Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Review

Regulatory Agilities in the Time of COVID-19: Overview, Trends, and Opportunities

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ABSTRACT

Purpose: Crucial steps have been adopted by health and regulatory authorities around the world to respond to the COVID-19 pandemic. This review aims to highlight these steps by providing an overview of the regulatory approaches adopted during the onset of the pandemic, provide an assessment of observed trends, and offer some reflections and proposals to leverage learnings and opportunities from this current pandemic.

Methods: Documents and informational materials on regulating the development and management of medical products during the COVID-19 pandemic were collected and classified. These materials were sourced from official websites and press releases from health authorities and international bodies from selected markets across the globe, and covered the period between January and July 2020. Additional information to support this study was gathered through a literature review and analysis of related data available from the public domain, and was complemented with the authors' personal experience.

Findings: Communication has been vital in addressing the impact of COVID-19. A total of 1705 documents and informational materials related to health or regulatory response to the COVID-19 pandemic were gathered. Of these, 343 (around 20%) were identified as regulatory agilities. These agile approaches were classified into 3 categories, namely, where health and regulatory authorities had: (1) facilitated product management across the entire lifecycle, notably in expediting medical product use for COVID-19, ensuring the continuity of clinical trials, and addressing supply chain issues; (2) strengthened international cooperation; and (3) addressed regulatory burden with the adoption of electronic and digital tools.

Implications: While many regulatory measures have been introduced temporarily as a response to the COVID-19 crisis, there are opportunities for leveraging an understanding from these approaches in order to collectively achieve more efficient regulatory systems and to mitigate and address the impact of COVID-19 and further future-proof the regulatory environment. (*Clin Ther.* 2021;43:124–139)

Key words: agilities, COVID-19, global response, pandemic, regulatory science.

INTRODUCTION

A global pandemic of the magnitude of COVID-19 has a significant, even transformative, impact on health care, particularly on those involved in developing COVID-19–related treatments, medical devices, and vaccines, and on those who ensure that already-approved medical products remain available to patients.

To address the effects of COVID-19 and to simultaneously ensure the continuity of development of non-COVID treatments, regulators

Accepted for publication November 22, 2020
https://doi.org/10.1016/j.clinthera.2020.11.015
0149-2918/$ - see front matter

have demonstrated significant regulatory agility while maintaining high standards of quality, tolerability, and effectiveness.[1]

Regulators have adopted and made public crucial steps to raise awareness and to provide guidance to stakeholders on how to respond and navigate the current pandemic. In doing so, they have demonstrated tremendous agility. This review provides a comprehensive overview and assessment of these steps and of the approaches made available by regulatory authorities. Through this, we include reflections on some lessons learned and how to leverage solutions that continue to provide value-added, streamlined regulatory processes, or to address regulatory burden for the benefit of all stakeholders; from the medical-product developers through the regulators to health care practitioners for the ultimate benefit of patients.

In this paper, we present several documents or informational materials related to the regulatory environment around the development and management of medical products concerning the COVID-19 pandemic. Some of these documents refer to actions, initiatives, or exceptional approaches where health or regulatory authorities have either: (1) advanced existing initiatives aimed at agile and responsive regulatory systems and processes; or (2) introduced new and innovative ways to expedite and improve such processes. For the purpose of this review, we refer to *regulatory agility* as the willingness of authorities to take quick action within the accepted regulatory framework to ensure that the regulatory ecosystem swiftly responds to the challenges imposed by the pandemic for the ultimate benefit of patients and society as a whole.

MATERIALS AND METHODS

The data collected for this analysis were extracted by the authors from COVID-19–related information (eg, guidance, guidelines, notices, administrative communications) issued by health authorities in selected markets and regional and international bodies (the African Union, the European Commission, the International Coalition of Medicines Regulatory Authorities, the Organisation for Economic Co-operation and Development, the Pan American Health Organization, and the World Health Organization [WHO]) from January to July 2020 during the initial outbreak. These relate to information that has an impact on the policy environment around the development or lifecycle management of medical products. The information was sourced from the official websites of health authorities or bodies, when available, but excluded policies or information related to confinement and lockdown measures or to situational reports (eg, monitoring the number of cases in a region or country).

The documents were then classified by zone, country, regulatory authority, information format, and topic area. These documents were also further classified into what we refer to as "regulatory agilities" by flagging those that explicitly indicate, within the text, the use of exceptional measures or flexible approaches of a regulation or regulatory process, which ultimately aim to facilitate the review, approval, and availability of medical products during the COVID-19 pandemic within the January to July 2020 time frame. We have then used these data as a basis for extracting trends, learnings, and potential ways forward. To put trends and learnings into perspective, additional information was gathered through a literature review and analysis of related data available from the public domain, as were the authors' experiences within the company.

RESULTS

Figures on COVID-19–related Documents and Information

As of July 2020, we collected 1705 documents and informational materials related to the policy environment affecting the development and management of COVID-19 medical products based on the aforementioned methodology. Fig. 1 presents an overview of the distribution of documents by month, which demonstrates a rapid increase in documents and information released by authorities and bodies in the March–April timeframe, followed by a gradual decline in new documents and information released from May onward. This finding shows the trend of COVID-19–management efforts across the world—more information was required at the onset of the pandemic, and subsequently less information was required in the later months as various approaches to better managing the situation were adopted.

Figure 2 shows the distribution by zone, with Asia–Pacific having the highest number of documents

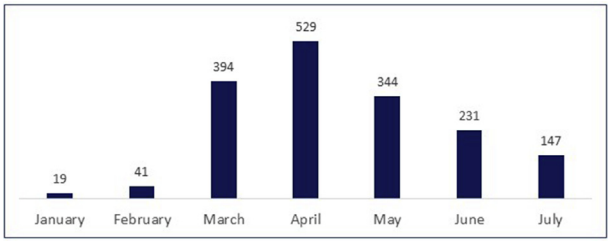

Figure 1. Number of COVID-19–related documents and information, by month. Source: Authors' elaboration, Sanofi COVID-19 regulatory guidance tracker, updated July 31, 2020.

issued. This number was driven by New Zealand and Australia, which respectively constituted 33% and 30% of the documents in the zone. China represented 13% of the total number of documents in the zone. The second-largest zone by number of documents came from Europe, of which 32% came from European Union–level authorities such as the European Commission and the European Medicines Agency. Fig. 3 provides a closer look at the distribution of these documents at the national level, hence excluding documents from regional (eg, African Union, European Medicines Agency) and/or global bodies.

These documents were further classified according to type (Fig. 4). Around 60% constituted documents that came in the form of communications (including announcement, notices, press releases, and circulars); 22%, guidance (including policies); 7% in the form of laws (including regulations, statutes, directives); and the rest as publications or "other." In terms of topic area (Fig. 5), excluding the category "other," most documents referred to information on clinical trials, safety, or multidisciplinary areas. The category "other" referred to documents and information that could not be otherwise classified (eg, agency operation and continuity, procurement, data protection, coordination mechanisms and platforms, meetings and response documents, among others).

From these documents and materials, 343 (20%) that referred to regulatory agility or flexibility were identified. Figs. 6 and 7 provide an overview of the distribution by zone and by type. Using these data, some information was extracted and coupled with information from public databases, literature reviews, and the authors' internal experiences and trends were identified and are described in the next section.

Trends in Regulatory Approaches

Facilitating Product Management Across the Entire Lifecycle

Expedited Regulatory Reviews and Approvals

To ensure that COVID-19–related medical products are rapidly assessed as potential treatments or vaccines, health authorities have considered expedited pathways,[3] either through an already-existing pathway or as a new COVID-19–related emergency pathway.[4] Table I describes some examples of the various regulator-offered expedited pathways for COVID-19–related medical products.

In addition to those offered by regulators at the national or regional level, the WHO made available 2 global pathways for facilitating access to medical products in emergency situations: (1) the WHO Emergency Use and Listing, which aims to provide guidance to United Nations procurement agencies and regulators of WHO member states on the quality, tolerability, and performance of *in vitro* diagnostics[10]; and (2) the WHO prequalification program, which aims to assess the quality, tolerability, and efficacy of medicinal products for priority diseases.[4,15]

Streamlining Clinical Trials

Flexible Approaches. Regulators have adopted approaches to facilitating the continuity of clinical trials of both COVID-19–related medical products and ongoing or planned studies outside of COVID-19.[16] Guidance on conducting clinical trials during the pandemic have been offered by several regulators[17–21]—many of which are nonbinding and require effective monitoring from the sponsor and clinical investigators. These approaches ensure that patient safety remains paramount and that open communication is maintained across the various stakeholders involved in clinical trials. Some of these approaches are further described in Table II.

Collaboration and Harmonization Efforts. In August 2020, some 4800 clinical trials were being conducted worldwide, including those of COVID-19 treatments. Study types during this period were mostly either interventional or observational.[22] Significant efforts to ensure greater harmonization of clinical trials of

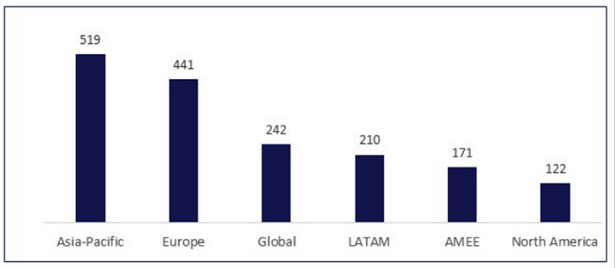

Figure 2. Distribution of COVID-19–related documents and information, by zone. AMEE = Africa, Middle East, and Eurasia; LATAM = Latin America. Source: Authors' elaboration, Sanofi COVID-19 regulatory guidance tracker, updated July 31, 2020.

COVID-19 treatments and vaccines are being made. These efforts include initiatives such as the WHO "Solidarity" Clinical Trial for COVID-19 Treatments,[23] the African Union's Consortium for COVID-19 Vaccine Clinical Trial[24]; guiding principles provided by the International Coalition of Medicines Regulatory Authorities[25]; and industry data-sharing efforts such as those facilitated by TransCelerate.[26]

Ensuring Continuous Supply of Medical Products and Avoiding Shortages

Ensuring the supply of medical products remains essential, especially in emergency health situations, when the risk for shortages can be elevated. Simplified and exceptional management of regulatory processes have therefore been adopted by various regulators to maintain supply and to lower the risk for such shortages. These processes have complemented industry efforts, such as increasing production and donating medical products where needed. Expedited reviews have been offered (Table I) and have been useful, especially for post-approval changes, such as in the case of the European Union's use of the exceptional change management process.[27] With regard to ensuring good practices, regulators have offered to conduct inspections remotely[28] or have granted sponsors existing marketing-authorization approval extensions, automatic recertifications, or temporary certifications.[27,29]

The use of flexible approaches to labeling has also been widespread. For example, printed labels and packages adopted to a specific market may take a long time to be approved and then produced to ensure their availability during a pandemic. Some of the proposed regulatory approaches to address this issue have included extending the permitted implementation time of the labeling update (except for significant safety updates),[30] allowing nonlocal-language labeling,[31] using electronic submissions of packaging and leaflets instead of physical samples,[32] and packing down of larger packs of medicinal products.[33]

In addition, open and transparent communication across stakeholders through virtual communication platforms and online notifications have proved useful in identifying any potential out-of-stock situations (eg, the US Food and Drug Administration's Drug Shortages database[34] and mobile app[35]), as well as the creation of industry–agency task forces and working groups that allow for regular interactions between industry and regulators on shortages (eg, the executive steering group on shortages and the industry single point–of-contact system in the European Union[36]).

Greater Work-sharing and Transversal Collaboration

The COVID-19 crisis has also increased collaboration both across and between health authorities and industry. Various government-led partnerships and global consortia have been initiated to facilitate working together with industry and other stakeholders, such as academia, to accelerate the research and development of medical approaches to combatting COVID-19.[37–39] In addition to the various bilateral partnerships that have emerged at the government and industry levels, multilateral partnerships and initiatives have aimed to bring together efforts to building scientific knowledge and to pool resources to offer solutions to the pandemic (Table III).

Addressing the Regulatory Burden

Evidently, the current pandemic has also seen progress in the swift adoption of electronic platforms across many countries around the world—propelling stakeholders into a predominantly digital work mode.

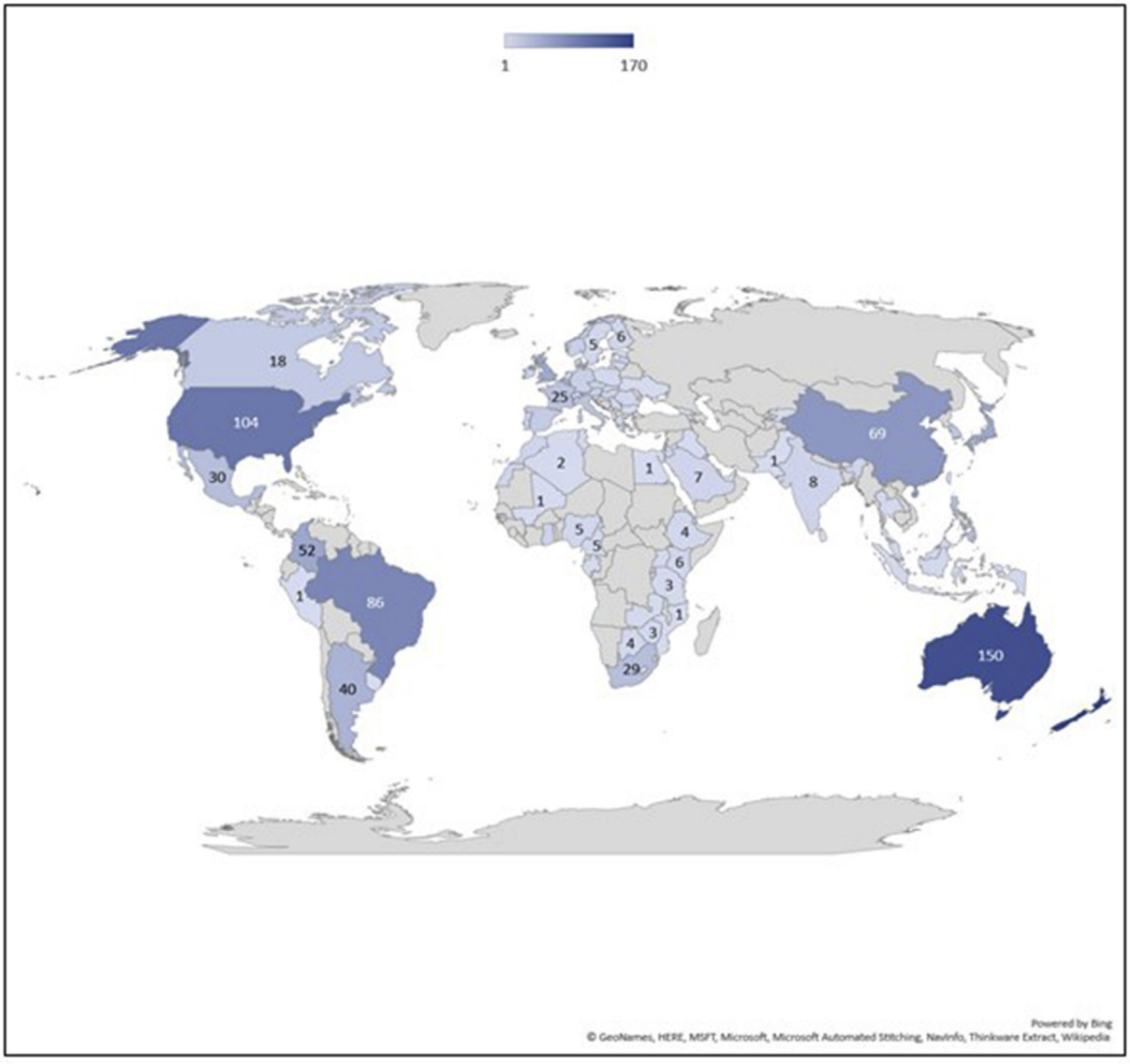

Figure 3. Heat map of COVID-19–related documents and information from authorities in selected countries, excluding regional or global organizations. Source: Authors' elaboration, Sanofi COVID-19 regulatory guidance tracker, updated July 31, 2020.

Based on information collected from our tracker and our experience when interacting with regulatory authorities, video calls have been used extensively, and even by default, to ensure regular interaction, while the use of the cloud and other online storage tools have been encouraged to store and share documents and information in real-time. Some countries have also opted for online submission of marketing-authorization applications, such as through an email-based or online platform, notably where they have not been previously or extensively used.

While efforts to modernize regulatory processes through eliminating dated regulations and processes, and through the waiving of supplemental requirements, are not new, the pandemic has undoubtedly demonstrated that it is possible to reduce

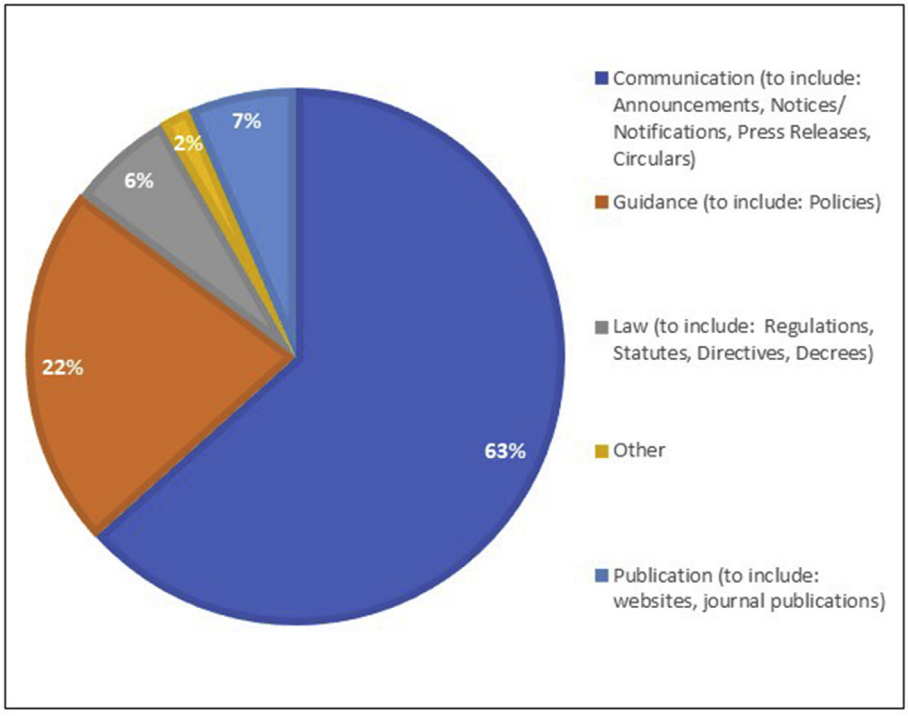

Figure 4. Type of COVID-19—related documents and information (in percentage). Other = documents or information that could not be classified elsewhere (eg, reports, meeting highlights or summary, or templates). Source: Authors' elaboration, Sanofi COVID-19 regulatory guidance tracker, updated July 31, 2020.

or even eliminate some unnecessary administrative steps and requirements that can often be burdensome for both regulators and stakeholders involved in the process. Some approaches that have been introduced to lower the bureaucratic burden include:

Issuance of electronic Certificates of Pharmaceutical Products that are signed and authenticated electronically[42];

Acceptance of e-signatures[43];

Waiving of legalizations/notarizations,[44,45] with the condition of submitting legalized documents after the COVID-19 pandemic[46]; and

Waiving of physical-sample requirements[47,48]

Implications of COVID-19 on Health Authority Operations

Many of the identified regulatory approaches have indeed been introduced temporarily to allow health authorities and stakeholders to manage the pandemic and to ensure the continuity of their respective operations. However, even with sustained operations, catching up on backlogs, delayed sponsor meetings, and other activities that had to be suspended during the pandemic constitute a challenge, as does resuming activities that have not yet been extensively tested in a virtual environment prior to the current pandemic (eg, remote inspections).

Furthermore, new priorities emerging from the pandemic, such as ensuring supply-chain integrity and managing increasing fake medicines,[49,50] may require health authorities to seek additional tools and resources. In addition, the pandemic has affected the implementation of some new provisions, such as the EU Medical Device Regulation[51] or Australia's adoption of TGO 91 labels,[52] to which resources have already been initially allocated.

These new and/or emerging challenges can be addressed by continuously leveraging the agile

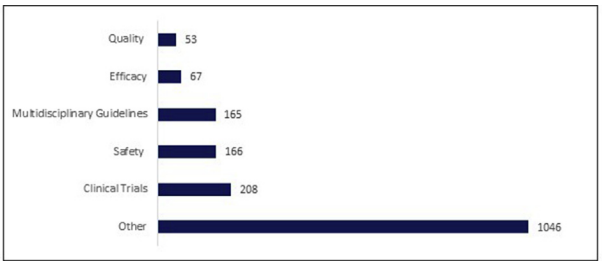

Figure 5. Number of COVID-19–related documents and information, by topic area. Other = documents or information that could not be classified elsewhere (eg, agency operation and continuity, procurement, data protection, coordination mechanisms and platforms, meetings and response documents, among others). Source: Authors' elaboration, Sanofi COVID-19 regulatory guidance tracker, updated July 31, 2020.

approaches implemented during this pandemic. While these agile approaches have been triggered by COVID-19, there is indeed additional opportunity to expand them beyond the current pandemic and to adopt them to other services or products that could also benefit all stakeholders involved, notably patients.

Leveraging Findings and Opportunities

COVID-19 has precipitated several opportunities that could be sustained beyond the pandemic. Based on the trends discussed earlier and the adoption of such approaches to date, 5 considerations in moving forward can be proposed: (1) embedding regulatory agility and lessons learned; (2) accelerating the development process of innovative medical products; (3) address manufacturing and supply bottlenecks; (4) strengthening international cooperation, notably for clinical trials and vaccine development; and (5) committing to easing the regulatory burden and adopting the use of digital technologies.

Embedding Regulatory Agility and Lessons Learned

Regulators have reacted quickly with the expedited issuance of relevant guidance during the acute phase of the pandemic, while making sure that these remain to meet quality requirements. This reaction was especially useful for the industry's understanding of "current" agency thinking and aligning approaches toward addressing the impact of the pandemic. To fully benefit from the gains achieved in the United States of these agile regulatory approaches and extracted lessons for the future, it would be useful to conduct ex-post or postimplementation reviews. These reviews would allow regulators to determine which specific approaches resulted in the most gains across the sector and to identify those that can be introduced temporarily during emergency situations or permanently adopted. Reviewing such approaches can also help to identify best practices that can be shared across regulatory authorities globally and allow for a closer examination to ensure that regulatory mechanisms remain fit for purpose,[53] are increasingly harmonized, and take into account the possible risks and consequences in its application.

Various ways of conducting ex-post evaluations can be pursued, such as in the form of programed review mechanisms or special-purpose reviews.[54] Effective stakeholder engagement throughout this process, through dialogue fora or other structured discussions and consultations, is essential for ensuring the uptake and implementation of any embedded regulatory approaches.

Accelerating the Development Process of Innovative Medical Products

In order to accelerate innovation of treatments and vaccines to meet (unmet) medical needs for the benefit of patients, expedited review and approval pathways continue to play an important role during the COVID-19 pandemic, especially among mature agencies. For example, the EMA implemented a rolling review tool to speed up the entire review process (Table I).

To also stimulate the uptake of innovative medical products in emerging markets, where no expedited pathways are already available, regulatory agencies can consider the use of such pathways beyond COVID-19 and for a wider gamut of products or services, such as in the case of emergency situations or in allowing for an expedited approval of medical products for serious, life-threatening diseases. Nonetheless, any new expedited pathway introduced need to be carefully crafted, and experiences from

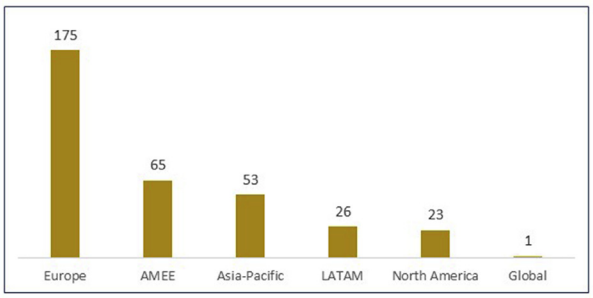

Figure 6. Number of COVID-19–related documents and information that refer to regulatory agilities, by zone. AMEE = Africa, Middle East, and Eurasia; Global = the PAHO document on clinical trials[2]; LATAM = Latin America. Source: Authors' elaboration, Sanofi COVID-19 regulatory guidance tracker, updated July 31, 2020.

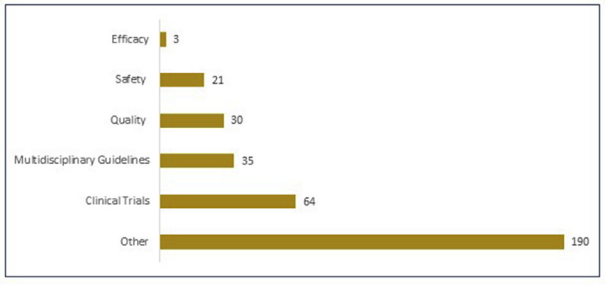

Figure 7. Number of COVID-19–related documents and information that refer to regulatory agilities, by topic area. Other = documents or information that could not be classified elsewhere (eg, agency operation and continuity, procurement, data protection, coordination mechanisms and platforms, meetings and response documents, among others). Source: Authors' elaboration, Sanofi COVID-19 regulatory guidance tracker, updated July 31, 2020.

other regulators that have implemented such pathways can be further leveraged.[55]

In addition, the use of existing expedited pathways during the pandemic also offers an opportunity for regulators to reflect on and review the effectiveness of them to identify challenges and solutions to eventually introduce improvements to the process.

In cases in which the current system of a regulatory authority is still on the path to maturity, and in which resources for dedicated expedited pathways are limited, regulators can adopt reliance or work-sharing approaches that help facilitate the application of such approaches. For example, regulators can rely on trusted regulatory authorities according to the WHO-Listed Authority Interim List of National Regulatory Authorities.[56] They can also depend on available global pathways and guidance through the WHO Emergency Use Listing or Prequalification program.[4,57]

Addressing Manufacturing and Supply Bottlenecks

Medical products should be made available across their entire lifecycle. With the current pandemic affecting the availability across the globe, maintaining sustainable and resilient supply chains became even more important. Agile regulatory approaches related to manufacturing and supply chains, adopted to address some of the issues, have therefore been useful in providing guidance and complementing efforts carried out within industry. With careful review and analysis, such approaches can be broadly adopted and even improved.

For example, the need for immediately available updated label or package information has resulted in agile approaches to the use of nonlocal language labeling or packed down versions of the product. While the waiving of labeling requirements can be useful for emergency purposes, developing the use of QR codes or adopting dynamic e-labeling can ensure that the most updated packaging and labeling information are made available and accessible to regulators, health care practitioners, and patients online or through pharmacies, even beyond the current pandemic.[57,58]

Broader application of remote inspections outside the pandemic, while risk-based approaches are maintained, may also be explored when both the regulatory authority and the manufacturers have an environment suitable for conducting the virtual

Table I. Examples of expedited pathways offered for COVID-19–related medical products.

Pathway	Description
Rapid scientific advice	Development of prompt guidance for sponsors on methods, study design, or robust data collection and generation for a medical product.[3]
On reviews	
Expedited reviews	Reduction of timelines to the absolute minimum possible for products with major interest in public health. This encompasses priority reviews, fast track designations, and accelerated approvals.[3,5–7]
Rolling reviews	A procedure that allows the regulator to assess data on a particular medical product as they are made available on a rolling basis. In the case of the EMA, this review procedure involves appointed CHMP rapporteurs during the development phase and the agency reviewing the data on a rolling basis. This can be done through several review cycles. Each cycle lasts around two weeks depending on the data to be assessed until the data package is considered complete. Once complete, the sponsor can submit a formal marketing authorization application that is reviewed under a shorter timeline.[3]
On approvals	
Conditional approvals	Regulators can grant a conditional marketing authorization for medical products where the immediate benefit outweighs the risk for having less available data than normally available. These are valid for one year and can be renewed each year, following specific obligations.[8]
Emergency use	Regulators allow for the use of approved or unapproved medical products to diagnose, treat, or prevent serious and life-threatening diseases and conditions during an emergency when there are no adequate, approved, and available alternatives.[7,9,10]
Expanded access	Also referred to as compassionate use, regulators allow for the use of an investigational medical product outside clinical trials for serious, immediately life-threatening diseases and conditions when no comparable, satisfactory alternative treatment is available.[11,12]
Special programs	
Coronavirus Treatment Acceleration Program (CTAP)	The US FDA's special emergency program that aims to use every available method to facilitate the discovery and development of new treatments for COVID-19.[13]
Operation Warp Speed (OWS)	OWS is a partnership across the United States' bodies and agencies and private firms, with the aim of accelerating the development of COVID-19 vaccines and distributing 300 million doses of these safe and efficacious vaccines by January 2021.[14]

CHMP = Committee for Medicinal Products for Human Use; EMA = European Medicines Agency; FDA = US Food and Drug Administration; OWS = Operation Warp Speed.

inspection. Remote inspections can also help to ensure a smooth site transition, in cases of issues encountered with the current manufacturing site, or the possibility of utilizing multiple manufacturing sites.

Furthermore, partnerships and platforms for discussion that have been leveraged or established during the COVID-19 pandemic, such as those that ensure efficient notification of medical product shortages, remain essential. These partnerships or

Table II. Facilitating clinical trials during the COVID-19 pandemic.

Topic	Description
On changes in the conduct of clinical trials	Some protocol changes are permitted without the approval of institutional review boards or ethics committees[18] or through a risk-based assessment from the sponsor.[17]
	Temporarily halting the trial, when it is not linked to the safety of the participant, to liberate resources to COVID-19 trials.[17]
On the delivery investigational medicinal products	Delivery of investigational medicinal products *directly to patients* in case the trial participant has no access to the hospital or investigation site.[17,19]
	Supplying larger amounts of Investigational Medicinal Products to trial participants, with the supervision of the investigator.[17]
On monitoring	Allowing for the *use of alternative methods for safety assessment* when in-person visits or on-site monitoring are unavailable, such as remote monitoring (phone contact, telemedicine, virtual visits) or use of alternative centers, as appropriate.[17,18]

platforms can play an important role when developing future guidance on the supply of essential medical products that need to be maintained beyond the pandemic (eg, life-saving medicines) or when introducing or enhancing tools for postmarketing surveillance or for the notification of supply shortages.[59,60]

Strengthening International Cooperation, Notably for Clinical Trials and Vaccine Development

The COVID-19 pandemic has demonstrated the increasing importance of working transversally across stakeholders to ensure that viable solutions are available for patients around the world. The benefits of different actors working close together is clearly evidenced by the various partnerships and platforms leveraged or initiated.

For example, lesser-resourced regulatory authorities, whose operations have been greatly impaired by the pandemic, can also benefit from insights from better-resourced regulatory authorities, and facilitate data sharing and approaches more broadly across different jurisdictions, especially on product development, clinical trials, and marketing authorization.[53,61] Reliance and work-sharing approaches can be further explored, as suggested by the WHO.[62] A recently released WHO draft guidance on good reliance practices in regulatory decision-making provides some additional information and insights on how these practices can be implemented by regulators.[63]

As various approaches are being pursued to test medical products during the COVID-19 pandemic, consistency and harmonization on the oversight, review, and management of clinical trials are important.[64] The Organisation for Economic Co-operation and Development offers some binding recommendations on the governance of clinical trials, including facilitating international cooperation, by which member states have agreed to abide.[65] Approaches that facilitate the management and oversight of clinical trials, such as the use of remote clinical trials, can be further explored.[66,67]

Maintaining international cooperation across all stakeholders will be especially important for vaccine research and development, which can be a rather lengthy and complex process.[61,68] Various approaches are already being pursued to speed up and support the clinical-trial process, such as the use of remote clinical trials, e-consent, and direct-to-patient delivery of investigational medicinal products. However, strengthened international regulatory cooperation with stakeholders not only should be limited to the current pandemic but also must persist even postpandemic.

Committing to Easing the Regulatory Burden and Adopting the Use of Digital Technologies

Already-existing approaches that simplify or facilitate certain regulatory processes, such as the use of electronic submissions and payments, digital signatures, or online platforms for meetings,

Table III. Examples of partnerships leveraged to collectively combat COVID-19.

Partnership	Description
Access to COVID-19 Tools (ACT) Accelerator	Pools together various stakeholders (governments, businesses, civil society, and international actors) to support in the development and equitable distribution of medicinal products to lower mortality and severe COVID-19 cases.[5]
COVID-19 Therapeutics Accelerator	Launched by the Bill & Melinda Gates Foundation, Wellcome, and Mastercard, this platform aims to support the acceleration and evaluation of new and repurposed medicines and vaccines to treat patients with COVID-19, and ensure equitable access by making these available and affordable notably in low-resource settings.[40]
International Coalition of Medicines Regulatory Authorities (ICMRA)	Serves as a forum for strategic co-ordination and international cooperation across regulatory authorities. In lieu of the COVID-19 pandemic, ICMRA members have aimed to expedite and streamline the research, development, and access of COVID-19 treatments and vaccines and ensure the effective and efficient approach to regulatory processes and decisions.[41]

discussions, or information sharing are also some practices that can be retained or adopted more broadly.

Opportunities to adopt innovative digital technologies, platforms, and tools can be further explored to propel the regulatory environment further into the future. These opportunities include data-sharing tools such as the use of a cloud-based data system to support a more agile regulatory decision-making process[69] and processes facilitated by artificial intelligence.[70] These can also be further classified into those that facilitate the drug development or clinical trial process and those that can be broadly adopted as a way of working.

Reducing the regulatory burden is a shared objective by all stakeholders, as it puts a strain on the limited resources available, and even more during emergency situations. This pandemic has provided an opportunity to look closely into regulatory tools and approaches that simplify operations and reduce unnecessary administrative steps to deliver more efficient, forward-looking regulatory systems.

DISCUSSION

Significant efforts to manage and address the COVID-19 pandemic are being made and demonstrated by all stakeholders across the health sector. At the heart of the attention is the tremendous commitment from health authorities and regulators to ensure that communication channels remain open across stakeholders in order to collectively address the impact of the pandemic. Health authorities and regulators have responded promptly and communicated widely. They have provided guidance and demonstrated regulatory agility to complement efforts in the industry. These approaches have ensured that COVID-19 medical products are developed and made available to society, that new medical innovations under development continue to progress, and that existing medical products remain available to patients around the world. Such guidance and agile approaches remain valuable in addressing this crisis and in future situations, especially when they are consistent and aligned across regulatory authorities.

The current pandemic has provided lessons learned in addressing global emergency situations, and these experiences—both the challenges and solutions adopted—can be leveraged for preparation for any future situations and can serve as an opportunity to reflect on current regulatory processes and tools. The authors propose that all relevant stakeholders work together to arrive at concrete proposals and actions in adopting learnings identified from agile approaches used during the COVID-19 crisis. Initiatives to review learnings are being undertaken by some health and regulatory authorities to embed enhancements into future regulatory processes. In some instances, it may help agencies to "leapfrog" into contemporary approaches (ie, maturing regulatory agencies looking

into advancing their regulatory processes and systems and strengthening collaboration with other regulatory agencies and stakeholders).

The use of digital tools during the pandemic has also been remarkable and has facilitated the continuity of business operations. It has provided the opportunity for the pharmaceutical sector to reevaluate the use of tools to ensure that they are able to facilitate the efficient functioning of regulatory processes and operations that ensure that medicines are developed and made available to patients. More importantly, this pandemic has underscored the importance and the benefit of working across all stakeholders, which can be continuously leveraged even postpandemic. A robust, coordinated approach will be beneficial, given the shared aims of ending the pandemic, ensuring a healthy population, and better managing emergency situations in the future.

The deployment of digital-communication tools has seemingly lowered the barrier of communication and perhaps increased the frequency by which they have occurred, which has proven to be beneficial for all parties involved.

CONCLUSIONS

The use of agile regulatory approaches during the pandemic has helped to ensure that medical products have remained available, and that new ones could be effectively researched to address patients' needs. Nonetheless, many of these approaches have been introduced temporarily to mitigate the impact of the pandemic on patients and society. A number of learnings can be leveraged to further improve the regulatory environment. Proposals include: (1) embedding regulatory agility and lessons learned; (2) accelerating the development of innovative medical products; (3) addressing manufacturing and supply-chain bottlenecks using flexible labeling requirements or digital approaches such as remote inspections to facilitate site transfers or use of multiple sites; (4) strengthening international cooperation, notably in clinical trials and vaccines development; and (5) committing to easing regulatory burden and adopting digital tools. The use of these agile regulatory approaches that add value and have the potential to create opportunities to progress innovative research and development of medical products will be crucial for the future benefit of patients and society.

AUTHOR CONTRIBUTIONS

All authors designed the commentary, analyzed the data, and wrote the manuscript.

DISCLOSURES

All authors hold positions within the pharmaceutical industry, but did not receive any grant, honoraria, or other compensation to author this article. The study was conceived, executed, and written up in the course of the authors' daily jobs. The authors have indicated that they have no conflicts of interest with regard to the content of this article.

DISCLAIMER

The views expressed in this research are the independent views of the authors and should not be understood or quoted as being made on behalf of or reflecting of the position of their respective companies or any other affiliation.

ACKNOWLEDGMENTS

We thank Sophie Miet-Eseverri, Sothavy Nguyen-Say, Camille Jackson, and Sara Ferragu for assistance in building part of the Sanofi COVID-19 regulatory guidance tracker. We also thank Lina Aljuburi for providing constructive feedback on the manuscript.

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