarifying the economics, risks, and rewards of collaboration:** Collaboration in business, and in scientific, technological, health care, educational, and other human endeavors, harnesses the benefits of specialization and cooperation. Specialization deepens knowledge; cooperation amplifies results. Collaboration in business is often hampered by lack of transparency and, at times, candor regarding potential costs, risks, rewards, and benefits. When risks and costs can be properly anticipated, identified, and measured, they can be allocated in ways that build trust. The same holds true for rewards and benefits. In general, establishing clarity around those elements and structuring terms to account for them—and for contingencies—leads to more productive, satisfying, and enduring collaborations.

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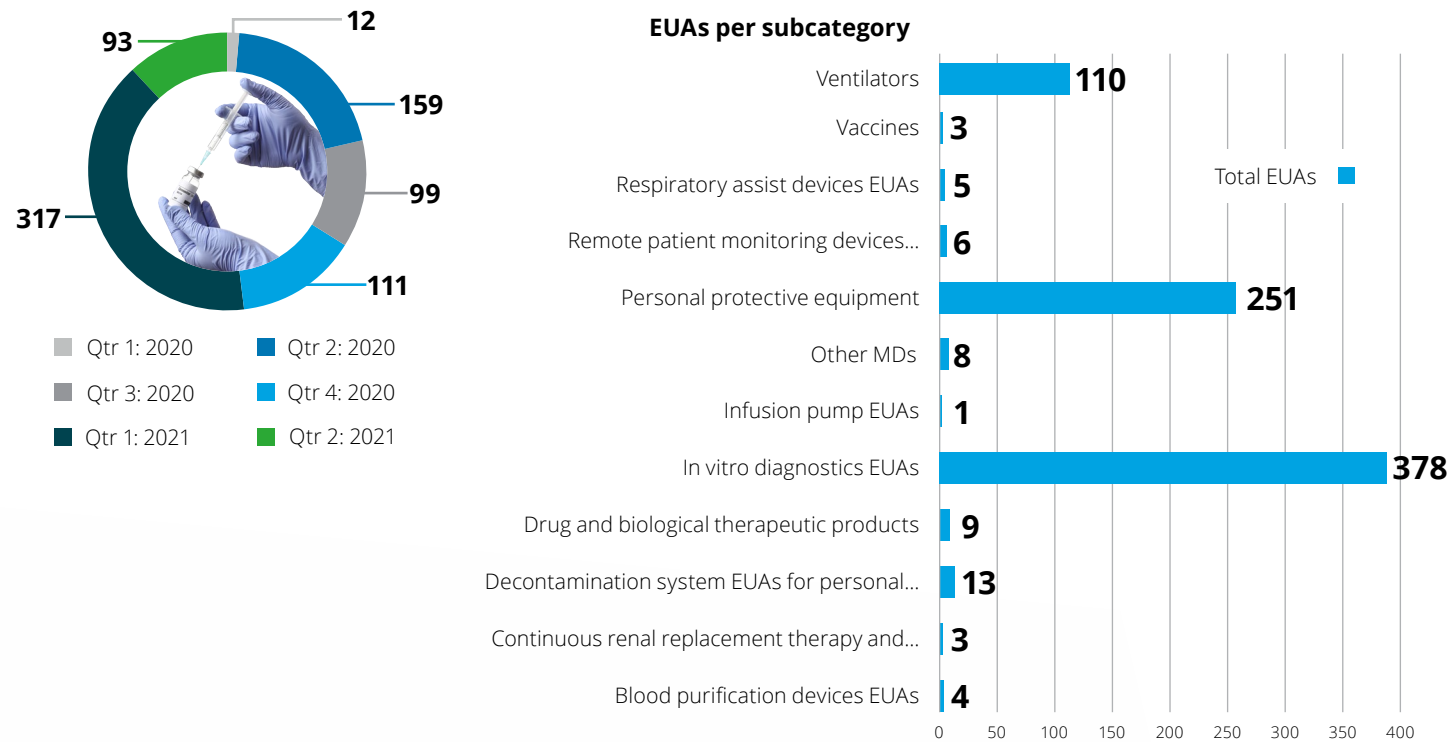
How the life sciences industry was impacted

The life sciences industry was both positively and adversely impacted during the pandemic. Significant positive effects included accelerated innovation, improved efficiency, and increased collaboration to address needs fostered by the pandemic. However, “normal business” became a lower priority and experienced some setbacks.

Actions taken by governments, regulators, and companies generated the following key impacts on the life sciences industry:

- Acceleration of innovation: Innovation accelerated, mainly due to emergency measures by regulators such as EUA¹²⁴ by the FDA, major funding commitments by governments, and unprecedented collaboration with regulators through initiatives such as OWS (figure 5).

Figure 5. Emergency use authorizations in the United States by FDA



Note: MD—Medical Device; EUA—Emergency Use Authorization.

Sources: US Food & Drug Administration (FDA), “Other medical device EUAs,” July 15, 2021; FDA, “Individual EUAs for molecular diagnostic tests for SARS-CoV-2,” November 10, 2021; FDA, “Drug and biological therapeutic products”; FDA, “Vaccines”; Deloitte analysis.

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Innovation was also boosted through relaxed regulatory requirements in certain areas of quality management and relaxed requirements for approval documents. Innovation accelerated in all segments of the life sciences companies, including drugs, vaccines, PPE, and medical devices, and was evident in four main areas:

- **New entrants into the life sciences market:**

Companies that had not been in the life sciences industry entered this market through new relationships with life sciences companies.¹²⁵ Prominent examples include GM's production of face masks and face shields, and Ford's and GM's production of ventilators.

- **Innovations in products:** University professors, in a March 2021 article,¹²⁶ noted three ways in which life sciences innovation can change in the future: genetic mRNA vaccines, wearable technologies for detection of disease, and mapping of human proteins for drug discovery. All were used during COVID-19 and represent potentially promising developments.

Also, the CRISPR-based diagnostic for COVID-19 from Sherlock Biosciences¹²⁷ is the first CRISPR-based product authorized for use in the health care industry. CRISPR, a technology for gene editing, represents a breakthrough in diagnostics. The pandemic presented the first opportunity to demonstrate the transformative potential of gene-editing technology. The FDA has granted EUA to two CRISPR-based diagnostic tests for COVID-19 (as of November 2020) from Sherlock Biosciences and Mammoth Biosciences.

- **Innovations in the supply chain:** Supply chains in the industry came under extensive stress during the pandemic due to raw material shortages, disrupted distribution, and personnel challenges. Many life sciences companies have reformulated their supply chains in response. For example, Cardinal Health¹²⁸ has updated their practices by changing sources of raw materials, bringing new efficiencies into manufacturing plants and procedures, and adjusting inventory levels as well as supply practices.

- **Accelerated adoption of new technologies and processes:**

As noted in a *Nature* article in September 2020,¹²⁹ "the pandemic has also highlighted outdated technical infrastructure, especially the lack of contemporary digital capabilities, slowness of interactions, sequential processes and patchy acceptance of new approaches that have existed for too long at the interface of sponsors and regulators." Although more widespread adoption of digital technologies was underway before the pandemic, it has clearly accelerated since very soon after its onset. (See sidebar on pages 34–35.)

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Adverse impacts on the industry

Of course, not all impacts were positive, and several prominent adverse developments should also be noted, including:

- **Disruption in clinical trials for non-COVID-19 products:**¹³⁰ Disruption in clinical trials peaked in June 2020 and was mainly due to challenges in recruitment, delayed initiation of trials, and hampered availability of sites and investigators. Many hospitals that serve as trial sites were inundated with COVID-19 patients and could not provide the clinical trial services they did before COVID-19.¹³¹

- **Reduction in regulatory inspections and oversight:**¹³² Regulators often found it difficult to conduct their usual oversight due to staff shortages and limited ability to conduct onsite inspections. Most regulators transitioned to remote inspections and alternatives to satisfy inspection requirements. For example, the FDA usually conducts more than several thousand inspections annually worldwide. In contrast, from March to October 2020, the FDA conducted hundreds of inspections at life sciences companies, a sharp reduction. The FDA also suspended most foreign life sciences company inspections (figure 6). In addition, the industry saw a dramatic reduction in FDA Form 483s and in pre-approval inspections, which led to fewer approvals of non-COVID-19 products. To help to address these issues, the FDA employed other agencies' reports, electronic document sharing, and virtual inspection, among other methods; however, those measures only partially helped.

Note: An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts.

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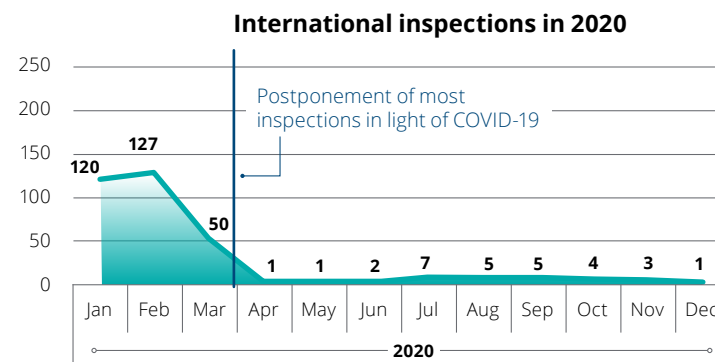
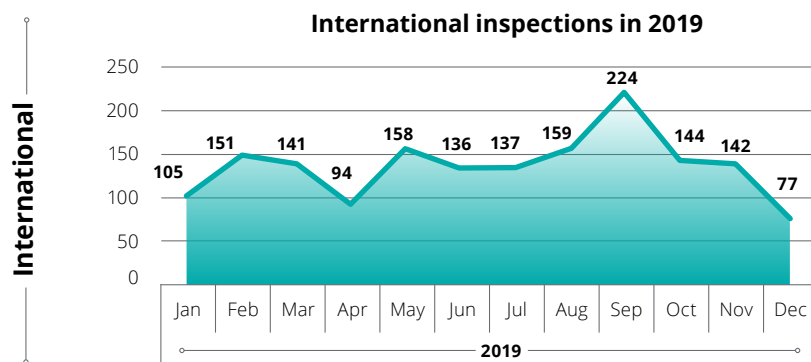
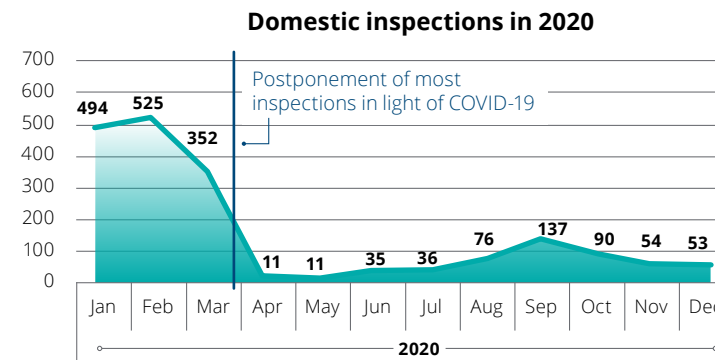
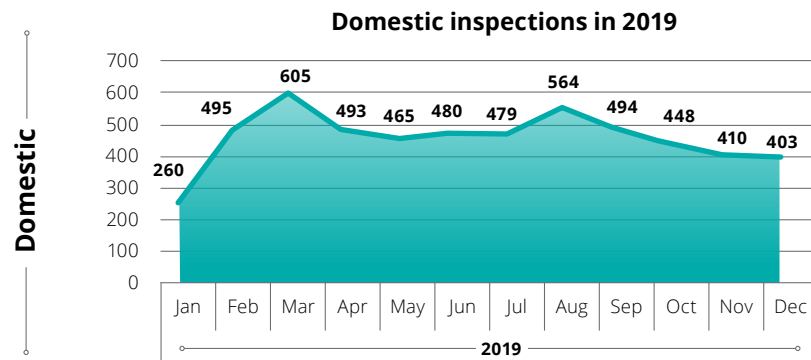
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Figure 6. FDA inspection reduction trends

Number of FDA-conducted domestic and foreign inspections (fiscal years 2019–2020 by month)



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.

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Figure 7 summarizes impacts of the pandemic on regulatory activities related to business as usual in the European Union.

Figure 7. Impact on business as usual in the European Union



Note: 2020 regulator audit numbers were available for Q1 and Q2 only. For Q1 and Q2 2019, the regulator audits total 395.

For the 2020 full year, the number of regulator audits was 643.

Sources: European Medicines Agency (EMA), *Human medicines highlights 2019*, 2020; EMA, *Annual activity report 2019*, May 15, 2020; EMA, *Mid-year report 2020*, September 25, 2020; Deloitte analysis.

Figure 8 lists impacts on business as usual in the five sectors covered in this report.

Figure 8. Impacts on “business as usual” in the United States, China, European Union, Japan, and India

	US	China	EU	Japan	India
Approvals for non-COVID-related products: 2019	91 ^a Drugs: 45 MDs: 46	1,779 ^b Drugs: 53 MDs: 1,726	Drugs: 66 ^c MDs: N/A	167 (all product approvals)	336 ^d
Approvals for non-COVID-related products: 2020	112 ^e Drugs: 53 MDs: 59	1,620 ^f Drugs: 48 MDs: 1,572	Drugs: 97 ^g MDs: N/A	153 (all product approvals)	61 ^h (through Q1)
Regulatory inspections of LS companies by country regulators: 2019	4,770 ⁱ	No public data	643 ^j	155	453 ^k
Regulatory inspections of LS companies by country regulators: 2020	2,788 ^l	19,900 ^m	185 ⁿ (Q1 & Q2)	Unknown	113 ^o (through Q1)

Notes:

MD—Medical Device.

US: The data for regulatory audits are for inspections from October 1, 2018, to September 30, 2019, for 2019; and from October 1, 2019, to September 30, 2020, for 2020.

EU: The EMA does not conduct audits itself; the authorities of the EU MS conduct these audits, in accordance with EMA guidance and regulations.

Sources: [a] US Federal & Drug Administration (FDA), “2019 device approvals,” February 11, 2020; [b] NMPA, “2020 Medical Device Registration Work Report”; [c] European Medicines Agency (EMA), *Human medicines highlights 2019*, 2020; [d] Sanjay Pingle, “Indian pharma companies secure 336 ANDA approvals from US FDA during 2019,” Pharmabiz.com, April 6, 2020; [e] FDA, “2020 device approvals,” August 16, 2021; [f] Xiao Zhu, “Encyclopedia of new drugs approved in China in 2019,” Baijiahao, November 13, 2020; [g] EMA, “2019 device approvals”; [h] Pingle, “Indian pharma companies secure 336 ANDA approvals from US FDA during 2019”; [i] FDA, “Inspection observations,” November 24, 2020; [j] EMA, *Annual activity report 2019*, May 15, 2020; [k] FDA, *Inspection Classification Database*, October 15, 2021; [l] FDA, “Inspection observations”; [m] China Food and Drug Administration, *Annual report on drug administration statistics (2020)*, May 14, 2021; [n] EMA, *Mid-year report 2020*, September 25, 2020; [o] FDA, *Inspection Classification Database*; Deloitte analysis.

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Despite the COVID-19 pandemic, some regulators were able to keep up with product approvals. For example: The FDA's product approval rate in 2020 remained high. As of December 23, 2020, 53 new non-COVID-related drugs had been approved by the agency's Center for Drug Evaluation and Research (CDER),¹³³ surpassing the 45 new drugs approved in all of 2019. An additional 72 first-time generics were granted marketing authorization in 2020.¹³⁴ As the year wound to a close, six small-molecule and two biologic drug applications had Prescription Drug User Fee Act (PDUFA) decision dates scheduled before the end of 2020, which would be comparable to 2018.¹³⁵

Observations

In the short term, COVID-19 has impacted business as usual and reduced the speed of development in some areas of the industry; however, the pandemic can be expected to stimulate most countries to work to enhance their public health systems, optimize health care resources, and adjust their regulatory approaches. In addition, technology adoption should continue to accelerate in life sciences industry operations.

Although product approvals were generally delayed during the outbreak, in the longer run the pandemic should speed up the drug registration and approval process and may lead regulators to establish emergency and rapid approval mechanisms. Going forward, governments, regulators, and the industry will likely evaluate ways in which efficiencies identified during the pandemic may be used in normal times.

Moving forward

Life sciences has gone through a potentially transformative event that has impacted the industry and will continue to impact it for years to come. It will undoubtedly prompt further changes, innovations, and improvements in how companies conduct their business, with the general aims of becoming more agile, responsive, and resilient.

As the industry and its regulators ponder these impacts and aims, potential points to consider might include identifying ways to:

- **Understand how priorities were set:** While priorities can change radically during a genuine crisis, matters that are given high priority during such an event can indicate what is truly important versus what is less so. So, it may be useful to realize not only that some activities are more critical than others—from both the business and regulatory perspectives—but also how decisions regarding various activities were made. On what bases were decisions made? Among non-COVID-19-related priorities, which ones retained high levels of importance, and which did not? How might this thinking and behavior inform future decisions about business and regulatory priorities?
- **Examine ways in which communications changed:** Private companies and regulators changed the ways in which they communicate—not only through digital documents and virtual meetings but through the faster pace of communications that the pandemic fostered. Which features of those modes of communication might work well for companies and regulators going forward? Did the organizational levels at which companies and regulators communicate change? How well did those changes work?
- **Assess how impacts were absorbed:** As the pandemic upended business as usual, the industry had to adjust quickly. Supply chains in certain areas of the industry were weakened while in other areas were strengthened. Relationships with regulators changed. Employees suffered dislocation and stress. How did the organization go about handling these changes? How well did leaders—and other parties—respond to sudden change? What contingency plans were in place, and how effective were they? How might the organization respond more effectively to future shocks?

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Digital technology adoption accelerated at full tilt

While digitalization of processes, transactions, and relationships had been underway for some time, pandemic-related developments and restrictions surely accelerated this trend. Organizations in all locations studied moved rapidly to technology-enabled work from home (WFH), digital communication, and digitalization for monitoring of clinical trials, as the following examples indicate.

United States

The FDA used digital platforms for reviews and approvals of products and clinical trials and for remote inspections. The Center for Medicare and Medicaid Services (CMS) issued temporary measures for people enrolled in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) to receive telehealth services during the public health emergency.¹ Changes allowed providers to conduct telehealth visits in patients' homes, practice remote care across state lines, and bill for telehealth services as if provided in person. Many individual states also relaxed telemedicine restrictions and allowed out-of-state professionals to provide telehealth services.²

Accelerated use of technologies also occurred in the following areas:

- Wearables for real-time vital signs monitoring
- Electronic diaries for real-time data capture
- Image harvesting through smartphone cameras
- Telemedicine technology and advanced analytics
- Electronic signatures for patient consent forms
- Use of electronic health records as a source of truth for remote monitoring³

China

The National Healthcare Security Administration (NHSA) and National Health Commission (NHC) issued guidance on "Internet +" medical insurance services during the pandemic.⁴ This guidance enables medical institutions to provide online follow-up for diseases and obtain insurance reimbursements.

The government also proposed relaxing the scope of internet diagnosis and treatment, including qualified services in the scope of medical insurance reimbursement, and unifying internet medical examination and approval standards.

European Union

The EMA expanded the types of trials that may use remote source data verification (rSDV) in addition to onsite, centralized, and offsite trial monitoring.⁵

As needed, remote site inspections of facilities were to be carried out, with onsite inspection to follow when circumstances permit.

EU governments approved remote working for life sciences companies where possible. To enable business continuity, in April 2020, the EMA issued guidance on regulatory expectations related to processes such as remote batch certification, remote audits, and remote inspections.⁶

Japan

Regulators conducted remote GCP inspections.⁷

In April 2020, MHLW deregulated the ban on use of telemedicine for first-time visits to hospitals and permitted prescriptions using fax.⁸ Although that is temporary, MHLW promised to enact telemedicine as a new form of health care based on expert opinion. MHLW will also likely consider promoting a system to complete interactions online, including medical examinations, electronic prescriptions, online medication guidance, and drug delivery.⁹

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Digital technology adoption accelerated at full tilt (cont.)

India

Clinical trial sponsors and contract research organizations (CROs) employed a number of initiatives to minimize disruptions to clinical trials. Key among these is use of telemedicine and virtual media by doctors to track the well-being of clinical trial patients and remote monitoring of data by the trial sponsors and CROs to ensure data quality.

Bangalore-based Cardiac Design Labs developed its Telemetric Patient Monitoring System, which is a vital signs monitoring system, to monitor multiple patients remotely and simultaneously from a central location. The system, which uses wearable devices, can monitor a patient's ECG, respiration, blood oxygen level, body temperature, and blood pressure.

Observations

The use of technology increased significantly during the pandemic and brought changes such as speed of interaction, improved remote capabilities, WFH capabilities, and business continuity solutions, as well as new risks and adverse impacts. The downsides included the blurring of lines between work and home

activities, long hours in front of computers reducing movement and affecting health, and heightened exposure to fraud and digital breaches—impacts that should be further examined and more deeply understood.

Move forward, with caution

While the speed, convenience, safety, and reliability of these technologies are becoming evident, their use in life sciences, health care, and regulatory agencies must be well thought out and carefully implemented.

Steps to consider might include:

- **Assessing things that have gone right and wrong:** All parties who engaged in new or broader uses of digital technologies should assess their positive and negative experiences. Although many interactions that occurred during the pandemic simply could not have happened even 20 years ago, speed and convenience often come at the cost of exposure to inaccuracies and fraud, as well as less emotionally rich human communication.

- **Ensuring adequate training and support:**

Much of this digital adoption, undertaken under severe pressure, was painful. People worked long hours and endured mental, physical, and emotional fatigue while adapting digital technologies to analog purposes. Designing and providing the right platforms, training, and support may help to enable smoother adoption going forward.

- **Dealing with the underlying economics:**

As seen when other industries and activities have moved online, significant disruption and benefits can occur. Given the importance of health care—and of government support of the industry—leaders face formidable analytical, policymaking, and decisioning tasks. Key among these are understanding and addressing the economics that accompany a shift from analog to digital processes. Where are the costs? Where are the savings? How are these to be apportioned? What relief can and should be provided to whom during a transition? What are the impacts on safety, data integrity, and data privacy?

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What's next?

Companies and regulators face both an ongoing pandemic and significant backlogs of work, which is hard to predict how long it will last. However, now, while experiences and perceptions are fresh, is the time to assess the impacts of this health crisis, the strengths and vulnerabilities it has exposed, and the most useful direction to take going forward.

As part of that exercise, these final steps and points of emphasis may be worth considering:

1. Prepare for the next pandemic or other crisis

Responses to COVID-19 on the part of your agency or company, particularly in the first year, have stress-tested the speed, effectiveness, and efficiency of capabilities. 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.

This would be a good time to review methods of goal setting; communicating; coping with change; and managing an often remote, stressed, and diminished workforce. Note also that widespread events other than a pandemic—such as a crisis related to weather, terrorism, war, economic collapse, or other disaster—could challenge the life sciences and health care industries and regulators in the future.

2. Take a proactive approach to regulatory agencies

If you are in the private sector, this would be a good time to review the ways in which regulatory responses affected your organization and how they benefitted or hindered its efforts. Useful activities might include:

- Identifying potentially negative impacts of changes to date, such as costs to your organization and to the industry and health care system, as well as the potential costs of a return to pre-pandemic practices
- Considering changes that would benefit your organization and the larger industry and health care ecosystem, if they were institutionalized and carried forward
- Developing positions on these matters and presenting them to relevant regulators, either directly or in concert with other companies, for example, through industry associations

Potential regulatory changes to focus on might include relaxed standards for test validation, clinical trials, and GMP compliance, among others—while recognizing that regulatory actions taken during a global health crisis will not necessarily be possible, or applicable, in non-crisis times.

3. Consider—and accelerate—digital transformation

Regulatory agencies in most of the locations covered in this report approved remote telehealth visits for existing and new 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. At companies, interactions between sales representatives and health care providers have

occurred through virtual meeting platforms, which can save time, money, travel, and human resources. Digital transformation is to be embraced, but also planned for carefully and with all due attention to security.

4. Foster closer collaboration with other organizations

Vaccine, drug, and medical device companies—as well as regulators—were able to collaborate fruitfully in the face of the pandemic. Consider ways in which some heightened level of interorganizational collaboration could be beneficial going forward. Continuing and facilitating this on an ongoing basis may require sharing—to appropriate extents—selected information on goals, strategies, resources, and risks and being more transparent to foster trust as well as cooperation.

5. 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. Can this become true for regulators and life sciences companies as a result of COVID-19? Perhaps, but it will require new habits of mind as well as new ways of operating. The simple yet demonstrated exercise of asking, “What if?” can open new pathways, both strategically and operationally.

Into the future, together

It would be beneficial for companies and regulators—and the broader health care ecosystem—to develop and promulgate leading practices in each of the areas covered in this report, on the basis of the needs raised by this global health crisis; health care system risks and opportunities; and costs, benefits, and oversight considerations.

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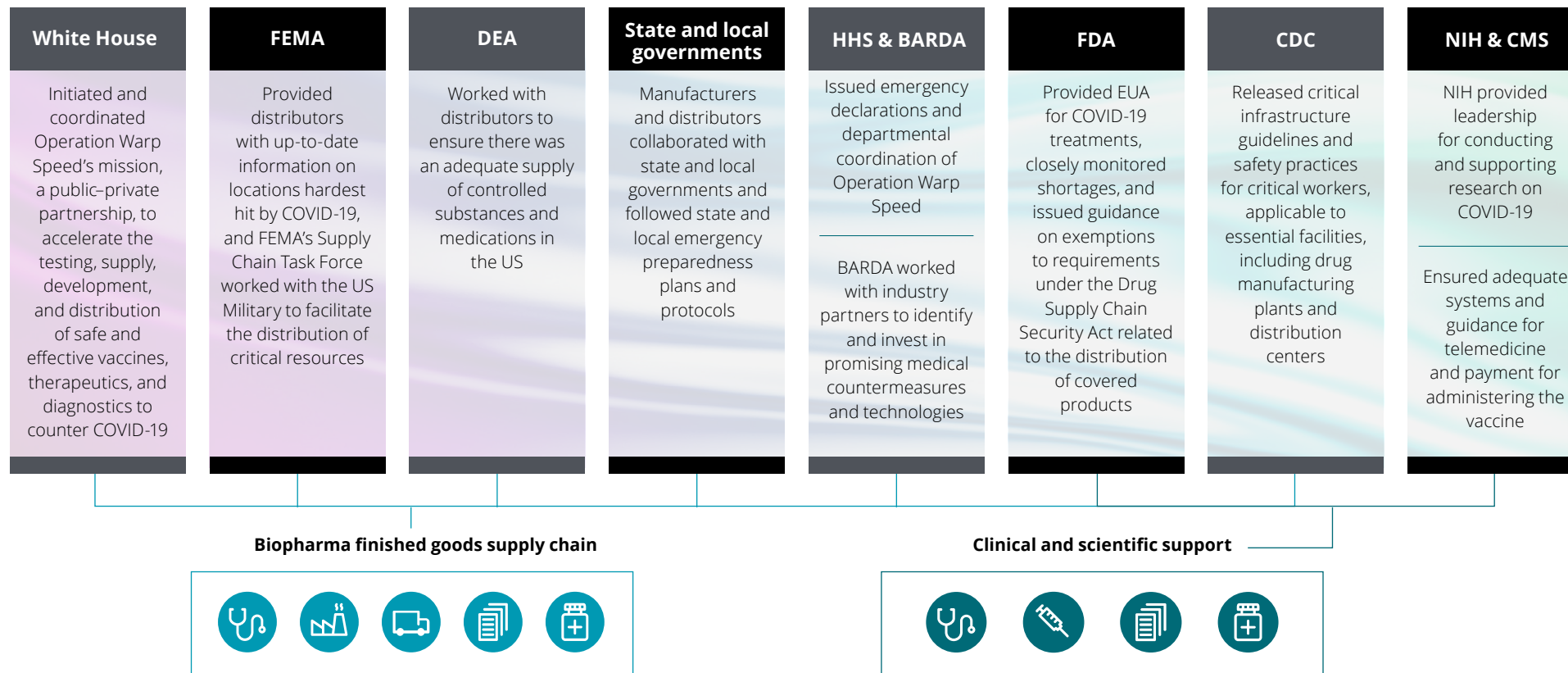
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Appendix A: Key regulatory agencies in the United States, China, the European Union, Japan, and India

United States: Overview of the state and federal COVID-19 response coordination

The coordination of clinical research, testing, and resource supply chain was the result of a multi-stakeholder effort across state and federal governments.



Note: Graphics for Appendix A were created by each country team and are based on all the information from the paper.

Sources: FEMA, DEA, FDA, CDC, SNS, BARDA, NIH, Deloitte analysis.

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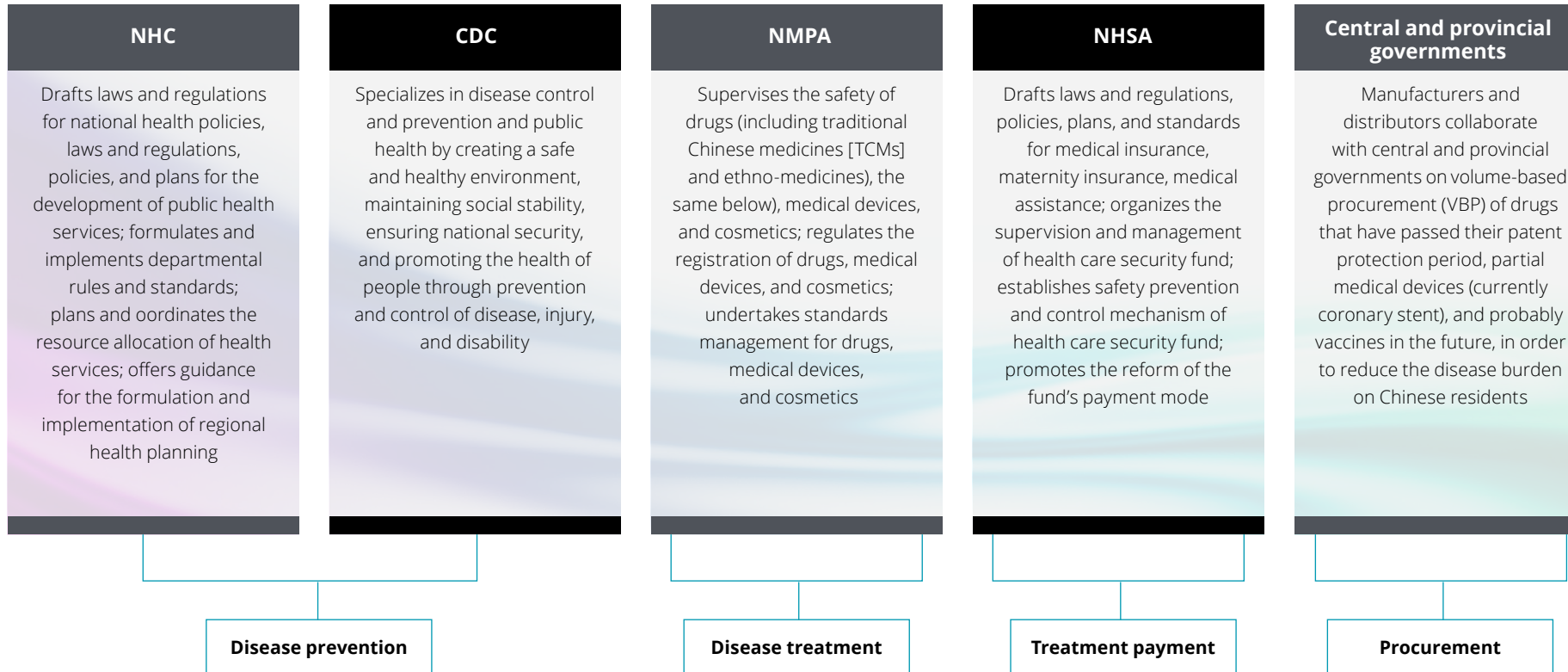
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Appendix A (cont.)

China: Overview of COVID-19 response system by Chinese regulators



Sources: NHC, CDC, NMPA, NHSA, Deloitte analysis.

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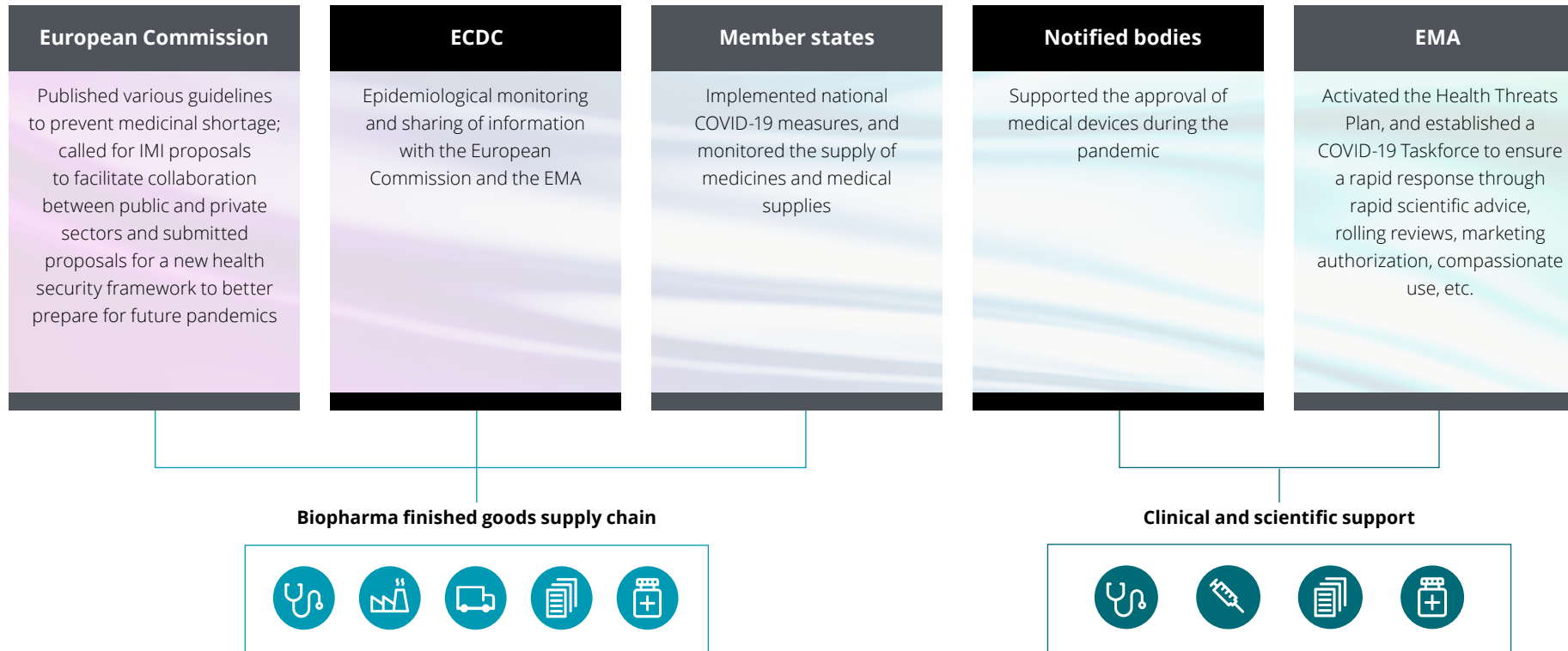
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Appendix A (cont.)

European Union: Overview of the EU COVID-19 response coordination

The coordination of clinical research, testing, and resource supply chain was the result of a multi-stakeholder effort across the European Union and Member State level



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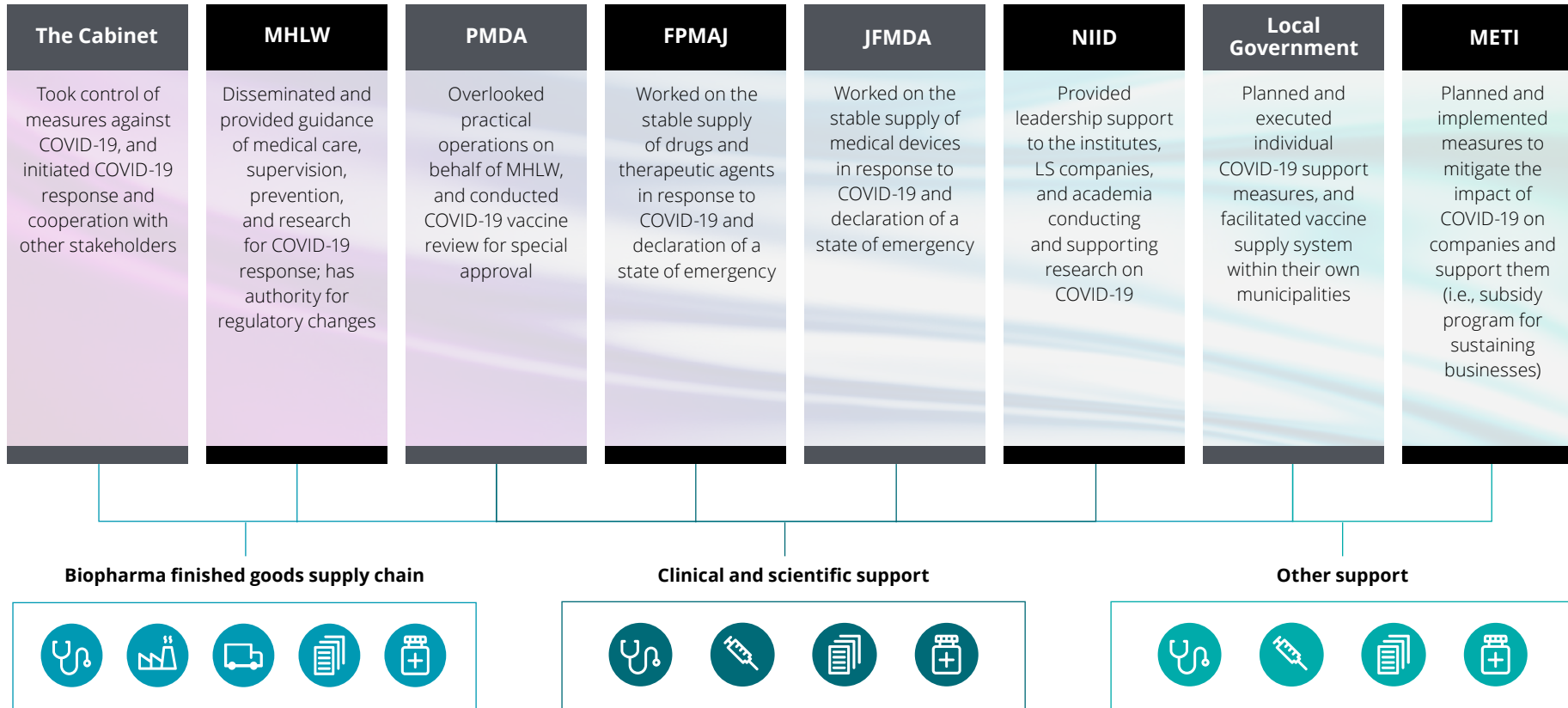
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Appendix A (cont.)

Japan: Overview of the government's COVID-19 response coordination

The coordination of clinical research, testing, and resource supply chain was the result of a multi-stakeholder effort across Japanese government



Sources: Cabinet, MHLW, PMDA, METI, JPMA, NIID, Deloitte analysis.

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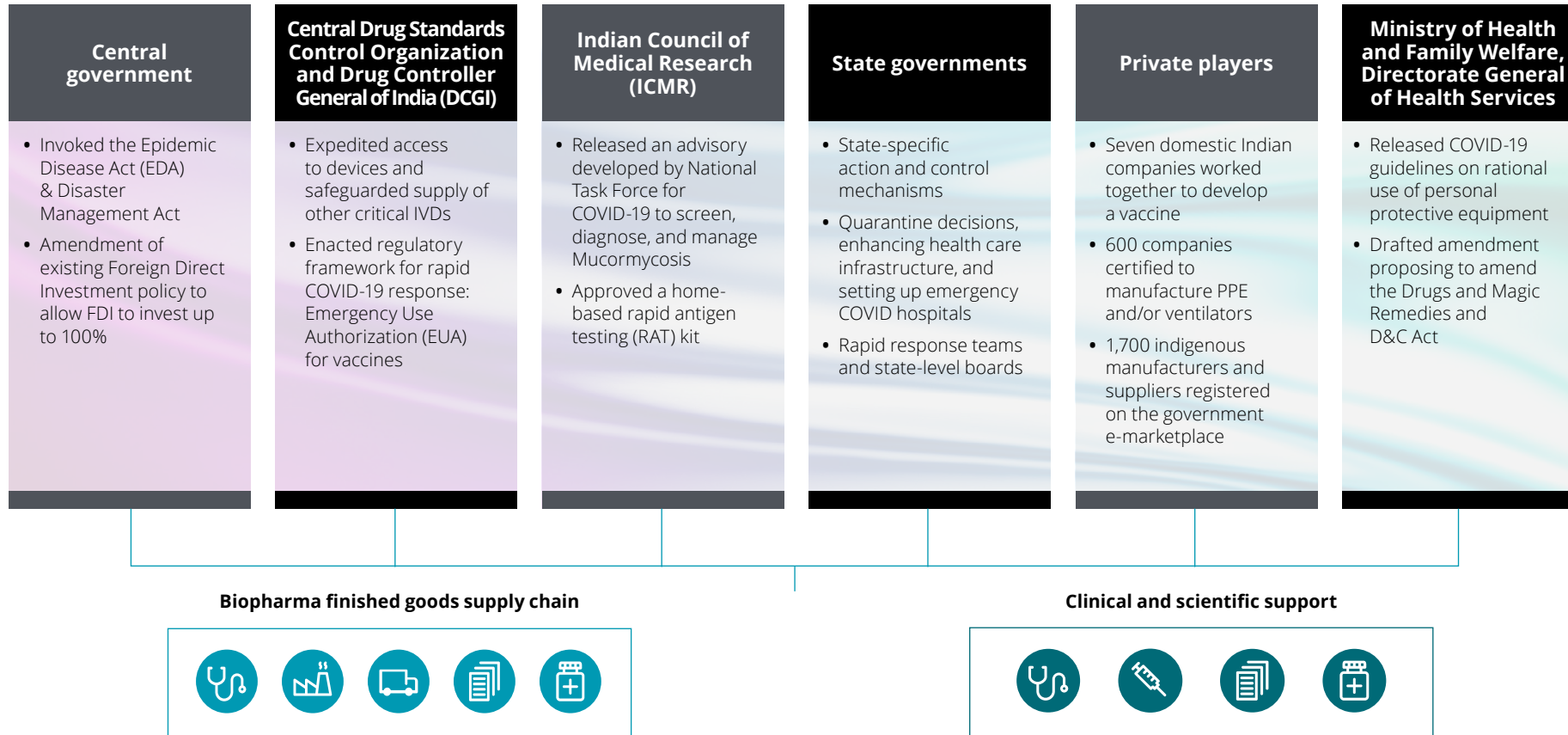
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India: Overview of the COVID-19 response coordination

The coordination of clinical research, testing, and resource supply chain was the result of a multi-stakeholder effort across Japanese government



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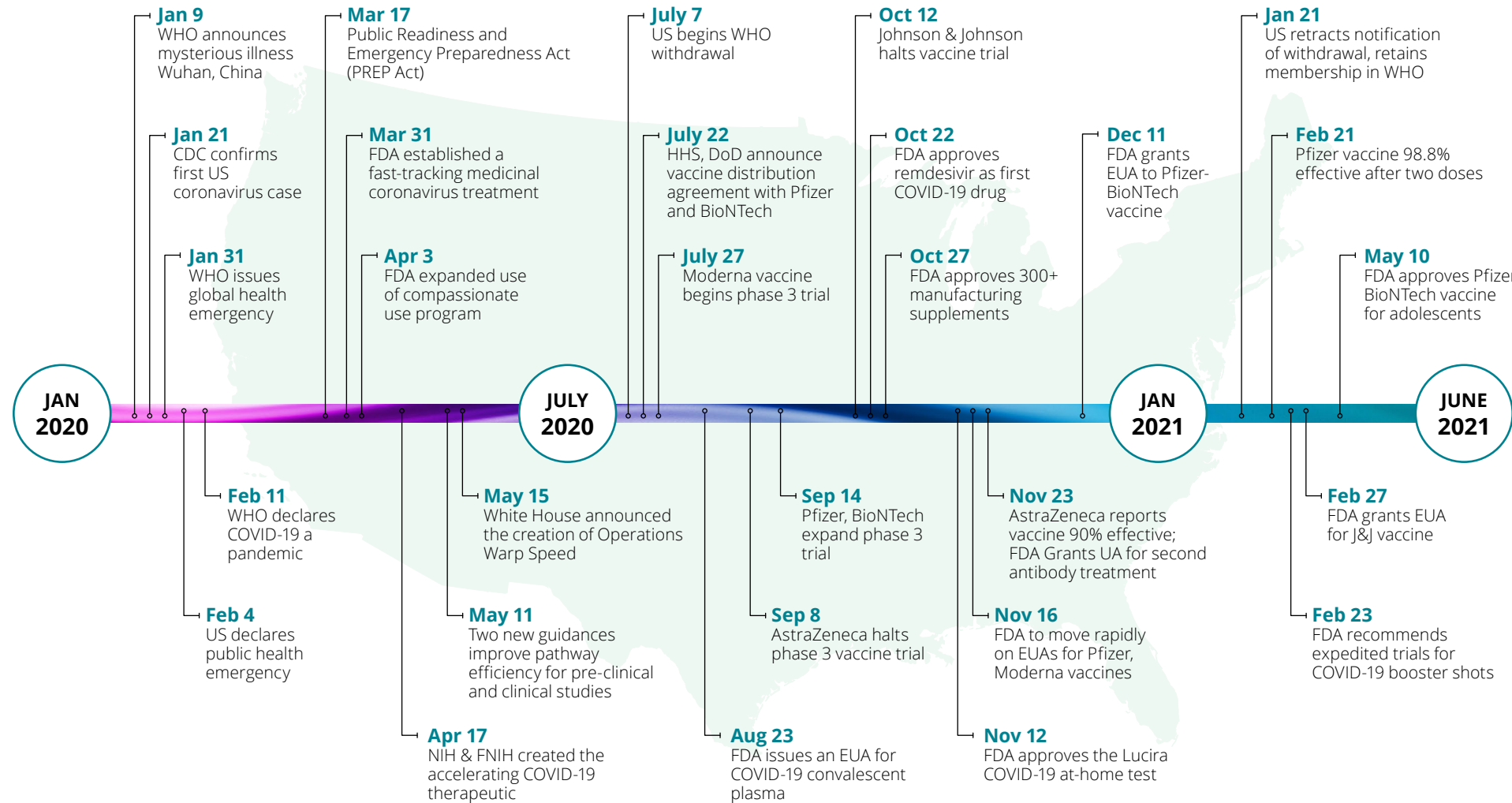
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Appendix B: Timelines of significant actions and activities in the United States, China, the European Union, and Japan

Note: Graphics for Appendix B were created by each country team and are based on all the information from the paper.

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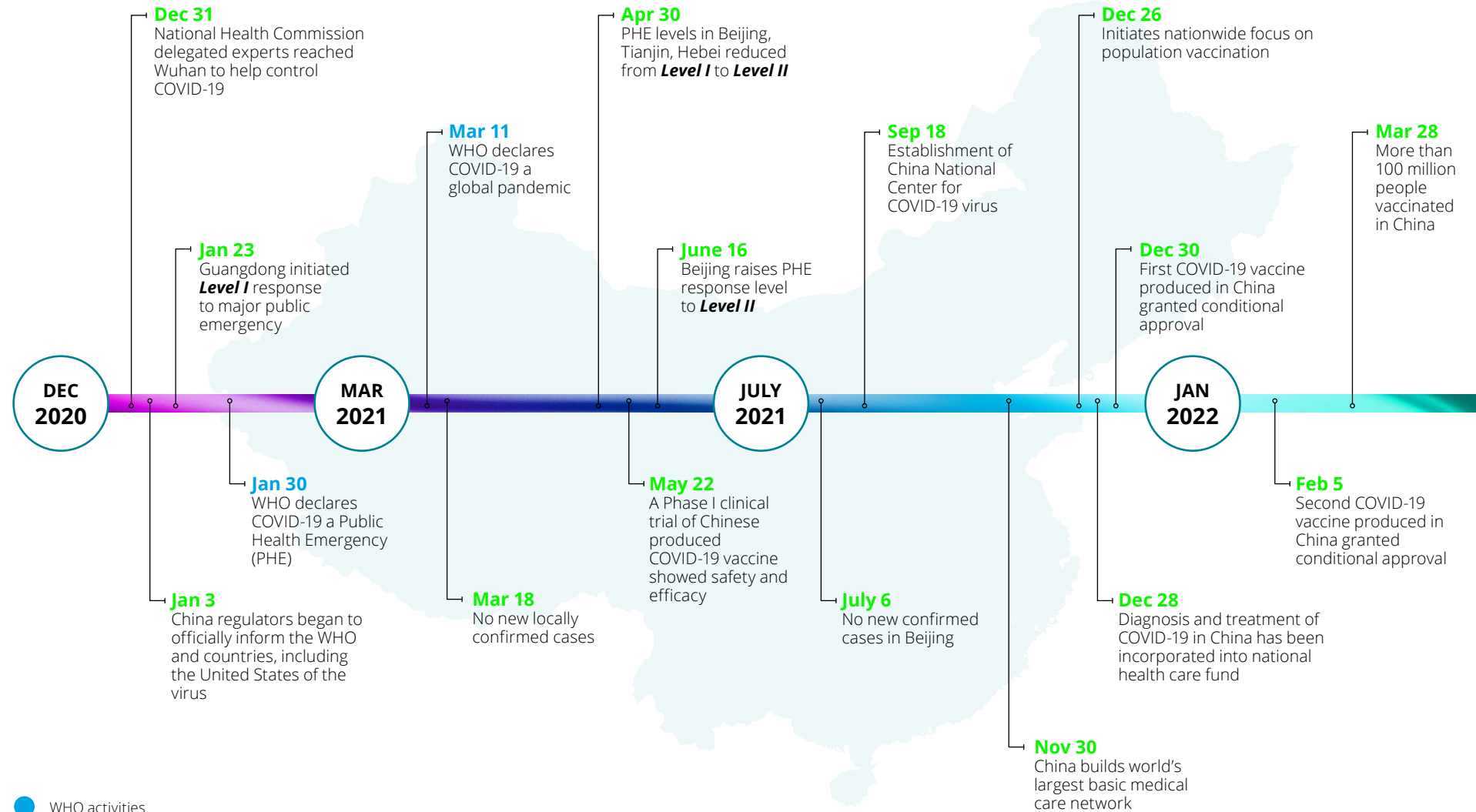
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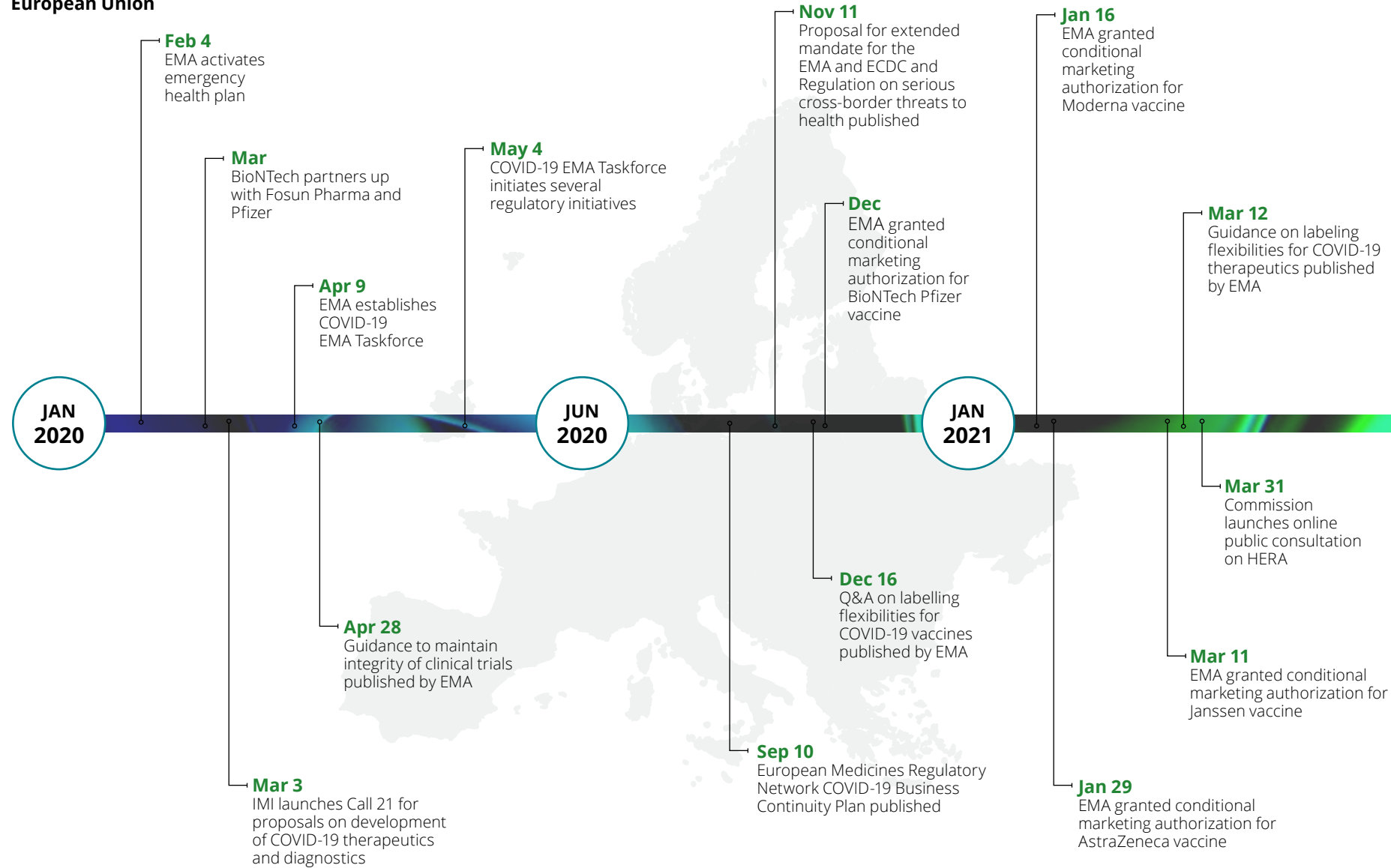
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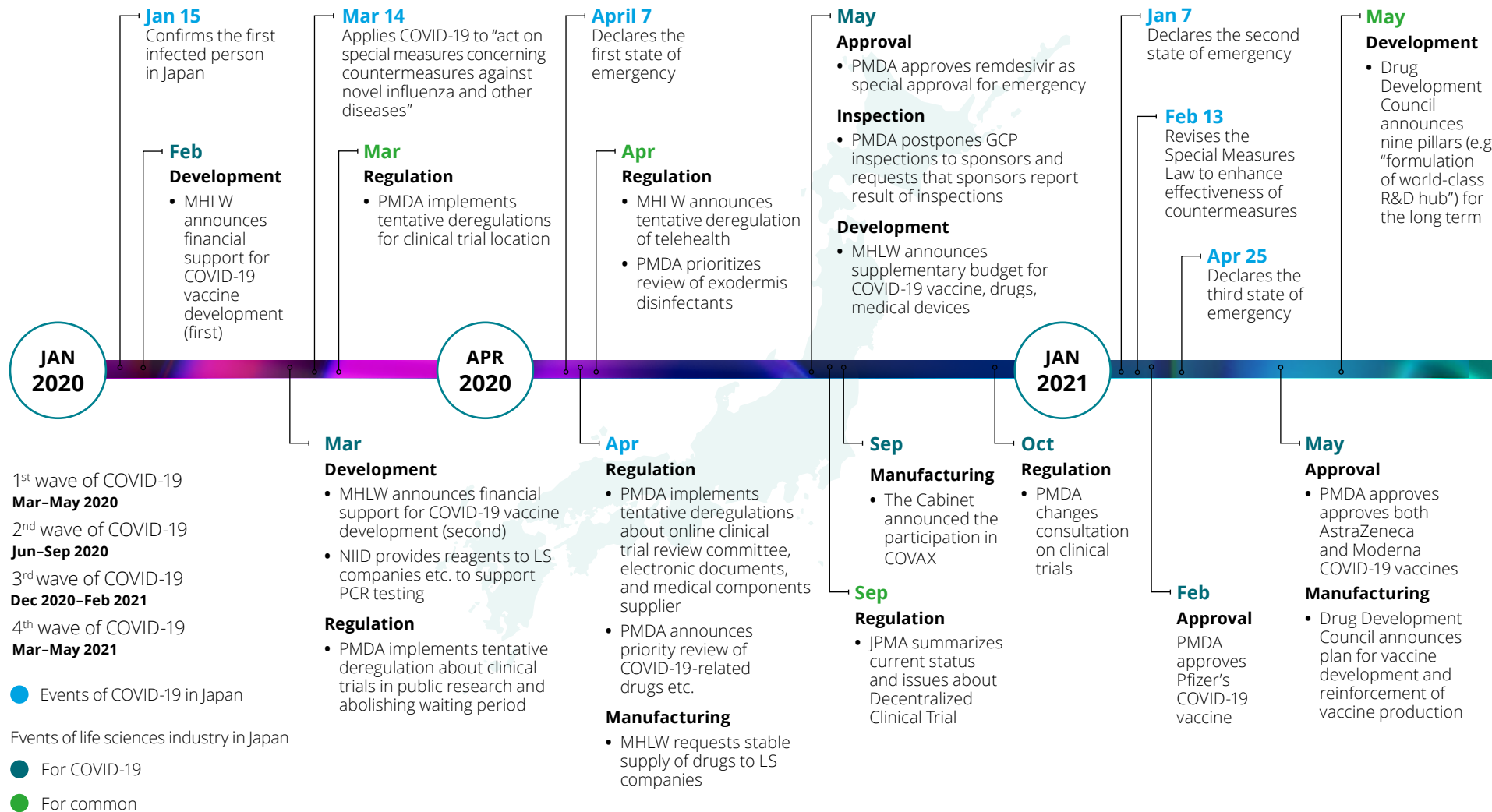
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Japan

Responding to the wave of COVID-19 infection, Japan has taken steps to end the COVID-19 outbreak and prepare for the next pandemic



Source: Deloitte analysis.

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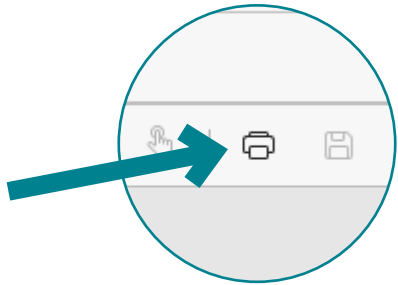
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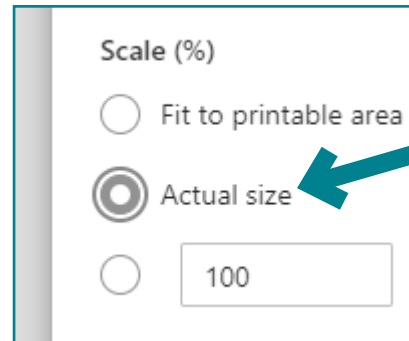
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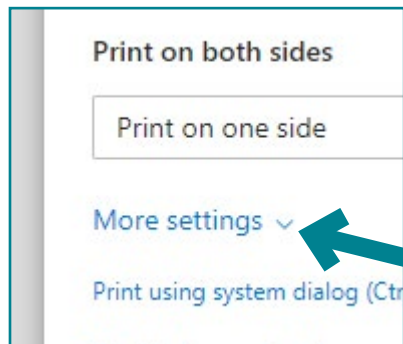
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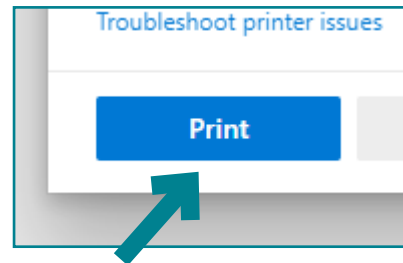
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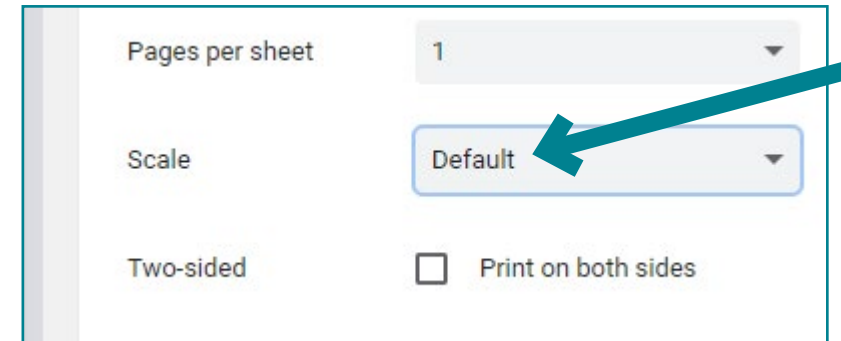


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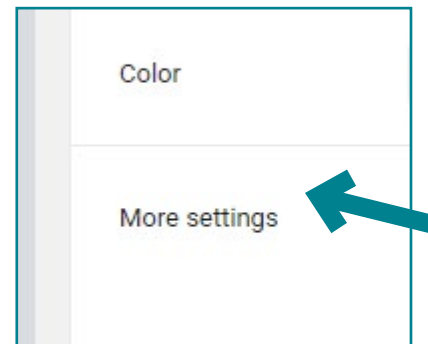
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