INTERNATIONAL GENERIC AND
BIOSIMILAR MEDICINES ASSOCIATION

IGBA Position Paper

Medicines Shortages

Background

The International Generic and Biosimilar Medicines Association (IGBA) strengthens cooperation between associations who represent manufacturers of generic and biosimilar medicines from around the world. The IGBA is at the forefront of preserving sustainable competition within our industry, by stimulating competitiveness and innovation in the pharmaceutical sector; thereby, ensuring millions of patients around the world have access to high quality, pro-competitive medicines. IGBA's full-members include the Canadian Generic Pharmaceutical Association, Medicines for Europe, the Association for Accessible Medicines (USA), Japan Generic Medicines Association, Jordanian Association of Pharmaceutical Manufacturers, Indian Pharmaceutical Alliance, Generic & Biosimilar Medicines Southern Africa, and Taiwan Generic Pharmaceutical Association. In addition, IGBA has associate members including the associations of Australia, Brazil, Malaysia, Mexico and Saudi-Arabia. Generic and biosimilar medicines manufacturers are an essential and integral part of the solution to increasing patient access to medicines, while also controlling costs.[1] IGBA believes that the use of generic and biosimilar medicines should be encouraged and seen as an opportunity to increase patient access, while reducing healthcare costs and helping to prevent medicines shortages through greater choice and availability of treatments. IGBA believes in the importance of providing patients with timely access to generic and biosimilar medicines and its

[1] In the U.S., generic medicines filled 89 percent of dispensed prescriptions, while accounting for only 26 percent of drug spending in 2016. In 2016, generic medicines were dispensed to fill 71 percent of all retail prescriptions in Canada but accounted for just 22 percent of the $25.8 billion Canadians spend annually on prescription medicines.

members are committed to providing a safe and continuous supply of high quality medicines as a key public health objective.

The World Health Organization (WHO) has spearheaded global efforts on countering medicines shortages, emphasizing the need for coordinated action among stakeholders around the world. The IGBA has answered the WHO's appeal for international collaboration on medicines shortages by fostering cooperation across the pharmaceutical supply chain to help prevent and/or mitigate medicines shortages. IGBA continues to encourage a patient-centric, proactive dialogue to address the root causes of medicine shortages and improve mitigation efforts. This dialogue should involve all stakeholders: patients, payers, healthcare professionals, regulators and supply chain participants to achieve the most benefit.

INTERNATIONAL GENERIC AND BIOSIMILAR MEDICINES ASSOCIATION

Introduction

Medicines shortages[2] (also referred to as "shortages" throughout this paper) are a complex issue of global relevance. Simply put, medicines shortages occur when multisource alternatives are not available to patients. According to a July 2016 report by the United States Government Accountability Office (GAO), supply-side factors that contribute to shortages include manufacturing complexity, lack of speed of regulatory reviews, decreased (financial) margins of certain medicines, and inventory- and quality-related issues. Demand for medicines fluctuates due to changes in clinical guidance or indications, prescribing patterns, population change, and changes in the number of available suppliers. Globally, medicines likely to be in short supply have a low margin, are difficult to formulate or produce (high-cost), have a short shelf life, and/or have few or only one manufacturer.[3] In these vulnerable markets, introducing disruptions such as difficulties obtaining raw materials and unstable or unpredictable market demand can result in shortages of critical medicines. In a U.S. Department of Health and Human Services (HHS) study, medicines that eventually experienced a shortage saw average prices decrease every year leading up to the shortage.[4]

Medicines shortages highlight the unique market dynamics faced by the generic pharmaceutical industry, dynamics to which most shortages can be traced back.[5] In most consumer product markets, unmet demand results in higher prices, causing new participants to enter the market; however, tightly-controlled regulation (often country-specific requirements), substantial up-front investment, and existing contracts with manufacturers prohibit new entrants and existing companies from responding quickly to changes in the market for generic medicines. The generic pharmaceutical industry is competitive in the long-run, but low margins and high regulatory burdens mitigate against manufacturers' ability to respond to changes in the market in real time.[6]

While the pharmaceutical industry manages a regular supply of medicines, shortages do occur and are being reported across the globe, with increasing frequency.[7] Shortages may lead to adverse health outcomes, create challenges for health care professionals, and precipitate greater spending on

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[2] Creating a common definition of "medicines shortages" could be the first step for international partners working to address shortages. A WHO study found 56 definitions in use across the globe. IGBA's position is that a shortage cannot occur if patients can access a generic version.

[3] Addressing the global shortages of medicines, and the safety and accessibility of children's medication. World Health Organization. 18 December, 2015. Accessible at: http://apps.who.int/iris/bitstream/10665/250709/1/B138_41-en.pdf.

[4] Economic Analysis of the Causes of Drug Shortages. *ASPE Issue Brief*. Office of the Assistant Secretary for Planning and Evaluation. October 2011. Accessible at: https://aspe.hhs.gov/system/files/pdf/108986/ib.pdf

[5] Quality issues are a reported cause of shortages along the supply chain, but an economic analysis by the Office of the Assistant Secretary for Planning and Evaluation for the U.S. Department of Health and Human Services found that frequently, quality issues can also be traced back to economic causes.

[6] Economic Analysis of the Causes of Drug Shortages. *ASPE Issue Brief*. Office of the Assistant Secretary for Planning and Evaluation. October 2011. Accessible at: https://aspe.hhs.gov/system/files/pdf/108986/ib.pdf.

[7] *Id.*

pharmaceuticals.[8] Around the 2012 peak of the U.S. drug shortage crisis, an estimated 500,000 cancer patients experienced shortage of oncology medicine[9] leading to interruptions in their treatment protocols and threatening treatment outcomes. Medicines shortages affect almost all product categories (oral solid, injectables, etc.) and therapeutic classes. Shortages were observed most frequently in anti-infectives, anaesthetics, cardiovascular medicines, oncolytics, CNS, and endocrine/metabolic medicines.[10] [11] The United States Food and Drug Administration (FDA) reported 456 instances of medicines shortages (only tracking medically necessary products[12]) in the U.S. between 2011 and 2014.[13] A U.S. GAO report indicated that 6 out of 10 health care associations believed medicines shortages are worsening.[14]

Medicines shortages are detrimental to both the health of patients and health care budgets. An analysis by the Premier Healthcare Alliance in the U.S. found that medicines shortages cost hospital budgets a minimum of US$200 million annually through the forced purchasing of expensive alternatives to essential medicines.[15]

Causes of Medicines Shortages

Over the past decade, the number of generic manufacturers in Europe has decreased, while scope and volume of medicines has increased. In the U.S., the market entry of generic manufacturers has slowed, according to national pharmaceutical sales data.[16] According to the WHO, a supplier base of at least three different manufacturers per product is considered desirable to minimize the potential for medicines

[8] The estimated cost of substituting medicines in shortage for hospitals in the U.S. is $230 million annually. Drug Shortages. Pew Charitable Trusts and ISPE. January 2017. Accessible at: http://www.pewtrusts.org/~/media/assets/2017/01/drug_shortages.pdf
[9] Boshnakova, Anelia. Cancer Medicines Shortages in Europe: Policy recommendations to prevent and manage shortages. *The Economist* Intelligence Unit. 2017. Accessible at: http://www.eiu.com//graphics/marketing/pdf/ESMO-Cancer-medicines-shortages.pdf
[10] Based on data from the U.S. and Australia. While many countries track current medicines shortages, few translate the data into publicly-available reports.
[11] Boshnakova, Anelia. Cancer Medicines Shortages in Europe: Policy recommendations to prevent and manage shortages. *The Economist* Intelligence Unit. 2017. Accessible at: http://www.eiu.com//graphics/marketing/pdf/ESMO-Cancer-medicines-shortages.pdf
[12] "Medically necessary" is defined by FDA as a "drug product is a product that is used to treat or prevent a serious disease or medical condition for which there is no alternative drug, available in adequate supply, that medical staff has determined to be an acceptable substitute." Accessible at: https://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM441583.pdf.
[13] Drug Shortages. Pew Charitable Trusts and ISPE. January 2017. Accessible at: http://www.pewtrusts.org/~/media/assets/2017/01/drug_shortages.pdf
[14] Drug Shortages: Certain Factors Are Strongly Associated with This Persistent Public Health Challenge. GAO. 7 July, 2016. Accessible at: https://www.gao.gov/products/GAO-16-595.
[15] Medicines Shortages in Australia. Accessible at: https://www.shpa.org.au/sites/default/files/uploaded-content/website-content/shpa_medicines_shortages_in_australia_report_june_2017.pdf
[16] The Landscape of US Generic Prescription Drug Markets, 2004-2016 (working paper.) Berndt; Conti; Murphy. National Bureau of Economic Research. Accessed July 2017.

shortages.[17] In markets with limited returns on investment (ROI) such as mature generic medicines markets, the manufacturing base is even more likely to be limited.[18] Complex standards, country-specific requirements and long timelines for regulatory approval for both products and manufacturing facilities lead to uncertainty and higher costs for generic manufacturers.

Medicine shortages are often the result of health care policies impacting generic medicines, wherein the main focus is on cutting prices, rather than securing increased patient access to high-quality medicines. Additionally, extreme downward pressure is exerted on prices due to short-term cost containment measures such as tendering or competitive contract bidding, external reference pricing, and price capping mechanisms such as CPI penalties in the U.S. and payback mechanisms. These policies, implemented by authorities, challenge the sustainability of the generic medicines industry and force manufacturers to withdraw medicines from the market, thereby increasing the risk of medicines shortages.

Furthermore, active pharmaceutical ingredient (API) manufacturing is also consolidating into a smaller number of companies concentrated in China and India.[19] The WHO wrote in 2016 that in China and India, tensions between supplying local and international markets with APIs may limit raw materials availability in a concentrated global market. This raw materials supply friction causes shortages because the API market is so concentrated that critical production cannot be easily or quickly replaced.[20]

Due to their multisource nature (multiple equivalent medicines available), the generic medicines sector should be less vulnerable to medicine shortages versus the originator sector: generic medicines increase patient access and prevent medicines shortages through increased choice and availability of treatments. Nevertheless, due to the combination of extreme price pressure and short-term cost-containment measures applied to the generic medicines sector, leave manufacturers little choice but to withdraw their medicine(s) from the market, which consequently increases the risk of medicine shortages.

Industry participants applaud regulatory efforts to increase the safety and accessibility of medicines around the world, however, greater emphasis should be placed on regulatory harmonization. Harmonization allows generic medicines manufacturers to face fewer regulatory barriers and a lesser financial burden.[21] Heightened regulatory requirements, often country-specific, while intended to improve patient safety, can have the effect of increasing cost to the point where companies must make the difficult decision to adjust their portfolios, consolidate, or exit the market entirely. As a result, and for example, since 2010, nearly

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[17] Medicines Shortages. *WHO Drug Information*. Volume 30, No. 2. 2016. Accessible at: http://apps.who.int/medicinedocs/documents/s22463en/s22463en.pdf.
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] The Need for Global Regulatory Harmonization: A Public Health Imperative. Hamburg, Margaret; Zehrouni, Elias. 11 May 2016. *Science Translational Medicine*. Accessible at: http://stm.sciencemag.org/content/8/338/338ed6.

2,300 generic medicines have been discontinued and nearly 600 medicines shortages have occurred in the U.S. [22] [23]

Medicines Shortages Around the World

The World Health Organization wrote in 2015 that, "in recent years, shortages of essential medicines have been documented in most parts of the world with increasing frequency."[24] This continues to be the case in 2018. Factors that contribute to shortages around the world can be common among countries and areas, or they can be related to specific local policies. To ensure that society continues to benefit from affordable cost-effective generic medicines, it is important to develop a predictable and sustainable market model that addresses the unique characteristics of the generic medicines industry.

It is well established that the generics industry has provided patients around the world with access to cost-effective and high quality medicinal products. Generic medicines account for over 62 percent of the medicines dispensed in Europe at only 29 percent of the costs, which is only four percent of total healthcare budgets[25]. In the United States, generic medicines account for 89 percent of all prescription medicines dispensed at a total cost share of 26 percent.[26] Market conditions for generics in Canada and Australia are similarly beneficial for the countries healthcare budgets, with 67 percent of all prescription medicines distributed in Canada constituting generics at 23 percent of the market cost.[27] In Australia, generic medicines account for 77 percent of medicines dispensed while comprising 38 percent of the cost.[28] The freed investment obtained through the increased use of generic medicines enables governments to allocate funds towards the treatment of new and challenging diseases. Policies regarding the generic medicines industry must strike the proper balance to ensure access to these important medicines and sustainability of the important cost savings obtained.

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[22] See: Additions/Deletions for Prescription and OTC Drug Product Lists. Available at: https://www.fda.gov/drugs/informationondrugs/ucm086229.htm. Accessed October 2, 2017.

[23]Current Drugs ASHP Drug Shortage Resource Center. Available at: https://www.ashp.org/Drug-Shortages/Current-Shortages. Accessed September 25, 2017.

[24] Addressing the global shortages of medicines, and the safety and accessibility of children's medication. World Health Organization. 18 December 2015. Accessible at: http://apps.who.int/iris/bitstream/10665/250709/1/B138_41-en.pdf.

[25] QuintilesIMS MIDAS MAT Q4 2016; Rx bound; Europe includes Turkey; Generics include Non-original branded products and unbranded products.

[26] 2017 Generic Drug Access & Savings in the U.S. Accessible at: http://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf

[27] 2016 Generic Drug Market Alberta. Accessible at: http://canadiangenerics.ca/wp-content/uploads/AL_MarketShare_Eng.pdf

[2828]Making Medicines Affordable, Generic and Biosimilar Medicines Association. Accessible at: http://192.195.49.161/~/media/Treasury/Consultations%20and%20Reviews/Consultations/2015/2016%20Pre%20Budget%20submissions/Submissions/PDF/Generic%20and%20Biosimilar%20Medicines%20Association.ashx

Europe

In Europe, the practice of "tendering" is often cited as a major cause of shortages. Tendering is used to procure medicines in many European countries; in some cases, tendering involves the awarding of a large supply contract to the lowest bidder, effectively granting a monopoly to the winning manufacturer. The other competitors are often unable to achieve the scale necessary to remain in the market and are forced to exit, increasing the risk of a shortage should the awarded supplier experience a rise in demand that was not previously forecasted.

In Europe, in order to comply with the current short lead times of tender awards, manufacturers often hold stock as a precaution, to guarantee the supply and avoid medicines shortages. However, as a consequence in the case that the manufacturer does not win the tender, the manufacturer is stuck with an excess of stock which can have a shelf life of only 10-12 months. Consequently, the manufacturer has to destroy stock, which is very costly inventory, with added disposal costs, or face increased pressure to win the next tender. This quite often leads to a disruption of the competition with further dumping of inventory in other markets and at unsustainably low prices (sales at or oftentimes even below the level of cost of goods). Tendering has also been cited as evidence that drug shortages often occur because of price-related policies that are entirely unrelated to quality control.[29]

One extreme example of medicines shortages caused by price-related policies can be found in Romania, which has disproportionate pharmaceutical pricing policies on generic medicines. In Romania, as acknowledged by the European Commission[30] and due to inappropriate cost-containment measures (e.g. clawback tax, external reference pricing, etc.), approximately 2000 generic medicines have been withdrawn from the market in the last two years alone. As a result, Romania has suffered from chronic shortages of essential but inexpensive medicines such as methotrexate.

In Slovakia, under the umbrella of the Article 81 of Directive 2001/83/EC,[31] the government imposes a legal obligation on manufacturers to supply medicines within 24 hours to avoid a shortage. If manufacturers fail to supply, they are subject to penalties of up to one million Euro. These penalties (by SKU rather than INN) carry fines many times larger than typical generic medicines industry sales, undermining the sustainability of the pharmaceutical industry and increasing the risk of medicines shortages. Furthermore, these disproportionate sanctions should be prevented, as they promote retractions from manufacturers to exit

[29] Pauwels, Kim; Simoens, Steven; Castells, Minne; Huys, Isabelle. Insights into European Drug Shortages: A Survey of Hospital Pharmacists. Plos One. 16 March, 2015. Accessible at: http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0119322

[30] DG ECFIN and Economic Policy Committee (Ageing Working Group), Joint Report on Health Care and Long-Term Care Systems & Fiscal Sustainability, 2016. (Romania report page 217. Available at: https://ec.europa.eu/info/sites/info/files/file_import/joint-report_ro_en_2.pdf

[31] Article 81 of Directive 2001/83/EC: EU legislation that imposes legal obligation for the marketing authorisation holder to ensure, within the limits of their responsibilities, a continuous supply.

the market thus increasing the risk of supply shortages. If penalties are applied to guarantee supply, they should be proportionate to the revenue of manufacturers and applied in accordance with the contract criteria.

North America

The United States and Canada face similar conditions regarding generic medicines pricing, as well as frequency of medicines shortages.[32]

Over the last six years in the U.S., generic prices have decreased by 66 percent while brand prices have increased by 138 percent.[33] Globally, the cost to bring a generic medicine to market has increased significantly, now costing an average of $10 million to $100 million to bring complex generics to market and up to $200 million for biosimilars.[34] Originator industry tactics that delay generic entry and impose significant litigation costs contribute to this increased cost. This "squeezing" of generic manufacturers forces some players to exit the market and limits new entry.[35] In the U.S., middlemen (wholesalers, distributors, group purchasing organizations, etc.), that are almost exclusively for-profit entities, take two-thirds of the retail market generic drug price, versus only one-third of the originator retail market drug price through competitive contract bidding.[36]

Low and middle-income countries

Low and middle-income countries (LMICs) face greater challenges as they work to do their part to address medicines shortages. For instance, shortages in South Africa often stem from a deficit of long-term forecasting pertaining to APIs. Additional factors cited as contributing to shortages include, long lead times in registering alternate API resources, and little consideration by authorities of long lead times for production and planning, usually comprising six months for both production and planning, especially when a factory manufactures according to global requirements. In countries such as South Africa, the biggest concern is a medicines shortage of anti-retrovirals, given that more than four million people require this treatment. South Africa faces the same problem with the treatment of tuberculosis, when tenders are extended with less than a month's notice, because administrative procedures are not timely enough to adjudicate new tenders.

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[32] Canadian analyses of medicines shortages often rely on U.S. data as reported by FDA and ASHP.
[33] US Health and Human Services, Assistant Secretary for Planning and Evaluation. ASPE Issue Brief. 27 January 2016. Understanding Recent Trends in Drug Prices, referencing Express Scripts Drug Trend Report. Additionally, GAO's report (GAO-16-706) on "Generic Drugs Under Medicare" from August 2016, also indicated that generic drug prices fell 59% from Q1 2010 through Q2 2015.
[34] Whitepaper from Deloitte (2015): "Winning with Biosimilars, Opportunities in Global Markets"; Report by Corporate Research Division at Bank of Tokyo-Mitsubishi (2016): "Global Generic Pharmaceutical Industry Review."
[35] REMS and Restricted Distribution Programs: An Estimate of the Market By Alex Brill (June 2017).
[36] Sood, N et al. The Flow of Money Through the Pharmaceutical Distribution System (calculated using $450B prescription spend in 2016 from IMS).

China is the world's leading producer of critical pharmaceutical ingredients, particularly antibiotic and oncolytic APIs – the two leading categories of medicines in shortage in Europe in recent years. A study published in 2016 found that Chinese manufacturers were incapable of meeting increased demand if the price of the drug was too low or the materials were too expensive or insufficient.[37]

IGBA's Recommendations to Prevent Shortages

Ensure market predictability and sustainability

Generic manufacturing is highly competitive, focused on efficient operations that maximize product quality and speed to market, while providing high-quality, cost-effective products to patients and payers. But cost-containment measures such as government-mandated price reductions, internal and external reference pricing, price capping mechanisms such as CPI penalties in the U.S., and procurement through tendering and/or competitive contract bidding have undermined the long-term sustainability of the generic pharmaceutical industry, while increasing the risk of medicines shortages. This is acknowledged by the WHO, which stated there are more appropriate pricing mechanisms for off-patent medicines than external reference pricing. Similarly, most scientific articles reviewing shortages of generic medicines identify cost-containment measures as the underlying root cause of shortages.[38,39,40,41,42,43,44,45,46,47,48,49,50,51,52]

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[37] Yang, Caijun, et al. Current Situation, Determinants, and Solutions to Drug Shortages in Shaanxi Province, China: A Qualitative Study. Plos One. 25 October, 2016. Accessible at: http://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0165183&type=printable.

[38] Alevizakos M, Detsis M, Grigoras CA, et al. The Impact of Shortages on Medication Prices: Implications for Shortage Prevention. Drugs. 2016;76(16):1551-8.

[39] Barlas S. FDA strategies to prevent and respond to drug shortages: finding a better way to predict and prevent company closures. P & T: a peer-reviewed journal for formulary management. 2013;38(5):261-3.;

[40] Birgli. An Evaluation of Medicines Shortages in Europe with a more in-depth review of these in France, Greece, Poland, Spain, and the United Kingdom. Zug: Birgli, 2013. Available from: http://static.correofarmaceutico.com/docs/2013/10/21/evaluation.pdf.

[41] Bogaert P, Prokop A, Bochenek T. Prevention and Management of Medicine Shortages in Belgium, France and from The Perspective of the European Union. Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research. 2014;17(7):A412.

[42]De Weerdt E, Simoens S, Casteels M, et al. Toward a European definition for a drug shortage: a qualitative study. Frontiers in pharmacology. 2015;6:253.

[43] Holtorf AP, Rinde H, Maniadakis N. Drug shortages in Europe and the USA: The underlying reasons and consequences. ISPOR 15th Annual European Congress; 10th February 2017; Berlin. Germany: Presented at the ISPOR 15th Annual European Congress (Berlin, 5 November 2012); 2012

[44] Kaposy C. Drugs, money, and power: the Canadian drug shortage. Journal of bioethical inquiry. 2014;11(1):85-9

[45] Kweder SL, Dill S. Drug shortages: the cycle of quantity and quality. Clinical pharmacology and therapeutics. 2013;93(3):245-51.

[46] Markowski ME. Drug Shortages: The Problem of Inadequate Profits. Cambridge, MA: Harvard Law School, 2012. Available from: https://dash.harvard.edu/handle/1/11940215.

[47] McKeever AE, Bloch JR, Bratic A. Drug shortages and the burden of access to care: a critical issue affecting patients with cancer. Clinical journal of oncology nursing. 2013;17(5):490-5.

[48] Pauwels K, Huys I, Casteels M, et al. Drug shortages in European countries: a trade-off between market attractiveness and cost containment? BMC health services research. 2014;14:438.

[49] Pauwels K, Simoens S, Casteels M, et al. Insights into European drug shortages: a survey of hospital pharmacists. PloS one. 2015;10(3):e0119322.

[50] Reed BN, Fox ER, Konig M, et al. The impact of drug shortages on patients with cardiovascular disease: causes, consequences, and a call to action. American heart journal. 2016;175:130-41.

To ensure market sustainability, IGBA recommends a predictable and reasonable pricing and reimbursement environment that will increase the number of competitors in the market and reduce the risk of shortages. Implementation of a number of tender and/or competitive contracting bidding winners per product, market and country characteristics, along with longer lead times and penalties in proportion to the contract, and inclusion of criteria other than price are strategies which guarantee multiple players can supply a given product market. This will allow manufacturers to reasonably increase product manufacturing in order to avoid the risk of shortages.[53]

Improve regulatory efficiency and global regulatory harmonization

Above all else, IGBA believes that a sustainable solution to medicines shortages involves close technical collaboration and clear communication between the pharmaceutical industry and health authorities. The pharmaceutical sector is among the most regulated industries in the world, with regulatory standards differing from country to country. While IGBA encourages high standards that ensure quality medicines are available around the world, varying regulatory schemes are not necessarily scientifically justified and can be costly and inefficient. This discourages future investment and may cause manufacturers to leave markets or not enter at all. A global harmonized system should be sufficiently flexible to allow for fast-tracking approval of product submissions and/or approving manufacturing sites that would aid in alleviating the impact of a shortage. A common definition of "shortage" should be adopted, but not at the expense of other efforts to ensure sustainability of the generic medicines market and decrease the frequency of medicines shortages. IGBA's position is that a shortage generally cannot occur if patients can access a generic version of a product, regardless of pack size, dosage form, etc., if patient safety is fully ensured.

On a country-by-country basis, regulators should be aware of the financial impact of their regulations and actions, particularly in relation to market size. Taking into account the deflationary pricing facts described above that are impacting the generic manufacturers, it is possible for the cost of regulation to make manufacturing of certain products economically unsustainable, thereby decreasing access and depriving patients of needed medicines, which is contrary to public health.

Improve communication

IGBA believes that a sustainable solution towards medicines shortages involves close technical collaboration and clear communication between the pharmaceutical industry and health authorities. IGBA

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[51] Woodcock J, Wosinska M. Economic and technological drivers of generic sterile injectable drug shortages. Clinical pharmacology and therapeutics. 2013;93(2):170-6.
[52] Yurukoglu AL, E. Ridley D.B. The Role of Government Reimbursement in Drug Shortages. US: Stanford University, 2016. Available from: https://web.stanford.edu/~ayurukog/shortages.pdf.
[53] See Medicines for Europe Country Specific Market Access Policies 2017 for more information on tendering reforms. Accessible at: http://www.medicinesforeurope.com/wp-content/uploads/2017/05/20170220-Medicines-for-Europe-recommendationsv1.0_FINAL.pdf.

supports the improvement of communication among supply chain partners and with local and national governments. Standard operating procedures should also be established in partnership with the generic medicines industry.

Identify essential medicines and vulnerable products

Countries should follow the WHO and adopt a list of essential medicines for a healthy society. Medicines that are vulnerable to shortages should be identified using a risk-based approach and proactive policies or measures should be put in place to prevent shortages, possibly including economic incentives. Existing monitoring of medicines shortages should be strengthened and leveraged to gain further insight into the root causes of shortages. Monitoring alone does not solve the shortage problem; it simply helps regulators to react more quickly. However, monitoring data can be used to form sensible policy solutions.