MEDICINE SHORTAGES IN EUROPE AND THEIR IMPACT ON PATIENTS
A Reflection Paper

Executive summary

Currently no agreed definition of shortages exists– and for the purpose of this paper, we mean that medicines are not available for a patient.

It is without question that the availability and continuous supply of medicines is the cornerstone of a healthy society and therefore a key priority for European healthcare systems.

GIRP welcomes the recent release of the EU Commission's Communication on Shortages.

Despite increasing medicines shortages, there is still a fundamental lack of clarity on their actual causes and there is an urgent need for robust solutions to resolve the problem.

Numerous plausible explanations have been put forward as reasons for medicines shortages. It seems that the reasons differ from country to country and from product to product. However, on a closer look, it is clear that there are some common underlying causes which seem to influence medicines shortages.

Based on the views of (full-service) healthcare distributors, this paper aims to initiate a deeper discussion and to outline distributors' perspectives on the causes of shortages, the impact and some potential solutions.

Our initial reflection reveals the following to be among the key underlying root causes of shortages:

- The increasing risk of supply disruption is attributed to the globalisation of production chains which do not have enough alternative sources of supply. The complexity and globalisation of production, where APIs are sourced in one country, products are produced in another one and packaged in a third country leads to a high sensitivity for the slightest failure, which then can create a general shortage across Europe, as evidenced by the recent global Valsartan® shortage[1]
- The Falsified Medicines Directive mandates that Active Pharmaceutical Ingredients (APIs) imported into the EU must comply with European Good Manufacturing Practice guidelines (GMP) which has a knock-on effect on the sourcing of 'approved' APIs for the production of medicines. The unavailability of APIs complying with the EU standards leads to production and supply disruptions.
- Lack of market attractiveness from an economic perspective for certain (older) medicines results in manufacturers stopping production of some low-income generating products. A similar effect is caused by comparisons to international reference pricing regimes (leading to a downward spiral of prices).
- Ongoing healthcare budget challenges are contributing to the problem. Member States are coming to terms with increasing healthcare costs associated with longevity which is resulting in reduced incentives such as price reductions and margin cuts for marketing products.
- Procurement policy failures such as the apparent race by payers to grant tenders based on the lowest price possible without due consideration to secondary impacts on market sustainability or to the supply chain operators.
- Unforeseen disruptions or extraordinary demand due to bad weather, force majeure or viral outbreaks can result in shortages of certain products which suddenly see a rapid increase in volume demand;
- Stringent supply quotas imposed by pharmaceutical manufacturers on pharmaceutical full-service healthcare distributors with the attempt to steer the supply of medicines on the national markets.

[1] https://www.fda.gov/Drugs/DrugSafety/ucm613916.htm

When supply quotas are imposed without flexibility and understanding of changes in the market they can be a reason for medicines shortages instead of avoiding them.

- Parallel trading (PT) by distributors is frequently cited by other stakeholders as a contributing factor to shortages. Our initial reflection has not uncovered any real-world evidence to support this, and it is notable that many academic studies on this subject recycle stakeholder claims rather than concrete facts and figures. We would caution others against forming conclusions without evidence to support this. To highlight this fact, medicine shortages are a common problem in USA, Australia and Switzerland yet parallel trade does not operate in these countries.

This paper also reflects on those impacted most by shortages and yields one clear conclusion – patients are the most affected by medicines shortages. Furthermore, pharmacists as healthcare professionals must spend valuable time sourcing medicines instead of caring for their patients.

Having considered some of the root cause of shortages and those impacted by them, the paper looks at some possible pragmatic solutions to addressing the following issues:

- Combating production-related shortages with the support of the European Medicines Agency (EMA) and the national Medicines Agencies is key to preventing, anticipating, mitigating and managing shortages of important medicines caused by manufacturing/GMP compliance problems to avoid competition for products in short supply. Anticipation is crucial to soften the impact of a shortages situation for patients allowing to swiftly implement alternative treatment measures.[2]
- The European Commission and national authorities should adopt actions to support the continuation of products through market attractiveness for older medicines.
- We would welcome measures to encourage API manufacturing back into the EU thereby reducing exposure to remote global API production problems.
- Disruptions of supplies and unexpected demand of medicines can be combated through closer cooperation with pharmaceutical full-service healthcare distributors and by using preparedness programmes and buffer stocks established at European and / or national level.
- Full Service Distributors can play an important role in the sourcing and importation of medicines in short supply.
- Shortages arising due to economic hardship are partially resolved by the significant contribution of pharmaceutical full-service healthcare distributors to the economics of the sector in terms of pre-financing (function of pharmaceutical manufacturers and pharmaceutical full-service healthcare distributors) medicines' stocks in retail pharmacies' and hospitals.
- System failures can be dealt with through the effective monitoring and enforcement of Article 81, paragraph 2 of the Directive 2001/83/EC which refers to a joint obligation of pharmaceutical manufacturers and wholesalers to *"ensure appropriate and continued supplies of medicinal products to pharmacies and other persons authorised to supply medicinal products to the public so that the needs of patients in the Member State in question are covered".* The introduction of a Public Service Obligation (PSO) on wholesale distributors combined with the right of the pharmaceutical full-service healthcare distributors to be supplied by pharmaceutical manufacturers, including the enforcement of these obligations, could be an efficient way to mitigate supply related shortages in order to fulfil the demand of the national market.
- In order to combat unjustified supply quotas, stakeholders in the supply chain should aim for increased collaboration, responsibility and accountability.

[2] Dominique Martin, CEO of ANSM in Sciences et Avenir, 28 February 2018
https://www.sciencesetavenir.fr/sante/530-signalements-de-medicaments-en-rupture-de-stock-en-2017-une-augmentation-de-30_121655

Introduction

The continuity of supply and availability of medicines are key priorities of the European healthcare systems. Ensuring the availability of medicines for patients is therefore reflected in the EU legal framework governing the pharmaceutical sector, requiring supply chain partners to comply with it in accordance with Article 81 of Directive 2001/83[3]. However, medicine shortages have become an increasing problem in recent years. Due to the lack of availability of medicines, full-service healthcare distributors encounter difficulties ensuring the continuous supply of the full range of medicines. Recent studies have shown that medicine shortages not only adversely affect therapy and cause poorer treatment outcomes, but also compromise or delay medical procedures, lead to medication errors and to the use of less desirable, often more expensive, alternative medicinal products[4].

Healthcare professionals are increasingly alarmed about the effects that unavailability of medicines has on patients and the significantly increased resources required for sourcing the medicines for their patients[5]. Shortages have seen a growth in number (1483 products in Italy in May 2018[6], 530 products in France in 2017[7]) and complexity across Europe. Supply chain partners along with national and European authorities seek ways to prevent and solve this issue. Still, the measures adopted so far have not proved to be very effective at eliminating shortages of medicines.

Today, more and more Member States are facing shortages and discussions have been taken up not only at national level, but also on European level however, solutions are not easily found. The issue is as complex as the reasons for shortages of medicines are manifold and there is no quick fix available by implementing a single measure.

Medicines shortages are not only a European, but also an international problem. In the US, the Food and Drug Administration (FDA) has been working on reducing medicines shortages for over 12 years. In the past, the number of medicine shortages has annually tripled from 2005 to 2010.[8] More recently the US shortages overall seem to have decreased from 251 products in 2011 to 23 products in 2016. According to the FDA 66% refer to quality and manufacturing related issues and 27% to problems with raw materials.[9] While progress has been made, a high percentage of shortages are sterile injectables, including chemotherapy, anaesthesia and other acute medicines.

When considering medicines shortages in comparative terms between the US and Europe, it is worth noting that in Europe, parallel trade is among the most frequently cited reason for shortages, whereas in the US where shortages have been and continue to be a problem, no parallel trade activities occur.

Why do medicines shortages occur?

Until now, no clear answers could be given as to what triggers medicine shortages. Numerous reasons have been put forward, but they differ from country to country and from product to product. However, several dynamic forces appear to influence the lack of medicines such as the globalisation of manufacturing and subsequently their supply chains.

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[3] Directive 2001/83, Article 81, par 2: *"The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered."*

[4] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/11/WC500135113.pdf
[5] http://www.ashp.org/DocLibrary/Policy/DrugShortages/ASHP_shortage_guide09.pdf
[6] http://www.agenziafarmaco.gov.it/sites/default/files/elenco-medicinali-carenti_09.05.2018.pdf
[7] http://www.leparisien.fr/societe/penurie-inedite-de-medicaments-vitaux-en-france-27-02-2018-7582320.php
[8] http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/reports/ucm277755.pdf
[9] https://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm441585.htm

New provisions for Active Pharmaceutical Ingredients (APIs) and production related shortages

Pharmaceutical manufacturers increasingly encounter problems accessing active or key ingredients for the medicines they produce, due to the fact that many sources of active substances for life-saving medicines such as antibiotics are located outside the EU, including in countries with uncertain political and regulatory systems[10]. In addition, fewer medicines production sites, often scattered geographically, lead to supply shortages at a regional or even global level.

The European Union has increased quality assurance through new mandatory regulations for APIs imported from third countries with the adoption of the Falsified Medicines Directive. Under regulations in the Directive, which came into effect on 2nd July 2013, it is mandated that APIs imported into the EU must comply with European Good Manufacturing Practice (GMP) with written confirmation of compliance with EU standards. This increased API regulatory burden for manufacturers can also affect the certainty of medicines supply within the EU.

Lack of economic market attractiveness and policy failures

Reasons that may drive manufacturers to cease the production of specific medicines include the diminishing demand for products, lower profitability or the intention to move resources elsewhere. The lack of attractiveness of markets from an economic perspective is thus an important motive for unavailability of medicines. If medicines are to be made available on a national market, it is important that all operators, not only pharmaceutical manufacturers, but also pharmaceutical full-service healthcare distributors and pharmacies, can undertake their activities in a sustainable way. Especially in times of economic hardship it is crucial to consider the economic viability. Measures like international reference pricing lead to a downwards spiral of prices and the marketing of products in countries with the lowest reference prices becomes increasingly unattractive. The spill over effect of low prices therefore undermines the willingness for solidarity with countries, which are facing economic problems.

Shortages can also be a mirror of policy failures, caused by the constant aim of payers for the lowest price possible, often without considering the far-reaching consequences of the different measures used to bringing prices down. An increasing number of countries have introduced tendering procedures, creating in many cases shortages of products from the successful pharmaceutical manufacturer at least in the short term.

Disruptions of supplies and unexpected demand of medicines

Unforeseen medicine shortages may be caused by various interruptions in the normal delivery of medicines through the pharmaceutical supply chain and distribution network. Bad weather conditions, natural disasters, failed inspections or damage to production and storage facilities may result in a shortage of either raw materials or finished medicinal products. Furthermore, sudden outbreaks of viral diseases and a surge in demand for specific products can cause sudden shortages of specific medicines. Vaccines manufacturers in Europe are highly concerned about the continuous availability of vaccines and call for a multi stakeholder platform in order to improve the sustainable supply of vaccines[11].

Budgetary pressure and economic constraints

Due to constant budget pressure and economic constraints, the medicines supply chain is encountering an unprecedented economic burden. Supply chain partners and specifically pharmaceutical full-service healthcare distributors are often put in the position of having to pre-finance the healthcare system due to delayed

10 http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/11/WC500135113AI.pdf
11 http://www.vaccineseurope.eu/wp-content/uploads/2016/06/VE-Paper_shortagesFIN-2.pdf

payments. In some country's payment delays escalated to a worrisome level, causing supply chain partners to withdraw credit lines and to ask for pre-payment of medicine deliveries.

The tense economic climate also had a negative impact on wholesale remuneration, shrinking them to a level at which pharmaceutical full-service healthcare distributors are just about covering their costs. Current cost pressures on pharmaceutical full-service healthcare distributors might also lead to a reduction in the number of deliveries, which on the other hand would force pharmacies to increase their medicines stock.

Supply quotas

Supply quotas unilaterally imposed by pharmaceutical manufacturers can have a potential boomerang effect and cause supply shortages instead of avoiding them. Pharmaceutical manufacturers impose supply quotas on pharmaceutical full-service healthcare distributors to try to control and steer the supply of medicines on national markets. In practice, however, quotas when imposed without any flexibility have proven to aggravate the underlying problem rather than address it, causing major problems on a daily basis for pharmaceutical full-service healthcare distributors, who face significant challenges to obtain the needed stock of medication for the patients[12]. Pharmaceutical full-service healthcare distributors struggle on a daily basis with the reality of supply quotas which when applied with view to impeding parallel trade they constitute an abuse of a dominant market position under the anti-trust provisions of the Treaty of the European Union unless it provides objective justifications. The challenge for pharmaceutical full-service healthcare distributors lies in the fact that it is left to the competency of the national court to determine what constitutes an ordinary order which is a burdensome / disproportionate process for a pharmaceutical full-service healthcare distributor to pursue in the course of daily business transactions.[13].

The core problem is that in the case of quota restrictions full service healthcare distributors are supplied with only certain pre-set quantities of medicines, within defined time periods. The quantities are defined and allocated by pharmaceutical manufacturers and are often insufficient to meet the demands of full-service healthcare distributors, as usually quotas are based on historic data. If quotas are exhausted, full service healthcare distributors are not supplied with additional stocks of the respective products, even in circumstances where there is an obviously higher demand for these products from their usual customers and where pharmaceutical manufacturers clearly have the quantities available to meet the demand. Therefore, full service healthcare distributors are obliged to pass on quota restrictions, equally limiting their possibility to meet additional demand from pharmacies and patients, leading to shortages.

The way quota systems are imposed on pharmaceutical full-service healthcare distributors significantly differ between pharmaceutical manufacturers and Member States. Some pharmaceutical manufacturers do not communicate the volume of products comprised in their quota and only inform pharmaceutical full-service healthcare distributors once their quota is exhausted. This seriously affects the full-service healthcare distributor 's ability to plan the supply of the product for the national market. Quotas therefore can create tensions in the supply chain and sometimes hinder patients' access to their required medicines rather than facilitating it. Furthermore, the pharmaceutical full-service healthcare distributors are only able to deliver

[12] http://www.appg.org.uk/APPG%20Pharmacy%20-%20Report%20of%20Inquiry%20Into%20NHS%20Medicines%20Shortages.pdf

[13] In September 2008, the ECJ gave a preliminary ruling based on national proceedings between the pharmaceutical company GlaxoSmithKline and Greek wholesalers exporting pharmaceutical products to countries where prices for medicines are higher, following referral from the Athens Court of Appeal (Joined Cases C-468/06 to C-478/06 Sot. Lelos & Sia E.E). The ECJ ruled that a dominant company's refusal to supply wholesalers with a view to impeding parallel trade constitutes an abuse of a dominant market position under Article 82 of the EC Treaty unless it provides objective justifications. While differences in national price regulations and Member States' control over pharmaceutical prices are in themselves not sufficient justifications, the court found that a producer of pharmaceutical products must be in a position to protect its own commercial interests if it is confronted with orders that are out of the ordinary in terms of quantity. Whether such orders are out of the ordinary is an issue for national courts to decide, taking into account the needs of the particular national market and previous trading relations between the parties.

medicines that they have on stock. Even in countries such as Switzerland[14], where no medicines exports are allowed, it has been reported that pharmaceutical full-service healthcare distributors do not have sufficient supplies to satisfy the demand of the market[15] due to quotas.

Who is affected by medicines shortages?

Medicines shortages have far-reaching effects throughout the healthcare sector, but above all patients are the ones suffering the most from the lack of medication.

Due to supply shortages, pharmacists need to dedicate more and more time sourcing medicines instead of dedicating this time advising and consulting with patients. Pharmacists are healthcare professionals and their time is too valuable to chase up medicines instead of caring for their patients. In this context it should also be noted that pharmaceutical full-service healthcare distributors are bound to respect the orders made by the pharmacists and cannot substitute products out of stock with alternative ones (they are legally not allowed to deliver alternative or substitute products). Therefore, in case of shortages pharmaceutical full-service healthcare distributors cannot fulfil their public service obligation to provide pharmacies with all products needed by their patients. Medicines shortages have negative effects on pharmaceutical full-service healthcare distributors ability to distribute medicines whenever and wherever needed.

How can medicines shortages be overcome?

The solutions listed hereafter represent the pharmaceutical full-service healthcare distributors' views on how medicines shortages can be combated. Pharmaceutical full-service healthcare distributors firmly believe that any sustainable solution to resolve the problem of medicines shortages has to take into account all manifold reasons of their cause. Fostering a closer and more transparent discussion and collaboration between political decision makers, health authorities, the pharmaceutical industry, pharmaceutical full-service healthcare distributors, parallel-traders, pharmacists, healthcare providers, payers and patients at national and European level are a pre-requisite to address shortages of medicines.

Combating production related shortages

Although most shortages are dealt with by National competent authorities, the European Medicines Agency (EMA) is involved when a medicine shortage is linked to a safety concern or affects several Member States. The shortages catalogue of EMA therefore contains information on medicine shortages that affect more than one European Union (EU) Member State. For the substances on the list, EMA has assessed the shortage and provided recommendations to patients and healthcare professionals across the EU[16].

In November 2012 EMA published a reflection paper[17] concerning public health incidents that can arise due to manufacturing disruptions linked to problems such as quality defects or Good-manufacturing-practice (GMP) compliance issues, which was followed by an implementation plan (2012-2015)[18] defining actions to co-ordinate the assessment of shortages, develop risk-minimisation measures, alleviate the impact on patients and communicate within the EU regulatory network.

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14 https://www.watson.ch/schweiz/wirtschaft/866351797-schweizer-spitaeler

15 http://drugshortage.ch/index.php/uebersicht-2/

16 http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000376.jsp&mid=WC0b01ac058074f178

17 http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/11/WC500135113.pdf

18 http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/11/WC500135114.pdf

Furthermore, EMA organised a workshop on product shortages due to manufacturing and quality problems in October 2013, which led to the creation of an inter-industry association taskforce with the objective of proposing solutions to prevent the root causes of shortages due to manufacturing and quality problems. A stakeholder meeting on 9 October 2015 reviewed the progress made since the previous workshop and for the first time involved all supply chain actors.

Also, the Heads of Medicines Agencies Network (HMA) has teamed up with EMA in a Task Force on the Availability of Authorised Medicines for Human and Veterinary Use[19] to provide strategic support and advice to tackle disruptions in supply of human and veterinary medicines and ensure their continued availability. Its key priorities include: minimising supply disruptions and avoiding shortages by facilitating approval and marketing of medicines, strategies to improve prevention and management of shortages, encouraging best practices, improving information sharing and fostering collaboration with stakeholders.

Combating shortages due to a lack of economic market attractiveness

In the past, under the framework of the Corporate Social Responsibility initiative of DG ENTR – now DG GROWTH - a project group on facilitating supply in small markets carried out a survey on shortages of medicines in small countries. The surprising result of this survey showed that there is a significant shortage of products containing old molecules for which there is no economic incentive to bring to the market due to the very limited number of patients. The recommendations put forward, included a set of measures improving cross-border collaboration as well as the economies of scale[20].

National competent authorities should consider installing a monitoring system of the impact of their desire to constantly decrease medicines prices through various mechanisms (international reference pricing, tendering) as well as of specific national requirements to bring products to the market of their country on medicines availability.

Combating disruptions of supplies and unexpected demand of medicines

In October 2013 the European Parliament and the Council adopted a decision to better protect European citizens from a wide range of serious cross-border health threats[21]. Health threats can be biological, chemical or environmental in nature. Existing rules on preparing for and managing health emergencies were strengthened and the Health Security Committee was given a stronger mandate to react in a crisis.

The European Commission is currently tackling the problem of medicines shortages and plans, as one of the measures, to create a public portal of vaccine safety evidence and an EU-wide data warehouse to prevent shortages are currently on their way. The Commission envisions the system holding information on vaccine stocks, enabling details of an impending shortage in one country to quickly spread. Forewarning regulators could enable mitigating actions[22].

Whereas GIRP and its members warmly welcome this proposal, the role of the supply chain and its potential to mitigate availability problems of essential medicines in case of health threats has been underestimated. Practical examples in this respect can be found on national level such as consignment stock held in the premises of pharmaceutical full-service healthcare distributors. We believe that it is essential that all partners

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19 http://www.hma.eu/522.html

20 https://ec.europa.eu/docsroom/documents/7625?locale=en

21 https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/decision_serious_crossborder_threats_22102013_en.pdf

22 https://www.raps.org/news-and-articles/news-articles/2018/5/eu-regulatory-roundup-ema-proposes-changes-to-vac

in the supply chain, together with national and European competent authorities, collaborate on crisis preparedness and jointly elaborate emergency plans.

It is a joint responsibility that in cases of sudden disease outbreaks, bioterrorism, other cross-border health crisis, or in case of problems related to the production, storage or distribution of medicines, patients in Europe should be able to have access to the required medicines without delay.

Combating medicines shortages due to economic hardships

GIRP would like to raise the awareness of European and national decision makers as well as of our European and national supply chain partners about the significant pre-financing function of pharmaceutical full-service healthcare distributors, which in most cases is largely underestimated. According to a study published by IPF, pharmaceutical full-service healthcare distributors pre-finance 11.8 billion Euro in the 6 largest European countries alone[23].

It is out of the question that in the current economic climate pre-financing is further extended. Demands by the pharmaceutical industry for earlier or immediate settlement of invoices cannot be met without passing on a part of this demand to pharmacists who are also in a difficult position to request timely payments from governments or social security systems. Delayed payments, the withdrawal of credit lines and the demand for pre-payments of medicine deliveries aggravate the situation of medicines availability in cash-stripped economies.

GIRP therefore appeals to national competent authorities and to payers on national level to take note of the pre-financing function of pharmaceutical full-service healthcare distributors as well as of the savings they bring to healthcare systems through the bundling of orders from manufacturers to pharmacies. Further pressure on pharmaceutical full-service healthcare distributors' mark-ups would lead to a reduction of service levels and to higher capital demands on pharmacies to increase their stock without bringing any savings to the healthcare sector of a country.

Combating policy failures

In 2016, the Dutch Presidency invited the Commission to assess the impact of protection mechanisms and incentives on shortages of medicines and the Slovakian Presidency made "shortages of medicines" a priority for its Presidency. During the Working Party on Public Health on 15 July 2016 and the informal Health Council on 3-4 October, all Member States agreed that the topic deserves action at EU level. During the informal Health Council, many Member States supported the proposal to examine Article 81[24] of the pharmaceutical legislation which is difficult to implement and enforce and called for the Commission to better clarify the obligations of the marketing authorisation holders and full-service healthcare distributors (pharmaceutical full-line wholesalers) and what the limits of their responsibilities are.

[23] IPF study February 2017, Fig. 32, p. 46 http://www.girp.eu/files/GIRP-IPF%20Study%202016.pdf

[24] "*the holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered*"

In February 2017 also, the European Parliament also adopted recommendations on shortages of medicines in the context of the report on access to medicines in Europe[25]. This report calls on the Commission and the Council to formulate a better definition of the concept and analyse the causes of shortages of medicines[26].

Linked to the call of the Council and the European Parliament, the European Commission has asked Member States on their views on the implementation of Article 81 on the obligation of continuous supply with the objective to help Member States to exchange information and good practices to address more efficiently the problem of shortage of medicines.

Article 81, paragraph 2 of the Directive 2001/83/EC refers to a joint obligation of pharmaceutical manufacturers and pharmaceutical full-service healthcare distributors to *"ensure appropriate and continued supplies of medicinal product to pharmacies and other persons authorised to supply medicinal products to the public so that the needs of patients in the Member State in question are covered".* Public service obligations in place in several Member States oblige pharmaceutical full-service healthcare distributors to *"guarantee an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the entire area in question".*

The final assessment of responses received by the Member States was published by the European Commission on 25 June 2018.[27]

Several Member States have included additional provisions on both Marketing Authorisation Holders and wholesale distributors. 4 Member States (BE, DE, FR and SI) make a distinction between full service healthcare distributors, which are bound to Public Service Obligations and other distributors for whom such obligations do not apply.
The document maps current measures in place, however, does not provide guidance on best practices to follow.

Medicine shortages caused by policy failures could be addressed by the implementation and enforcement of public service obligations on pharmaceutical full-service healthcare distributors, which are carefully tailored to local market conditions and drafted in collaboration with national regulators. GIRP members already abide in several European countries by public service obligations and in the other EU countries voluntarily fulfil a public service function. In order for public service obligations to work effectively they need to be equally backed-up by the obligation of the pharmaceutical industry to provide adequate and continuous supplies to pharmaceutical full-service healthcare distributors, who - without this obligation of the industry - would not be in a position to fulfil their PSO obligations. Also, it is essential that these obligations are adequately controlled and enforced by public authorities and also enforceable between private parties i.e. by pharmaceutical full-service healthcare distributors without relying on public authorities.

GIRP firmly believes that all stakeholders should strongly collaborate in order to ensure the continuous supply of medicines to patients. Therefore, pharmaceutical full-service healthcare distributors stand ready to closely work together with all supply chain partners, national and European authorities as well as payers and other healthcare providers in order to combat medicine shortages. GIRP has already collaborated with the other EU level supply chain stakeholder associations to adopt a Joint Statement on Information and Medicinal Products Shortages.[28] All supply chain stakeholders strongly believe that the input, perspectives and experience of the variety of stakeholders affected by the issue of shortages needs to be sought and taken on board to reach

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25 http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A8-2017-0040+0+DOC+XML+V0//EN

26 http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A8-2017-0040+0+DOC+XML+V0//EN

27 https://ec.europa.eu/health/sites/health/files/files/committee/ev_20180525_summary_en.pdf

28 http://www.girp.eu/sites/default/files/documents/supply_chain_statement_on_information_on_medicine_shortages.pdf

best-informed conclusions. We strongly encourage further efforts in this direction together with National and European Authorities.

Combating negative impacts of supply quotas

From the pharmaceutical full-service healthcare distributors' perspective, a viable solution for the hurdle imposed by supply quotas on the continuous availability of medicines would be to ask pharmaceutical manufacturers to make the process of the allocation of supply quotas less burdensome for pharmaceutical full-service healthcare distributors, taking into account the variations of medicines demand and supply patterns in their country. As also stated by the Matrix Insight report, drafted for the European Commission "…*companies impose quotas and supply caps, which in turn lead to availability problems… If the quotas are exhausted, the wholesalers will not be supplied with further stocks of the product. The level of quotas differs between producers and Member States and in some cases may not be communicated to the wholesaler, affecting the wholesaler's ability to plan the supply of the product in advance*"[29].

In this respect GIRP once again appeals to the stakeholders in the supply chain for an increased collaboration, responsibility and accountability.

It is evident that the reasons for shortages differ from country to country, and product to product, so solutions should be sought ultimately at national level and implemented on the single product basis. However, the cross-border effects of various political and economic measures are not negligible and therefore an in-depth discussion at European level is indispensable to avoid negative impact on other countries' healthcare systems and find a sustainable way forward.

Full service healthcare distributors *call for and embrace opportunities for increased collaboration and cooperation with the supply chain partners and governments as well as payers in order to find feasible solutions to ensure patients in Europe have continued access to the medicines they require. We invite all parties to come together and move forward with a future vision for the adequate and continuous supply of medicines in a spirit of flexibility, trust and partnership. Our priority as well as our core role and function as pharmaceutical full-service healthcare distributors is to make sure that pharmacies receive the ordered medicines and patients can access them in a safe and efficient manner.*

GIRP
European Healthcare Distribution Association
Brussels, October 2018

[29] http://ehtpa.eu/pdf/Matrix_report.pdf