

# Increasing transparency in the medicines supply chain

Harnessing information to inform effective action  
to reduce vulnerabilities and prevent or mitigate  
disruptions in the global supply of quality medicines

July 2020



## Introduction

The relative globalization of the medicines supply chain has resulted in a complex web of ingredients suppliers, medicine manufacturers, packagers, and distributors. While globalization has likely resulted in certain efficiencies, it has created complications, complexities, and risks for regulators and healthcare providers as they seek a more resilient supply chain, which can be defined as a system of medicine production that can withstand disruptions and nonetheless provide health systems with their needed supply of quality essential medicines.

One of the implications of the complexities of the supply chain is the lack of consistent, standardized data that can identify, or at least signal, supply and quality concerns to regulators and healthcare providers. Without it, policymakers are under-informed in making investments to improve the resiliency of the supply chain, regulators are unable to pinpoint ingredient and medicine supply concerns as well as compliance gaps, and healthcare providers are blindsided by shortages in critical medicines. Greater transparency of key indicators of potential supply and quality concerns is not, alone, a solution to creating a more resilient supply chain, but is essential to understanding where investments and reforms are needed for greater resiliency.<sup>1</sup>

Most measures to improve the availability and accessibility of standardized information—i.e., transparency—require action that is tailored to national contexts. Yet, because the medicine supply chain is global for most countries, the information transparency imperative is international in nature. National governments, multi-lateral organizations, and industry will need to collaborate to make information flow. This paper highlights the challenges posed by information gaps across the supply chain and presents opportunities and considerations to expand transparency.

**Vulnerabilities** refer to underlying weaknesses that include but are not limited to geographically concentrated manufacturing and sourcing, disparate regulatory environments across the supply chain, and regulatory enforcement or inspection capacity constraints. Systemic vulnerabilities to the supply chain include poor-quality manufacturing, insufficient regulation, and lack of transparency in the medicines supply chain.

**Disruptions** meanwhile can be event-based, notably climate events, trade wars, and pandemics, as witnessed in the COVID-19 crisis.

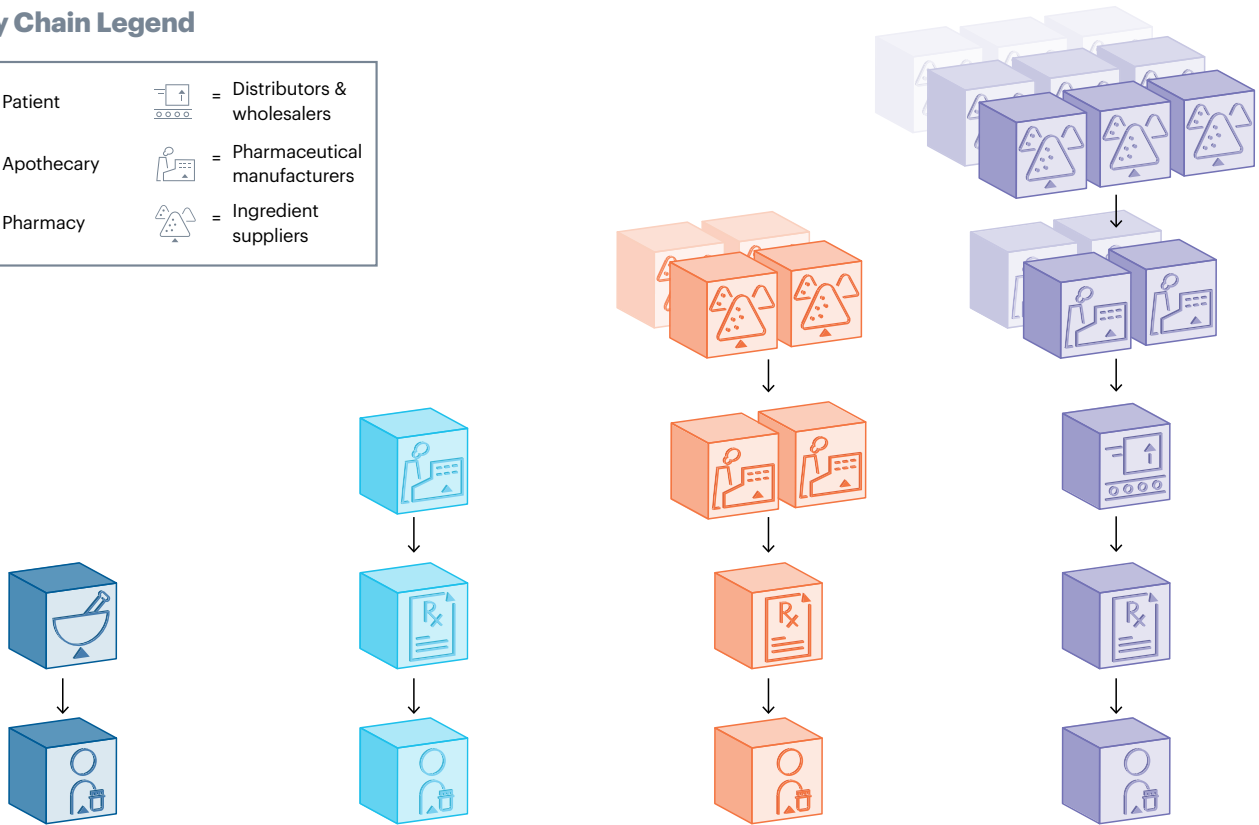
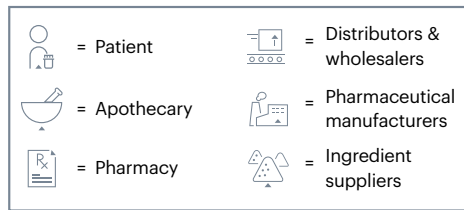
## Background

A diversified and transparent supply chain for medicines offers many potential benefits to patients around the world, including expanded access to, and reduced costs of, quality medicines. Manufacturing medicines in geographically distinct facilities and building redundancies into the system reduces the risk of interruptions to the supply of medicines. Unfortunately, the current medicines supply chain is threatened by both chronic vulnerabilities and acute disruptions, which present risks to patient access to quality medicines (see box). Moreover, key elements of the medicine supply chain are concentrated in one or two countries which

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<sup>1</sup> For more information, please read [“Key Elements to Building a More Resilient Supply Chain.”](#)

### Supply Chain Legend



1820s-1860s

#### Botanicals and herbal medicines

Local apothecaries with knowledge of botanicals, prepare remedies for patients.

1870s-1950s

#### Rise of manufacturing

Analytical chemistry and pharmacology along with advances in automation give rise to large-scale manufacturing.

1960s-1970s

#### Global expansion

Pharmaceutical companies continue expanding manufacturing plants to other countries to increase their markets and reduce operating costs. As a result medicines are produced and packaged at a greater distance.

1980s-2020s

#### Growth, distribution, consolidation

Rise of generics in the early 80s extends the supply chain as more companies manufacture medicines outside the U.S. Today, many intermediaries play a role in medicine's production, distribution, and delivery.

increases risk, including during crisis situations. The impact of these vulnerabilities and disruptions include widespread and long-lasting drug shortages, product recalls, price increases, and the increased potential for substandard and falsified medicines, all of which can result in reduced access and patient harm.

The global supply chain for medicines involves a complex web of ingredients suppliers, manufacturers, packagers and

distributors, providers, and regulators navigating different jurisdictional requirements, capacities, and information sources. The more diffuse and fragmented the supply chain is across multiple jurisdictions, the greater the risk that important information about the origin, production volume, distribution chain, and integrity of products can be lost, and with it the ability to identify potential problems and respond appropriately with investments and policy reforms.<sup>i</sup>





### Challenge: Gathering medicine manufacturing information across national borders

In the early months of the COVID-19 pandemic, as countries locked borders and implemented social distancing guidelines, most on-site inspections of manufacturing facilities were not possible, and regulators relied on other tools to conduct this oversight. In the United States, one such tool available to the U.S. Food and Drug Administration (FDA) is the authority granted in Section 706 of Title VII of the Food and Drug Administration Safety and Innovation Act (FDASIA) to request certain records from manufacturers in lieu or in advance of on-site inspections.<sup>ii</sup> Additionally, mutual recognition agreements (MRAs) are another tool that can enable regulatory authorities to share inspectional findings of manufacturers in their respective jurisdictions with regulators covered by an MRA. It is unknown the extent to which these agreements were utilized or effective during the early weeks and months of the pandemic. The suspension

of in-person inspections by many regulatory authorities during the pandemic emphasizes the need for greater use of recognition and reliance mechanisms and broader information-sharing among regulators.<sup>iii</sup>

At the same time, MRAs are extremely time-consuming and resource-intensive to develop<sup>iv</sup> and potentially limited in their effectiveness for several reasons. In many cases, regulators may share only heavily redacted reports with one another, which reduces the utility and value of the arrangement. Even if regulatory authorities were permitted to share information in less redacted or fully unredacted form, as a recent National Academies report recommended,<sup>v</sup> regulators still lack critical information from manufacturers, as described in the next section. Taken together, these circumstances inhibit the ability of regulators to detect issues with the supply chain for medicines, including concerns about poor quality or inadequate supply.

### Challenge: Identifying information gaps across the supply chain

Today, even in countries with the most robust regulatory oversight, it is often impossible to identify the sources of medicines and their ingredients. Representatives from regulatory authorities and the biopharmaceutical industry recognize that limited visibility into the supply chain creates problems for the quality of medicines and supply chain resilience.<sup>vi</sup> The more complex the supply chain, the greater the transparency challenges.

Much of the attention surrounding this issue to date has focused on assessing the supply of quality finished dosage form (FDF) products and active pharmaceutical ingredients (APIs). For both APIs and FDFs, it is difficult to ascertain the volume of products manufacturers produce—information critical to predicting shortages. Furthermore, product failure and supply chain disruptions can result from the materials other than APIs used to make finished medicines, otherwise known as excipients.<sup>2</sup>

Excipients come from a wide range of commodity industries, and only a small subset of these materials are manufactured for biopharmaceutical purposes. Increasing attention has

<sup>2</sup> Excipients serve many purposes, such as improving the delivery and bioavailability of the API. Excipients are not intended to have a therapeutic effect; however, they are not necessarily inactive. Worldwide, regulation of excipients varies by country and region. The diversity and variability of excipients, the fragmented supply chain for products used as excipients, and the lack of a harmonized global regulatory framework for excipients allow for potential quality risks and limited transparency on the production and sourcing of materials.

been focused on excipients and medicines quality, especially because of several incidents of poisoning due to diethylene glycol (a harmful imposter of glycerin, which is a substance commonly used as an excipient in medicines).<sup>vii</sup> However, the supply chain for excipients remains opaque. For these reasons, potential risks to quality or supply chain disruptions are difficult to anticipate.

In a highly regulated market, manufacturers are required to adhere to current practice guidelines for quality—good manufacturing practices and good distribution practices—for all medical products as they move through the supply chain. These practices produce documentation (e.g., Certificates of Analysis [CoAs]) that can assist with the traceability of medicines in FDFs, and in some cases, with APIs. For example, medicine procurement mechanisms may require manufacturers to provide this information for FDFs and APIs within those finished medicines. Yet mechanisms that are still in development (e.g., “track and trace” or the effort to build to an electronic, interoperable system that will identify and follow prescription drugs as they are distributed) only apply to FDFs and do not provide insight into sources for APIs and excipients. As such, even the most rigorous quality control practices are insufficient to fully address supply chain vulnerabilities without accurate traceability and reporting. In less regulated markets, challenges are even greater as documentation to verify quality and source of materials is less likely to exist, and much less likely to be shared.

### **Challenge: Balancing increased transparency with commercial interests**

While transparency is critical to proactively identify risks and empower critical decision-making, transparency requirements should be balanced with appropriate protections for confidential commercial and trade secret information. Increasing transparency about the supply of medicines and their ingredients does not necessarily mean the open sharing of all data and information. Nevertheless, the current balance between transparency and confidentiality puts public health at risk and therefore needs to be reassessed.



## **Transparency requirements**

**should be balanced with appropriate protections for confidential commercial and trade secret information.**

Determining which information is appropriate to share requires an understanding of the benefit–risk calculations made by private biopharmaceutical companies and their financial investors. In the simplest terms, private ventures protect proprietary information in order to realize a return on investment (ROI). Traditionally, this has meant that industry is permitted to protect trade secrets or otherwise maintain confidential commercial information (CCI) indefinitely or for a specified period of time (i.e., patent exclusivity). These protections cover different segments of the medicine lifecycle, including research and development (R&D) as well as manufacturing and distribution. However, if regulators or medicines procurers are unable to access information on manufacturing site, volume, and capacity, the fluid supply of medicines—particularly for essential drugs—may be in jeopardy.<sup>viii</sup>

In the current paradigm, balancing ROI potential and increasing information-sharing to benefit public health has inherent tensions. When considering strategies to increase supply chain transparency, it will be necessary to balance the protection of confidential information with reporting requirements for ingredients and drug products. These challenges must be prospectively considered, as the solutions proposed below will demonstrate.

## Opportunities to increase transparency across the supply chain

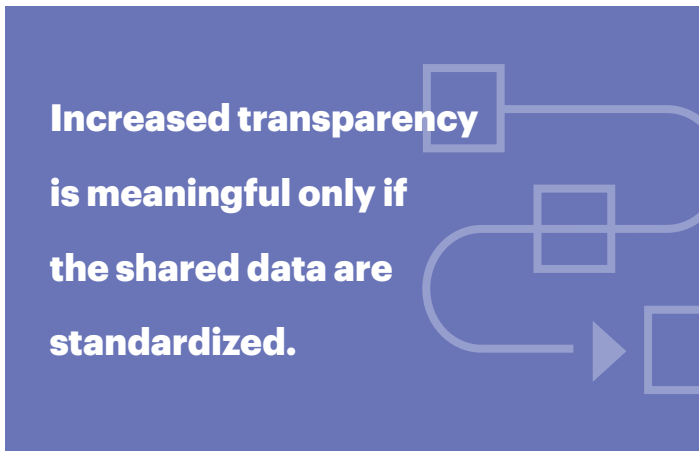
Increased transparency across industry, regulators, and healthcare providers will help reduce supply chain vulnerabilities and avoid some of the downstream effects of disruptions. Upstream visibility to manufacturers' suppliers and suppliers' suppliers in a real-time and robust way allows for an integration and flow of information up and down the supply chain. The following section presents opportunities where increased transparency will allow policymakers, regulators, industry, healthcare providers, and patients to anticipate and prevent or mitigate supply chain disruptions.

1. Information sharing **from industry** would increase visibility across the supply chain. Increased traceability would require industry to know, document, and be able to report the sources of all medical product materials and to prove that incoming materials and outgoing finished products meet quality specifications. In particular, manufacturers of FDFs and APIs should know and be willing to share standardized information with appropriate stakeholders, such as medicine regulators, about the types of products and the volume at which they are produced, the sources of raw ingredients (including APIs and excipients) and other materials (e.g., those required for packaging and distribution), the distribution channels utilized, and the customers who are procuring their products. Likewise, industry should report immediately on any planned or unplanned changes in the supply chain, the genesis of those changes, the expected impact on product availability from disruptions, and steps being taken to address any negative impact on product availability arising from the disruptions.
2. Information sharing **among regulators** is needed to leverage combined regulatory capacity from across countries and to mobilize resources. Individual regulators often are not sufficiently resourced to meet their public health responsibilities in a globalized supply chain. Therefore, the current barriers to mutual recognition and reliance should be addressed to allow regulators to work together and share information, especially in the event of supply chain disruptions, to ensure the drug supply is safe and adequate, while prioritizing the needs of patients within their countries. For regulators, increasing line-of-sight would mean knowing and being able to share with other regulatory authorities the details of a manufacturer's sources, as well as manufacturing

site, volume, and capacity. Pieces of this information may be available to some regulators, but not to all. While currently treated as proprietary and confidential to industry, if this information was available to all affected regulators through voluntary or mandated sharing, with appropriate safeguards, it would increase visibility and allow for risk assessments throughout the supply chain.<sup>ix</sup>

3. Information **from pharmacies and hospital systems** is needed to better understand demand for medical products. Drawing insights about the supply chain requires an understanding of both supply and demand. These considerations could include strategies for leveraging electronic health records (EHRs) to enable hospital systems or clinics to report information about medical product demand, without disclosing protected patient information. Beyond hospital systems and EHRs, retail pharmacies and script clearinghouses can track granular details about the medications dispensed and drug shortages encountered. Entities that procure medicines, such as pharmaceutical benefit managers, also may be able to contribute information on potential challenges to acquiring medicines for its customers.

In all cases, increased transparency is meaningful only if the shared data are standardized. Just as public quality standards for medicines provide the required quality expectations of a medical product, standards for data are important to ensure their quality and functionality. Currently, data from disparate sources in industry and regulatory authorities are heterogenous and fragmented, which limits interoperability. Standardization of data enables informatics tools to draw actionable insights from the data. Components that would need to be standardized include what to measure (e.g., suppliers, location, volume of units produced) with



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## Transparency across the supply chain

### Manufacturers should track and share information about:

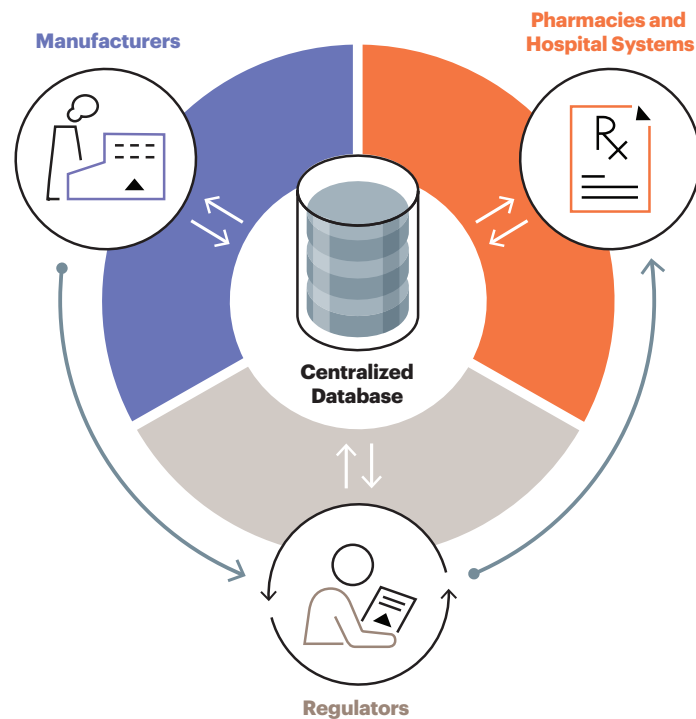
- ▶ Types of medical products and at what volume they are produced
- ▶ Sources of raw ingredients and other essential materials (such as for packaging)
- ▶ Information about distributors and distribution channels

### Regulators should:

- ▶ Have access to insights about manufacturers' sites, products, volume, and capacity
- ▶ Be able to share with other regulatory authorities

### Pharmacies and hospital systems should track and share information about:

- ▶ Prescription data from electronic health records (EHRs)
- ▶ Granular details about the medications dispensed and drug shortages encountered



prespecified, common units and context, how to measure it, and where to report collected data. Additionally, common definitions are needed; for example, what constitutes a “shortage” in a finished product, API, or other essential material. Interoperable digital tracking systems, including Blockchain, are methods that have been discussed as ways to gain visibility across the medicines supply chain, but these technologies still require the data to be standardized.

Some progress toward standardization and interoperability has been made. In the United States, the Drug Supply Chain Security Act (DSCSA) of 2013 mandated an electronic, interoperable system to enable the identification and tracking of select prescription drugs within the domestic supply chain.<sup>x</sup> While one of the primary objectives was to identify and reduce or eliminate illegitimate (i.e., falsified) medicines, the foundational principles also apply when mitigating supply chain disruptions and avoiding drug shortages. However, the provisions of the Act, which will not be fully phased in until 2023, apply only to the U.S. supply of medicines and fall short on providing necessary insight into sources of all relevant materials, including APIs and excipients.

Any solutions for providing additional transparency must expand to include APIs and excipients. One potential example for this type of additional transparency can be found in the New Zealand medicines regulatory agency initiative known as Medsafe, which requires all approved drugs to specify the API and FDF manufacturers, as well as any company involved in re-packing or re-labeling medicines and the local site of product release. In the interest of transparency, Medsafe captures standardized data in a centralized database and makes this information publicly available.<sup>xi</sup>

While the information needed is evident, as well as the need to gather it in a standardized format, it is not clear where that information should be collected and shared for greatest impact. Regulatory authorities, which may seem to be the natural collection point for this data, already make trade-off decisions about the allocation of their finite resources. Furthermore, as described above, regulators’ ability to share information with one another is limited at present. The following section describes some possible and practical approaches for sharing information across the medicines supply chain.



## Solutions to increase transparency: from voluntary to mandated

Out of the disruptions of the COVID-19 pandemic, new models are emerging that support greater information sharing and transparency throughout the supply chain. Some of these models involve voluntary approaches, and some are the result of statutory changes that mandate new reporting requirements. For either voluntary or required approaches to be effective, it will be necessary to predetermine what information will be shared, where it will be shared, and how it will be analyzed in order to draw insights on collected information. Such planning should also make clear how increased transparency will benefit public health and private commercial interests.

In 2019, the U.S. FDA suggested that procurement agencies, including federal and private buyers, have the capability to create incentives for manufacturers to make investments to develop mature quality management systems that prioritize quality, then lowest cost, rather than making decisions based primarily on cost.<sup>3, xii</sup> Likewise, procurers could create incentives for manufacturers and distributors to share information and develop plans for supply chain resilience. To make informed decisions when purchasing medicines, procurers in the United States and globally would need access to information that is not available to them currently. Such information would include documentation that verifies quality, knowledge of any regulatory action taken, and the existence of redundancies in a manufacturers' supplier pool as well as other mitigation plans to avoid drug shortages.

In R&D, some public-private partnerships (PPPs) have been useful in addressing the need to balance greater information-sharing with protection of commercial interests, while also prospectively planning for standardized approaches to increase the liquidity of the data and produce meaningful outcomes.<sup>4</sup> PPP models demonstrate that, in the face of a compelling public health need, industry and government entities are willing to come together to collaborate and work toward a common goal that would benefit the greater good. Transparency and commercial profitability in R&D can be balanced through PPPs that engage in voluntary information-sharing.

PPPs provide an imperfect model for increasing transparency in the supply chain; the drivers and incentives for manufacturers and distributors are dissimilar, and PPPs do not include the participation of all industry. For greater information-sharing to support supply chain resilience effectively, virtually all industry would need to participate. However, PPP models offer useful approaches—including prospective planning with key stakeholders (e.g., regulators and industry) to identify what data will be shared, for what purpose, in what format, with whom, and how the information will be safeguarded from competitors. A plan to establish this framework with the involvement of all key stakeholders may compel manufacturers to participate to ensure their perspectives are fully understood and considered. Such an approach might include voluntarily providing the missing information needed to draw insight into both upstream and downstream aspects of the supply chain, where visibility remains poor.

Voluntary arrangements may provide only a partial solution. Ultimately, in the absence of willingness to share, broader legal and policy changes are likely to be needed to overcome the current limits on sharing among regulators or the lack of requirements on industry to share. As such, mandatory approaches would serve to complete information gaps in the interest of the public. In the United States, for example, a provision in the recently passed Coronavirus Aid, Relief, and Economic Security (CARES) Act creates additional manufacturing reporting requirements. The CARES Act (sections 3112 and 3121) requires manufacturers, among other things, to:

- Provide information annually to the U.S. FDA about the volume of certain drugs produced at registered facilities.
- Notify U.S. FDA when manufacturers of certain drugs experience a discontinuance or interruption in the manufacture of an API.
- When an API shortage is the reason for a drug shortage notification, provide U.S. FDA with information on the source of the API and known alternative sources of the API.
- Submit information during a public health emergency about a critical medical device shortage or critical device component shortage to the U.S. FDA.

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<sup>3</sup> Most medicines procurement agencies prioritize cost over other factors in their due diligence of suppliers because they can access only that information. As a result, manufacturers focus on reducing cost over investing in quality and supply chain resiliency leading to a “race to the bottom.”

<sup>4</sup> For example, Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) comprises representatives from 16 biopharmaceutical companies, multiple government agencies, and academic research centers. The partnership demonstrates a commitment by participating companies to discuss openly investigational therapies in development and to pursue collectively only the most promising therapeutic or vaccine candidates, regardless of which company developed them. Furthermore, a central focus of the partnership involves standardization—the partners agreed to establish common elements and share resources for studying potential treatments and vaccines for COVID-19, such as access to laboratory facilities, standardized methodology and endpoints, a common control arm, and a system to coordinate clinical trials.



These requirements address some information gaps that would help to better predict and plan for drug shortages. However, they fall short of addressing potential quality concerns upstream in the supply chain, possibly preventing or mitigating drug shortages in a more proactive manner. History has demonstrated that in the face of ingredient shortages, suppliers may turn to sources that have not been verified for quality, resulting in adulterated or fraudulent ingredients. Additional and stronger requirements would reduce vulnerability, while requiring documentation (e.g., CoAs) for all APIs and excipients would improve line of sight into the source and volume of quality materials.

Because additional reporting requirements create additional burdens for both industry and resource-constrained regulators, medical products could be sequenced by prioritizing those that are a) essential (as defined by each country or region), and either b) at risk of shortage, or c) at risk of quality challenges. A risk-based approach to mandating increased transparency would need to address each step of the supply chain for medicines, including development, manufacturing, and distribution. This approach could be led through existing regional or international cooperation mechanisms, such as the APEC Center of Excellence,<sup>xiii</sup> or the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), which brings together global regulatory authorities and the biopharmaceutical industry to discuss scientific and technical issues pertaining to medicines development and regulation.<sup>xiv</sup> This approach would need to involve the perspectives of patients, prescribers, suppliers, manufacturers, and regulators. It would also need to develop a prospective plan for the type and format of data to be collected and where that information should be shared to achieve greatest impact. Also, as discussed, global regulatory cooperation should be strengthened and expanded through recognition and reliance mechanisms, such as unilateral or mutual recognition agreements.

The example from New Zealand suggests that it is possible, with enough political will, to make additional pharmaceutical supply chain information available in the interest of patient safety and ensuring patient access to quality medicines. Similarly, the recent passage of the CARES Act demonstrates there is political power among U.S. lawmakers to make broader compulsory changes. With this in mind and with the understanding that voluntary measures are likely to have worthwhile but limited impact, policymakers around the world should require additional transparency measures, such

as aligning requirements for excipients with those applicable to APIs and finished medicines and expanding medical product reporting to include data on manufacturing volume or capacity.

## Conclusion

There are no easy or quick solutions to increasing transparency around the manufacture and distribution of medicines. Doing so may require a mixture of voluntary and mandatory approaches resulting from statutory and regulatory changes as well as financial incentives. Ultimately, the political will to move forward will require continued advocacy from patients, providers, and society at-large.

### USP supports policies that:

- Encourage cooperative mechanisms among manufacturers and regulators to share information regarding the downstream effects of supply chain disruptions.
- Expand reporting requirements for indicators of drug shortages, by both industry and regulators, and provide additional incentives to manufacturers for developing medical product shortage mitigation plans.
- Using a risk-based framework to prioritize reporting requirements for essential medicines, or medicines at risk of shortage or at risk for having quality concerns. For these medicines, manufacturers of their FDFs and APIs should be required to monitor and report standardized information about their product volume and capacity, as well as the quality and source of ingredients, including excipients and other critical materials (e.g., vials and other containers, packaging, labels).

In recognition that there are multiple perspectives and possible approaches to increasing transparency throughout the supply chain, USP commits to convening or otherwise participating in multi-stakeholder discussions to move toward effective solutions. Increased transparency, through voluntary and required approaches, will help ensure patient access to quality medicines by ensuring quality upstream and minimizing the downstream effects of disruptions to the supply chain. Doing so will build resilience and greater assurances across the supply chain, build trust in the public health system designed to safeguard medicines, and help ensure the supply of quality medicines. ▲

## About USP

Founded in 1820, USP is an independent, nonprofit, science-based organization that safeguards the public's health globally by developing quality standards for medicines, dietary supplements, food ingredients, and healthcare quality. USP standards describe specifications and tests for identity, strength, quality, and purity; they assist industry in the development, manufacturing, and testing of medicines. USP standards have been used in more than 140 countries and are enforceable by the U.S. Food and Drug Administration (FDA) for medicines and their ingredients imported into or marketed in the United States. Standards in the USP compendia are developed by independent experts through a transparent and scientific process, with input from stakeholders and U.S. federal agencies such as FDA and the Centers for Disease Control and Prevention.

USP's Promoting the Quality of Medicines Plus (PQM+) program improves access to quality-assured priority medicines and addresses the proliferation of poor-quality

medical products in low- and middle-income countries. PQM+ strengthens medical product quality assurance systems in low- and middle-income countries through cross-sectoral and systems strengthening approaches and the application of international quality assurance standards across the pharmaceutical system.

USP is implementing a comprehensive program to support the public health response to the COVID-19 pandemic. Our immediate work is focused on facilitating the supply of quality medicines across the global supply chain—especially for those medicines that treat symptoms associated with the virus—by working closely with regulators, manufacturers, and other stakeholders around the world. We are also engaging in middle- and long-term activities to assess vulnerabilities in the global supply chain for medicines, advocate for greater transparency and more diversity in the sources of medicines and their ingredients, and ultimately help build a more resilient supply chain.

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