



**AFFORDABLE
MEDICINES
EUROPE**

WORKING IN PARALLEL FOR A BETTER DEAL

MEDICINE SHORTAGES

POSITION PAPER

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The European Court of Justice:

“Parallel trade is liable to exert pressure on prices and, consequently, to create financial benefits not only for the social health insurance funds, but equally for the patients concerned, for whom the proportion of the price of medicines for which they are responsible will be lower. At the same time, as the Commission notes, parallel trade in medicines from one Member State to another is likely to increase the choice available to entities in the latter Member State which obtain supplies of medicines by means of a public procurement procedure, in which the parallel importers can offer medicines at lower prices.”

Joined Cases C-468/06 to C-478/06 Sot. Lelos kai Sia and Others, EU:C:2008:504, para. 56.



EXECUTIVE SUMMARY

Medicine shortages are an increasing problem and a growing concern of patients and healthcare providers. It is a problem for which we must find practical solutions both short- and long-term. To this purpose, **Affordable Medicines Europe in this paper presents 20 concrete actions** that can be taken by policymakers.

Firstly, we provide evidence of the known root causes of shortages, such as manufacturing problems, global concentration of production, and commercial considerations. To ensure better transparency throughout the EU into the problem, we suggest that a common EU-level definition of shortages be adopted. Secondly, we provide insight into the nature of the main causes of shortages and recommend concrete actions on how to mitigate them.

On mitigation of the root causes Affordable Medicines Europe recommends:

- 1 | **That the HMA/EMA definition of shortage be written into EU legislation.**
- 2 | **That the obligation for MAHs to notify shortages be written into EU legislation.**
- 3 | **That, when an MAH reports a shortage, it should be obliged by EU legislation to make a prevention and/or response plan.**
- 4 | **That a legal obligation for MAHs to maintain a safety stock of 2-4 months for medicines of major therapeutic interest be introduced at EU-level.**
- 5 | **That EU legislation should provide for the possibility to impose financial sanctions if the responsibilities related to shortages plans and stockpiling are not met.**
- 6 | **That requirements for having diversified supply sources be incorporated in public tenders.**
- 7 | **A stop to the wide-spread use of 'winner-takes-it-all' tenders.**
- 8 | **Decreasing tender periods to 3-6 months.**
- 9 | **Making a fast-track procedure for parallel import licenses and the granting of a reimbursement price where an MAH decides to withdraw from the market for commercial reasons.**

As shortages will occur even in the best policy frameworks, and as many of the solutions proposed by policymakers will take years to have an effect, Affordable Medicines Europe also proposes that policymakers consider making use of the parallel import framework provided by EU and national legislation.

Evidence from the Baltic States has shown that **90% of shortages are national or regional** (e.g. within the Baltic States) in Europe. For all these shortages, parallel imports are a viable alternative, as excess stocks of the medicine are typically available elsewhere. In practice, the flexibility of parallel imports can alleviate shortages in a very short timeframe, as our members do every day around Europe.

On alleviation of shortages by parallel imports, Affordable Medicines Europe recommends:

- 10 | **That products placed on a given national shortages list should automatically qualify for emergency imports by licenced parallel importers.**
- 11 | **That an obligation be placed on MAHs to pay the price difference (if positive) between emergency or parallel imports and the normal reimbursement price for products in shortage in a given Member State. A so-called 'PSO-responsible-pay' principle.**
- 12 | **The 'PSO-responsible-pay' principle also be extended to the import of suitable substitution medicines which may be more readily available.**



- 13 | **That in case of shortages of medicine more regulatory flexibility is permitted by authorities to parallel importers, not least in relation to the language requirements.**
- 14 | **That packaging of medicines be harmonised at EU level.**

One important step for patients and healthcare providers is to provide answers on what to do when a given medicine is lacking. In order to furnish this, national competent authorities (NCAs) and stakeholders must work better together and share available information, so as to ensure that satisfactory answers result. Sometimes, such collaboration may also reveal that the medicine is actually available, but just not where the patient is geographically situated, allowing for fast re-distribution.

Experience shows (see Bulgarian case study, p. 14) that platforms operated by supply chain stakeholders involving patient and healthcare provider associations are also an efficient way to provide fast and useful answers to patients – including in many cases getting them the medicine they need within 24 hours.

On patient-oriented solutions Affordable Medicines Europe recommend:

- 15 | **That Member States set up NCA-led national dialogue platforms between supply chain stakeholders to exchange information on products in shortage or in risk of shortage.**
- 16 | **The creation of patient/healthcare provider platforms to directly assist patients/healthcare providers with their needs.**

Evidence shows that NCAs do not detect parallel exports as a significant cause of shortages. This seems to suggest that European patients are generally already sufficiently safeguarded by the Public Service Obligation (PSO) enshrined in Article 81 of Directive 2001/83. **As a sector, we firmly believe that exports should never cause shortages**, which is why we acknowledge that besides the PSO, it can be justified to have appropriate, necessary, and proportionate legal frameworks to safeguard this principle. We do, however, strongly object **when parallel export restrictions inherently aim to protect the pharmaceutical industry's economic interest in fragmenting the internal market**, with the purpose of extracting the maximum price of medicines in each Member State, rather than to protect patients. Austria, Belgium, Bulgaria, Czechia, Estonia, France, Germany, Greece, Hungary, Italy, Latvia, Norway, Poland, Portugal, Romania, Slovakia, Spain and the UK already have legal frameworks in place – some proportionate, some not.

In relation to parallel exports, Affordable Medicines Europe support:

- 17 | **The proper enforcement of the PSO, including, if necessary, proportionate, and appropriate restrictions of parallel exports if there are real shortages in the given Member State, based on six specific criteria (see p. 16).**

As a sector we take our responsibility seriously, but we also cannot accept that pharmaceutical companies are given the freedom to fragment the Internal Market with excessive territorial supply constraints in the form of supply quotas. **A pattern is evolving, where competition in the Internal Market is increasingly dismantled by driving NCAs into unjustified bans of exports** in order to secure even normal supplies.

In relation to supply quotas, Affordable Medicines Europe strongly recommends:

- 18 | **Restricting Direct-to-Pharmacy (DTP) or similar schemes.**
- 19 | **That wholesalers who are under a PSO obligation themselves should have a right to be supplied in order to meet patient needs and ensure sufficient buffer stocks and a competitive internal market.**
- 20 | **That supply quotas must always be sufficiently transparent, flexible, and justified, and that 'black-box' quotas be banned.**



DEFINING SHORTAGES AND IDENTIFYING THEIR ROOT CAUSES

Over the past years shortages of medicine have been on the rise, not only in the EU but all over the World.¹ The reasons for medicine shortages are multiple, but some main problems have become evident over the last years: dependency on and the concentration of the supply chain to fewer suppliers in predominantly India and China², and problems with quality in the production like those witnessed in the Valsartan case.³

According to the European Medicines Agency:

“Medicine shortages can occur for many reasons, such as manufacturing difficulties or problems affecting the quality of medicines that can impact on patient care.”⁴

Lack of manufacturing capacity, natural disasters, manufacturing lag times, GMP issues, surges in demand, and API and excipient supply problems have also been identified as manufacturing and quality related root causes by the supply chain stakeholders.⁵

Furthermore, commercial withdrawals – that is where a Marketing Authorisation Holder (MAH) decides for business strategic reasons no longer to market the product in a given Member State – are a growing trend, especially in Southern and Eastern European countries.⁶ **For example, in May 2020, the Italian Medicines Agency, AIFA, lists 1056 medicines as being in shortage due to permanent commercial withdrawal, while in October 2019 the number was 891.**⁷

In general, stakeholders have identified a number of economically related root causes, such as pricing policies, tender practices, general market conditions, and cost-containment measures. Also, supply chain related issues can be a cause, such as logistical inefficiency and manufacturer supply quotas. Special attention will be given to the latter at the end of this position paper.

Affordable Medicines Europe welcomes the upcoming study from the European Commission into the causes of medicine shortages. While the main causes for shortages are well-known, more in-depth studies may cast a light on the proportionality each cause plays in the daily lives of European patients. In order to have the most appropriate and effective policy response, it is important to analyse which causes pose in fact the most significant problems, and tackle these as a priority. Considering the abundant knowledge already available, Affordable Medicines Europe in the following pages will suggest a number of concrete actions to help solve the problems around medicine shortages, based on current evidence.

Evidence of causes of medicine shortages

Whereas it is often claimed little is known of the causes of medicine shortages, this is not actually the case. Most Member States already have shortages databases where medicines in shortage are recorded.⁸ Not only are most databases publicly accessible, but many also contain the reason for the shortage.

Since every Member State has different categories assigned to given types of shortages comparisons are made difficult, but nonetheless a clear pattern is easily detected. According to the data collected by the national medicine agencies, **manufacturing problems are by far the largest problem across the EU.**

¹ WHO, 2016: https://www.who.int/medicines/publications/druginformation/WHO_DI_30-2_Medicines.pdf?ua=1.

² European Commission, DG SANTE, note to the Pharmaceutical Committee, November 2019: https://ec.europa.eu/health/sites/health/files/files/committee/ev_20191217_788_en.pdf.

³ EMA: <https://www.ema.europa.eu/en/news/ema-reviewing-medicines-containing-valsartan-zhejiang-huahai-following-detection-impurity-some>. Website accessed 2 May 2020.

⁴ EMA: <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/availability-medicines>. Website accessed 2 May 2020.

⁵ Stakeholder paper “Addressing the root causes of medicines shortages”, 6 December 2019; https://affordablemedicines.eu/wp-content/uploads/2020/01/addressing_the_root_causes_of_medicines_shortages_-_eu_supply_chain_stakeholders_views_on_root_causes_and_solutions.pdf.

⁶ Data compiled from national shortage reporting in Hungary, Czechia, Croatia, Italy, and Romania.

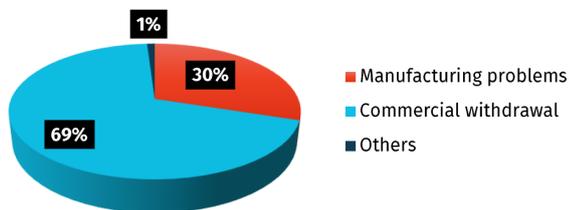
⁷ AIFA shortages list, accessed October 2019 and May 2020: <https://www.aifa.gov.it/en/web/guest/farmacici-carenti>.

⁸ See EMA shortages catalogue, for EU-wide and national shortages registers: <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/availability-medicines/shortages-catalogue>.

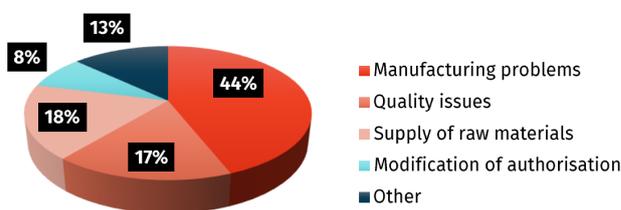


However, in Eastern and Southern European countries commercial withdrawals also have a very high prevalence among the root causes for shortages.

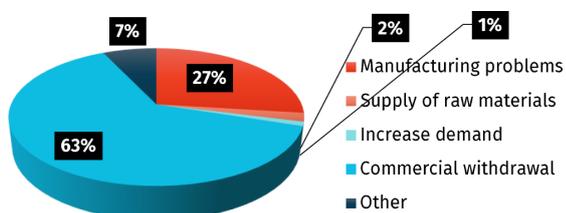
Romania



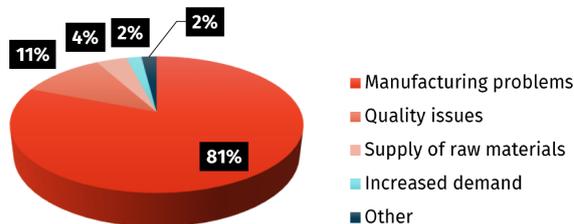
France



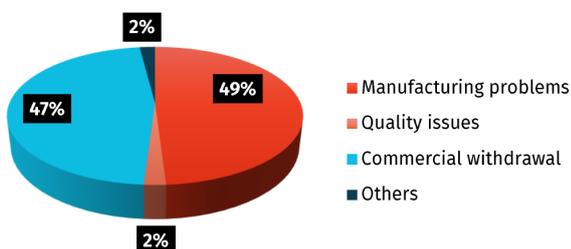
Hungary



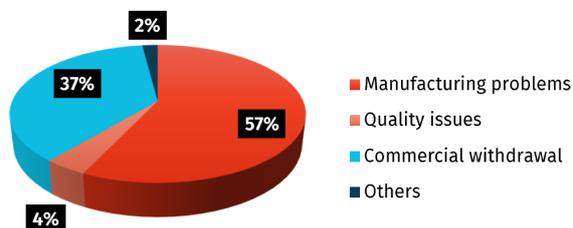
Germany



Croatia



Italy



Source: data from the national medicines agencies registers of shortages; ANMDM in Romania, 2019; ANSM in France, 2015; OGYEI in Hungary, 2019; BfARM in Germany, 2019; HALMED in Croatia, 2019; AIFA in Italy, 2019.

Due to the difference in and wide meaning of some categories, making in-depth conclusions may be difficult based on the above. However, for policy purposes, it clearly indicates which areas should be given priority in terms of solving shortages: manufacturing and economic related root causes.

Shortages of medicine is a global issue

Shortages of medicine is not only a European problem. Worldwide shortages are an increasing issue. While the COVID-19 crisis may have exacerbated shortages of some few medicines used in the treatment of COVID-19 (such as medicines used in intensive care units (ICU)), it is not the main reason for the increasing problems around shortages. Rather, it has illuminated by example some of the challenges Europe faces in relation to its supply of medicines.

A study on the cost of shortages found that U.S. hospitals alone spend US\$ 359 million per year to manage shortages of medicines.⁹

⁹ Survey/study by Vizient Inc., 2019: <https://www.beckershospitalreview.com/pharmacy/drug-shortages-cost-hospitals-359m-in-labor-costs-survey-finds.html>.



The U.S. Food and Drug Administration (FDA) published a thorough report; ‘*Drug Shortages: Root Causes and Potential Solutions*’ in 2019.¹⁰ The FDA identified three root causes for shortages:

- Lack of incentives for manufacturers to produce less profitable drugs;
- The market does not recognize and reward manufacturers for “mature quality systems” that focus on continuous improvement and early detection of supply chain issues; and
- Logistical and regulatory challenges make it difficult for the market to recover from a disruption.

The main solution singled out was the development of a system economically to incentivise manufacturers to invest in quality management maturity for their facilities and promoting more sustainable procurement practices, ensuring there is a reliable supply of medically important medicines.

The Canadian authorities have made similar findings to those found in the EU and the U.S. Four reasons are listed by the Canadian government:

- Supply issues (related to API’s and excipients),
- Manufacturing issues (including quality issues),
- Contracting issues (related to procurement), and
- Economic decisions (including commercial withdrawals).¹¹

Also, countries like Australia¹², Switzerland¹³, and Japan experience increasing levels of medicine shortages. It is worth noting in this context that parallel trade is a purely European concept which does not take place outside the EU/EEA (Switzerland is not part of the EEA). Hence, seeing that shortages and their causes are typically the same for the major advanced economies of the World, one should not assume that parallel trade plays a specifically important role in terms of shortages in the EU. Shortages are a global phenomenon.

An EU-level definition of medicine shortages

As the call for European action on shortages of medicines increase, it becomes of growing importance that we have the same frame of reference. Hence, in 2019, the Heads of Medicines Agencies (HMA) and the EMA, settled upon a joint EU definition of medicine shortages as hitherto none existed:

“A shortage of a medicinal product for human or veterinary use occurs when supply does not meet demand at a national level.”¹⁴

The guidance from the HMA/EMA also clearly defines every important concept (such as supply and demand) in the above definition. Until now differing definitions of a shortage have in fact complicated the cross-border collaboration and work on the issue.

Recommendation 1:

Affordable Medicines Europe recommends that the HMA/EMA definition of shortage be written into EU legislation.

¹⁰ The full report can be found here: <https://www.fda.gov/media/131130/download>.

¹¹ Official Canadian Government website on causes of drug shortages: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-shortages/causes-drug-shortages-canada.html>, accessed on 3 May 2020.

¹² The Society of Hospital Pharmacists of Australian (SHPA) report ‘Medicine Shortages in Australia’; https://www.shpa.org.au/sites/default/files/uploaded-content/website-content/shpa_medicines_shortages_in_australia_report_june_2017.pdf.

¹³ <https://www.swissinfo.ch/eng/medication-bottleneck- medicine-shortage-worries-swiss-pharmacists-/44262408>.

¹⁴ EMA/674304/2018, https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-detection-notification-shortages-medicinal-products-marketing-authorisation-holders-mahs_en.pdf.



TACKLING THE MAIN CAUSES OF SHORTAGES

Defining and identifying the root causes of medicine shortages is an important step, but in order to provide concrete solutions to European patients in the coming years, we must also act with resolve. Affordable Medicines Europe recommends a number of policy solutions available to policymakers at the EU-level.

Monitoring and transparency of shortages

A key aspect of working with medicine shortages is to monitor upcoming or imminent shortages – preferably before they affect patients. For example, this allows authorities and other suppliers of equivalent or alternative treatments to prepare for an increase in demand of a substitutable or alternative product while the usual product is in shortage, reducing the immediate impact on patients.

In July 2019, the HMA/EMA adopted their '*Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA)*'.¹⁵ According to this document, Manufacturing Authorisation Holders (MAHs) are obliged to notify authorities of upcoming shortages two months in advance. If unforeseen shortages occur, they are obliged to report as soon as possible. Following this, MAHs are expected to make a shortage prevention or shortage response plan, where they outline how they will overcome the problems and have supply restored, including a timeline. Affordable Medicines Europe fully supports the guidance of the HMA/EMA.

Recommendation 2:

Affordable Medicines Europe recommends that the obligation for MAHs to notify shortages be written into EU legislation.

Tackling manufacturing related root causes

As identified by the national medicines' agencies, EMA, and the literature, manufacturing problems such as quality issues and capacity problems (e.g. closure of a factory or production lag times) are among the main root causes of shortages. Such problems may arise irrespective of where factories are located and whether they are part of a longer or shorter supply chain. Tackling such problems require clear placement of responsibility, so that such problems are handled systematically, efficiently, and urgently irrespective of the costs associated with them. To this end, shortages prevention and shortages response plans are the crucial tools. Such plans outline a clear strategy for handling the shortage; steps to be taken to mitigate the core issue, timeline, alternatives etc. Legal obligations on MAH's to make such plans already exist in several countries around the World, e.g. France.¹⁶

Recommendation 3:

Affordable Medicines Europe recommends that when an MAH reports a shortage, it should be obliged by EU legislation to make a prevention and/or response plan.

Some manufacturing problems relate to the just-in-time principles on production adopted by many manufacturers. Such production principles lead to extremely low stock levels throughout the supply chain in an effort to reduce inventory costs, which makes the production chain less resilient to even minor shocks – such a production cycle gone wrong creates a cascading effect of delays throughout the production chain. As a response to this development, some countries have started to introduce requirements to have larger stock levels readily available (even before the COVID-19 crisis the Netherlands and France introduced such

¹⁵ *Ibid.*

¹⁶ *Code de la santé publique, Article L5121-31: <https://bit.ly/3b00sYT>.*



requirements). As a consequence, stockpiling nationally may distort the proper and fair distribution of medicine to patients across the EU, and should thus not be a policy solution; rather, EU-level stockpiling requirements would provide the benefits of higher supply certainty without the problems associated with uneven access between Member States.

Recommendation 4:

Affordable Medicines Europe recommends that a legal obligation for MAH's to maintain a safety stock of 2-4 months for medicines of major therapeutic interest be introduced at EU-level.

In order for planning and stockpiling obligations as recommended above to be met, it will be necessary to also have an EU legal basis for sanctions in place. In France, such a provision exists in the national legislation and in December 2018 the pharmaceutical company, MSD France, was fined for not respecting their obligations in relation to a long-standing shortage on the medicine Sinemet (named Nacom in Germany).¹⁷

Recommendation 5:

Affordable Medicines Europe recommends that EU legislation should provide for the possibility to impose financial sanctions if the responsibilities related to shortages plans and stockpiling are not met.

Affordable Medicines Europe suggests that the level of the sanctions could be inspired by the French model. Financial sanctions in this model can go up to 30% of the average daily benefit made in the given market but should not exceed 10% of the annual turnover or 1 million euro.¹⁸

Tackling root causes related to global concentration of production

Over the last year, and spurred more recently by the COVID-19 crisis, it has become clear that most advanced economies, including the EU, are deeply dependent on manufacturing in China and India. Besides security related concerns, global concentration on ever fewer producers makes the supply chain vulnerable to any type of disruption (be it political or physical) that may occur in or around that producer, as witnessed by the Valsartan case.¹⁹ **While many have suggested to move production back to the EU, this will not alone be a sufficient response to this problem.** Therefore, the EU should look into other tools at its disposal which may guarantee a more diversified supply chain with more sources of API's, excipients and semi- or finished products, irrespective of the geographical location of those sources. One such tool involves the requirements laid out when procuring medicines, whereby the concentration of production on ever fewer producers may be counteracted.

Recommendation 6:

Affordable Medicines Europe recommends that requirements for having diversified supply sources be incorporated in public tenders.

¹⁷ ANSM, 2018: https://france3-regions.francetvinfo.fr/hauts-de-france/sites/regions_france3/files/assets/documents/2019/01/18/sf_sinemet_msd_20181228-4045171.pdf.

¹⁸ ANSM Guidelines for the method of determining financial penalties (11/23/2015): https://www.ansm.sante.fr/content/download/82869/1046923/version/1/file/methode-determination-sanctions+financiere_nov2015.pdf

¹⁹ Reportedly one Chinese company had 45% market share of the API for Valsartan in the U.S.; https://www.robinlo-urIELaw.com/files/valsartan_article_written_by_rpl_src_published_in_the_verdict.pdf.



Tackling economic related root causes

There are two main strands of economically related root causes: one is related to decisions on withdrawal and/or disinvestment as a consequence of truly unsustainable price levels (relevant for generics); a second revolves around commercial decisions aiming at dropping lower priced products to move patients to new and more expensive treatments.²⁰

Price is often the only parameter of importance in tenders of medicines in the EU (the same issue has also been identified by e.g. the U.S. FDA). In order to obtain ever lower prices, healthcare systems have concentrated their buying power over the last years. Furthermore, tenders are done almost exclusively on a winner-takes-it-all basis. Besides effectively pushing prices down, such practices have the consequence that manufacturers seeking cost reductions in production in order to compete in the generic product tenders tend to outsource and amalgamate.²¹ Hence, in accordance also with the proposals on more diversification requirements above, tender practices such as the 'winner-takes-it-all' should be reduced significantly (for large tenders (regional/national above a certain threshold), unless they have a very short running period).

Recommendation 7:

Affordable Medicines Europe recommends a stop to the wide-spread use of 'winner-takes-it-all' ten-

A second aspect that has a similar effect is the duration of tender periods. In general, very long tender periods (typically 1-2 years) favour larger suppliers. Over time this leads to consolidation and fewer suppliers in the market, which again makes the supply of medicines reliant on fewer actors with less diversified sourcing.

Recommendation 8:

Affordable Medicines Europe recommends decreasing tender periods to 3-6 months.

In order to avoid that pharmaceutical companies withdraw old, lower priced products in the attempt to move patients towards new more expensive drugs, parallel imports could be utilised as a deterrent. Parallel importers may be able to source the old products in other Member States and subsequently parallel import them where to markets where the manufacturers have withdrawn. This already happens under market conditions every day. However, in many countries obtaining parallel import licenses and being granted the normal reimbursement price can take a very long time – making it less of a deterrent.

Recommendation 9:

Affordable Medicines Europe recommends making a fast-track procedure for parallel import licenses and granting of reimbursement price where an MAH decides to withdraw from the market for commercial reasons.

²⁰ WHO, 2016: https://www.who.int/medicines/publications/druginformation/WHO_DI_30-2_Medicines.pdf?ua=1.

²¹ PwC Germany 2019; 'Current trends and strategic options in the pharma CDMO market': <https://www.pwc.de/de/ge-sundheitswesen-und-pharma/studie-pharma-cdmo-market.pdf>.



PARALLEL IMPORTS AS A SOLUTION TO SHORTAGES

As pointed out by the Council in June 2016, availability of and access to medicines is increasingly challenged in the EU:

“NOTES WITH CONCERN an increasing number of examples of market failure in a number of Member States, where patients access to effective and affordable essential medicines is endangered by very high and unsustainable price levels, market withdrawal of products that are out-of-patent, or when new products are not introduced to national markets for business economic strategies and that individual governments have sometimes limited influence in such circumstances.”²²

Parallel imports offer two unique opportunities for policymakers; 1) by introducing price competition, we help lower the prices of especially patented medicines, creating significant savings for healthcare systems²³, and 2) we help alleviate national and/or regional shortages in the EU. Both are to the benefit of healthcare systems and more importantly patients.

Whereas parallel imports markets are most developed in the older EU Member States, over the past 5-10 years substantial parallel import markets have developed in e.g. Poland and Latvia.²⁴ Parallel imports are also developing in countries such as Bulgaria and Czechia.

An analysis of shortages of medicine in the Baltics done by the Lithuanian Association of Parallel Import of Pharmaceuticals found that:

- **66% of shortages were a problem in only one of the three Baltic States**
- **24% of shortages were a problem regionally (two or three of the Baltic States)**
- **10% of shortages were an EU-wide problem.**

Consequently, in principle 90% of shortages could be alleviated by parallel imports in the Baltic States.

These are significant numbers and are not unique to the Baltic situation. In fact, every day parallel importers help alleviate shortages around the EU. A few examples: In 2019 parallel importers managed to place more than 200,000 packs of medicines in shortage on the Spanish market. In Belgium during a shortage in 2019, Belgian parallel importers managed to import more than 800,000 packs of medicines in shortage. Also, in 2020, Romanian parallel traders imported and donated more than 5,000 packs of medicines to treat thyroid hormone deficiency (Euthyrox).

Consequently, **Affordable Medicines Europe urges EU policymakers to make better use of the opportunities presented by parallel imports of medicines.** Such opportunities are multifaceted. In the section on tackling economic related root causes, we have already recommended a fast-track procedure in case of commercial withdrawals. In the same way, such procedures could be used systemically for products in shortage.

Recommendation 10:

Affordable Medicines Europe recommends that products placed on a given national shortages list should automatically qualify for emergency imports.

²² Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States, June 2016; <https://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-balance-pharmaceutical-system/>.

²³ Mendez, S. J. (2016). *Parallel Trade of Pharmaceuticals: The Danish Market for Statins*. Melbourne: Melbourne Institute of Applied Economic and Social Research. Retrieved from https://melbourneinstitute.unimelb.edu.au/downloads/working_paper_series/wp2016n08.pdf, Enemark, U., Pedersen, K., & Sørensen, J. (2006). *The economic impact of parallel import of pharmaceuticals*. Odense: University of Southern Denmark. Retrieved from <https://pdfs.semanticscholar.org/92f1/eb32d32370ea06ae76abd7d009d7759e62ce.pdf>, Posada, P. (2019). *Indirect Savings from Parallel Trade in the Pharmaceutical Sector: the German and the Swedish cases*. Madrid: NERA Economic Consulting, and Verband der Ersatzkassen. (2019, April 16). *Keine Streichung der Importförderklausel für Arzneimittel*. Retrieved from <https://www.vdek.com/presse/pressemitteilungen/2019/streichung-importfoerderklausel-arzneimittel.html>.

²⁴ Poland's parallel import market is today around 120m EUR/year, making it the EU's 6th largest import market. In Latvia, parallel imports have a share of 2% of the total pharmaceutical market.



Emergency import procedures already exist, as in the German Medicinal Products Act, § 79, Abs. 5 and the Dutch Medicines Act, Art. 3.17a, and should be more widely used.²⁵ Emergency imports are possible under Directive 2001/83, but the provisions on when and how it may be used lack clarity and lead to an underutilisation. Currently, Member States such as Germany are consequently using the safeguard clause in Article 347 TFEU as legal basis for imports in case of shortages, instead of Directive 2001/83.

Since manufacturers do not always have sufficient economic interest in rapidly finding a solution to shortages in some Member States (e.g. they prefer to allocate stocks to Member States with higher prices), it would make sense that following the Public Service Obligation (PSO) on the MAH, which is enshrined in Article 81 (2) of Directive 2001/83, they should be held responsible for the additional costs associated with securing access to the medicines in shortage.

Recommendation 11:

Affordable Medicines Europe recommends that an obligation be placed on MAHs to pay the price difference (if positive) between emergency or parallel imports and the normal reimbursement price for products in shortage in a given Member State. A so-called ‘PSO-responsible-pay’ principle.

Recommendation 12:

Affordable Medicines Europe recommends the ‘PSO-responsible-pay’ principle also be extended to the import of suitable substitution medicines which may be more readily available.

More widely the Council in December 2019 considered that in order ensure easier access to medicines, one option was:

“Transferring medicines from one member state to another with some exemptions concerning the requirements on the information accompanying the products concerned.”²⁶

This acknowledgement, that making better use of the Internal Market in alleviating shortages, also signifies why part of the solution to shortages in individual Member States should be parallel imports. Parallel importers have the capacity, knowledge, and experience in the re-packaging or re-labelling of medicines, making sure patients can receive imported medicines safely in their own languages. However, in cases of urgent shortages such language requirements may be the difference between getting the medicines to the patient in time or not.

Recommendation 13:

Affordable Medicines Europe recommends that in case of shortages of medicine more regulatory flexibility is given to parallel importers, not least in relation to the language requirements.

Besides the possibility for regulatory flexibility, the best option for increased mobility of medicines in cases of shortage would be harmonisation at EU level of packaging. This would in general lead to less fragmentation of the Internal Market.

Recommendation 14:

Affordable Medicines Europe recommends that packaging of medicines be harmonised at EU level.

²⁵ Bundesamt für Justiz: https://www.gesetze-im-internet.de/englisch_amg/englisch_amg.html#p1919. Overheid Wettenbank: <https://wetten.overheid.nl/BWBR0022160/2018-08-01/0/Hoofdstuk3/Paragraaf5/Artikel3.17a/>.

²⁶ Outcome of 3737th Council Meeting, EPSCO 9-10 December 2019: <https://www.consilium.europa.eu/media/41736/st14932-en19.pdf>.



SOLVING PATIENT EXPERIENCED SHORTAGES BY COLLABORATION

Many patients experience that they return empty handed of their essential medicines from their visit to a pharmacy. Sometimes this is caused by actual shortages of medicines, but at other times it is simply a matter of the medicine not being in the right pharmacy at the right time for that patient. The patient will experience this as a shortage. However, for the purposes of making policy on prevention and mitigation of shortages, such situations cannot strictly speaking be considered a shortage. The medicine is available, just not at the right place in the right moment. However, policymakers and the supply chain stakeholders must make sure that everything possible is done to respond to such situations, so patient will not have such experiences. In this context, Affordable Medicines Europe firmly believes that much can be done via collaboration between the supply chain stakeholders and the relevant authorities.

An authority led multi-stakeholder approach

Signals of shortages from patients and pharmacies are invaluable tools in detecting e.g. shortages driven by increases in demand (which cannot always be predicted by manufacturers). Hence, patients and pharmacies must have a central place to report such signals, and they must subsequently be considered in a systematic and comprehensive manner. To ensure this, it is crucial that national authorities lead such an effort. They have both legal possibility and commercial independence to do so.

At the same time, it is essential that supply chain stakeholders are involved. They have the information on stock levels available, movements, needs, timelines etc. throughout the supply chain. Without this information patients cannot get the immediate answer to which they are entitled. Also, many suspected shortages may in the eye of patients manifest as real shortages, whereas the product is actually available in that country.

Recommendation 15:

Affordable Medicines Europe recommends that Member States set up NCA-led national dialogue platforms between supply chain stakeholders to exchange information on products in shortage or in risk of shortage.

Supply Chain Initiatives that deliver for patients

While much can be done by the involvement of authorities, supply chain stakeholders and patient associations have also joined forces in order to solve many of the problems experienced by patients. Such solutions may deliver results for patients immediately, whereas most other solutions in relation to shortages unfortunately are long-term. The case from Bulgaria in the following page illustrates just how well such initiatives can deliver for patients and healthcare providers such as pharmacies.

Recommendation 16:

Affordable Medicines Europe encourages the creation of patient/healthcare provider platforms to directly assist patients/healthcare providers with their needs.



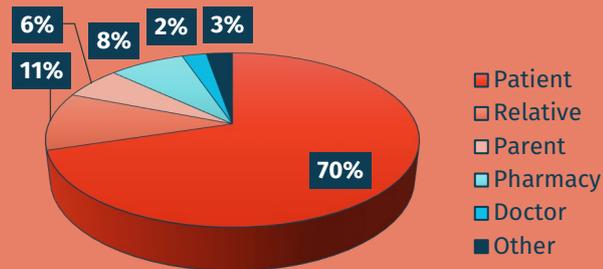
THE CASE OF BULGARIAN COOPERATION

In 2018 the Bulgarian Association for Medicines Parallel Trade Development (BAMPTD) initiated the creation of an online platform where patients can signal missing medicines. A Memorandum of Cooperation with the Federation of Bulgarian Patient's Forum (FBPF) was signed on June 8. Via the patient associations and the media, the platform was popularised widely, leading to a large uptake by patients and healthcare providers.

Since 9 June 2018, the platform has received almost 1000 signals from patients and healthcare providers from all regions of Bulgaria.

Patient signals received
965

Who reports to the platform?



For patients to experience a real benefit of the platform, two key elements are central: speed and practical usefulness of the solution. **In 66% of the cases, patients will have an answer within 12 hours.** Within 48 hours all signals have been given a final response. The solutions provided depend on the nature of each individual signal. The signals reveal that:

34% of signalled products are available in another nearby pharmacy

26% are permanently withdrawn by the manufacturer

20% are temporarily withdrawn by the manufacturer

The remaining 20% cover 17% medicines not registered in Bulgaria at all and 3% hospital medicines.

Based on the above, patients will e.g. receive either information on which local pharmacy has the product available or receive it directly from the distributor/platform. In other cases, e.g. where a product is permanently withdrawn, the patient may receive this information with the instruction to go seek their doctor to discuss alternative treatments. Typically, possible alternatives will be indicated to help both the patient and doctor identify the best alternative option.

Solution example: Breast Cancer Medicine Missing in Bulgaria

Tamoxifen tablets 10 mg - 62 signals from February 12, 2020

1st signal
received 12
February 2020
from patients
and media.

Check done
immediately.
Reason: tem-
porary supply
stop by MAH
until June 2020.

Parallel import
initiated already
by 14 February.
Immediate re-
lease procedure
launched.

Supply solution:
On 18 February
pharmacies
were supplied
by parallel im-
ports.

Source, BAMPTD 2020: <https://bit.ly/3cWxDx8>.



SHORTAGES OF MEDICINE AND PARALLEL EXPORTS

As the evidence on shortages presented above show, that **national medicines agencies do not recognise parallel exports as a significant cause of shortages**. This seems to suggest that European patients are generally already sufficiently safeguarded by the Public Service Obligation (PSO) enshrined in Directive 2001/83 Article 81, which states in paragraph 2 that:

“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.”²⁷

Hence, as a basic principle medicines may not be parallel exported until the needs of patients in the Member State are satisfied.

Also, in a majority of Member States authorities already have legal frameworks that allow for the restriction or ban of exports of medicines if there is a shortage or risk of shortage of a given product. Countries with legal frameworks giving authorities the chance to ban/restrict exports: Austria, Belgium, Bulgaria, Czechia, Estonia, France, Germany, Greece, Hungary, Italy, Latvia, Norway, Poland, Portugal, Romania, Slovakia, Spain and the UK.²⁸

As a sector, we firmly believe that exports should never cause shortages, which is why we acknowledge that having appropriate, necessary, and proportionate legal frameworks to safeguard this principle can be justified. We do, however, strongly object when such legal frameworks are disproportionate, inappropriate or unnecessary to tackle the problem at hand, or worse, when they inherently aim to protect the pharmaceutical industry’s economic interest in fragmenting the internal market, with the objective to extract the maximum price of medicines in each Member State. **Contrary to general perception, more than 50% of parallel exports are from high-income EU Member States**, because prices of individual medicines may be much higher in e.g. Poland than Norway.²⁹

Whereas parallel import of medicine brings significant savings to Member States’ healthcare systems³⁰, for authorities which are in price negotiations with pharmaceutical companies, restricting exports is not a direct economic concern. Hence, if promises by pharmaceutical companies of lower prices or increased supply (ending supply quotas) is followed by demands of export restrictions, the individual Member State may be tempted to succumb to such demands. Such examples are well-documented, especially in relation to supply quotas in higher income countries and price negotiations/threat of commercial withdrawal in lower income countries. Albeit proven by experience, that agreeing to restrictions on these grounds does not reduce shortages, it is furthermore inherently illegal following Articles 35-36 TFEU.³¹

As a sector, we have therefore called for and welcomed the principles put forward by the European Commission and Member States in the ‘Paper on the obligation of continuous supply to tackle the problem of

²⁷ Directive 2001/83/EC, Article 81.

²⁸ For further information, Affordable Medicines Europe may provide interested policymakers with a full overview of the relevant national legal frameworks, including a description of their basic features and an assessment of their conformity with EU law.

²⁹ Affordable Medicines Europe, Trade Flow Study, 2020: [insert link].

³⁰ Mendez, S. J. (2016). *Parallel Trade of Pharmaceuticals: The Danish Market for Statins*. Melbourne: Melbourne Institute of Applied Economic and Social Research. Retrieved from https://melbourneinstitute.unimelb.edu.au/downloads/working_paper_series/wp2016n08.pdf, Enemark, U., Pedersen, K., & Sørensen, J. (2006). *The economic impact of parallel import of pharmaceuticals*. Odense: University of Southern Denmark. Retrieved from <https://pdfs.semanticscholar.org/92f1/eb32d32370ea06ae76abd7d009d7759e62ce.pdf>, Posada, P. (2019). *Indirect Savings from Parallel Trade in the Pharmaceutical Sector: the German and the Swedish cases*. Madrid: NERA Economic Consulting, and Verband der Ersatzkassen. (2019, April 16). *Keine Streichung der Importförderklausel für Arzneimittel*. Retrieved from <https://www.vdek.com/presse/pressemitteilungen/2019/streichung-importfoerderklausel-arzneimittel.html>.

³¹ Judgment of the Belgian Constitutional Court no. 146/2019 of 17 October 2019.



shortages of medicines' agreed by the Ad-hoc technical meeting under the Pharmaceutical Committee on shortages of medicines on 25 May 2018 on how to implement such restrictions.³²

Recommendation 17:

Affordable Medicines Europe supports the proper enforcement of the PSO, including, if necessary, proportionate and appropriate restrictions of parallel exports if there are real shortages in the given Member State, based on the following criteria:

- **is established through transparent and audible criteria that are known in advance;**
- **takes into account the possibility of substitution and/or availability of alternative treatments in the Member State;**
- **is revised on a regular basis taking into account the latest occurrences or risks of shortages of medicines for public health;**
- **that the assessment forming the basis for the inclusion on a shortage list based on the above criteria is made available to wholesale licensed entities in the given Member States;**
- **the decisions implementing its application are taken within a reasonable time period; and**
- **the decisions are open to be contested before the relevant administrative bodies or courts of justice.**

Learning from the COVID-19 crisis

During the COVID-19 crisis, it has become evident how damaging export restrictions and bans can be, if applied disproportionately or unnecessarily, detrimental to the EU's integrated medicine supply chain.

"In order to achieve this objective [solidarity], it is critically important that Member States lift export bans on medicines within the internal market. Whilst it is understandable that countries wish to ensure the availability of essential medicines nationally, export bans are detrimental to the availability of medicines for European patients even when they are legally justifiable."³³

Considering the lack of evidence that parallel exports are among the main or significant causes of medicine shortages, and learning from the COVID-19 crisis, Affordable Medicines Europe recommends to policymakers to work towards a fully sustainable model for parallel trade in Europe. A clear and strong PSO with only the necessary, appropriate, proportionate restrictions, while fostering and promoting parallel imports where they are hampered and suppressed by commercial interests of the pharmaceutical industry. Also, several Member States already actively support parallel imports while, contrary to Articles 35-36 TFEU, they restrict excessively or entirely exports. In a closed system, such as parallel trade in medicines in the EU, this is not an acceptable policy.

Affordable Medicines Europe recommends to policymakers to work towards a fully sustainable model for parallel trade in Europe. A clear and strong PSO with only the necessary, appropriate, proportionate restrictions, while fostering and promoting parallel imports where they are hampered and suppressed by commercial interests of the pharmaceutical industry.

³² European Commission, May 2018; https://ec.europa.eu/health/sites/health/files/files/committee/ev_20180525_rd01_en.pdf.

³³ European Commission, C(2020) 2272 final; https://ec.europa.eu/health/sites/health/files/human-use/docs/guidelines_isc_en.pdf.



PUTTING AN END TO SUPPLY QUOTAS CAUSING SHORTAGES

In recent years, it has been observed that among national authorities responsible for the supply of medicines, there is a growing trend of accepting the introduction by manufacturers of ever more supply quotas. Manufacturers claim that only by limiting the quantities of a medicinal product placed on every market, will they be able to fulfil the needs of all European patients. Such claims are typically unfounded, while the real motivation is a wish to restrict parallel export from given Member States. Some manufacturers have openly admitted this, while also many seminars and conferences are held every year around the EU to educate employees of pharmaceutical manufacturers on how to implement business strategies that restrict parallel exports by the introduction and application of supply quotas.

As parallel trade, as we know it, is a concept restricted purely to the EU Internal Market, the total quantity of medicines needed for European patients are not affected by parallel trade. Parallel trade merely re-distributes some products in marginal quantities – the sector represents just below 3% of the EU pharmaceutical market in terms of value³⁴ – which fosters a competitive pressure on the prices of the given medicinal products to the benefit of healthcare systems and patients.³⁵ In other words, supply quotas are nothing more than territorial supply restrictions introduced to fragment the Internal Market for reasons of profit maximisation. It should be pointed out that supply quotas bear the risk to create shortages when they are not properly adjusted to the specific demand of the national market.³⁶

Direct-to-Pharmacy schemes (and similar)

Limiting supply to the market demand based on market shares and historical orders of wholesalers bears the risk that wholesalers cannot supply all orders from pharmacies themselves due to reasonable market fluctuations such as changes in prescribing practice or changes in the number of pharmacy customers of a wholesaler. Therefore, shortages also arise for products under quota that are not exported at all. For many years, pharmacists all over Europe are experiencing the consequences of supply quota systems implemented by manufacturers.³⁷

After the introduction of Direct-to-Pharmacies and quota schemes in the UK, Community Pharmacy Scotland asked for an investigation into the use of quotas, stating that:

What we are now seeing are huge pharmaceutical companies through their chosen wholesalers driving strict quota systems – often bearing no reality to actual individual pharmacist and patient need. They do this purely to seek to ensure that they control the price for all of their drugs in all of their international markets.³⁸

In Germany and elsewhere in the EU, supply quotas even resulted in a situation in which a manufacturer refused to supply a greater amount than the allocated quota to a pharmacist even though the pharmacist

³⁴ Based on data from IQVIA and EFPIA.

³⁵ Mendez, S. J. (2016). *Parallel Trade of Pharmaceuticals: The Danish Market for Statins*. Melbourne: Melbourne Institute of Applied Economic and Social Research. Retrieved from https://melbourneinstitute.unimelb.edu.au/downloads/working_paper_series/wp2016n08.pdf, Enemark, U., Pedersen, K., & Sørensen, J. (2006). *The economic impact of parallel import of pharmaceuticals*. Odense: University of Southern Denmark. Retrieved from <https://pdfs.semanticscholar.org/92f1/eb32d32370ea06ae76abd7d009d7759e62ce.pdf>, Posada, P. (2019). *Indirect Savings from Parallel Trade in the Pharmaceutical Sector: the German and the Swedish cases*. Madrid: NERA Economic Consulting, and Verband der Ersatzkassen. (2019, April 16). *Keine Streichung der Importförderklausel für Arzneimittel*. Retrieved from <https://www.vdek.com/presse/pressemitteilungen/2019/streichung-importfoerderklausel-arzneimittel.html>.

³⁶ *Position Paper on Addressing the root causes of medicines shortages, supply chain Stakeholders' views on root causes and solutions of 6 December 2019*, <https://www.efpia.eu/media/413378/addressing-the-root-causes-of-medicines-shortages-final-051219.pdf>.

³⁷ PGEU, 2019: <https://www.pgeu.eu/wp-content/uploads/2019/03/190514E-PGEU-Position-Paper-on-Medicine-Shortages-1.pdf>.

³⁸ <https://www.pharmaceutical-journal.com/news-and-analysis/drugs-industry-blamed-for-medicines-shortages/10965338.article?firstPass=false>.



could submit a prescription confirming the patient need.³⁹ Single distribution channels increase risk of shortages.

Recommendation 18:

Affordable Medicines Europe recommends restricting Direct-to-Pharmacy (DTP) schemes.

Misuse of supply quotas

In some Member States, the application of supply quotas has become so dominant, that **governments have openly admitted, that in order to end the supply quota systems they will introduce or have introduced legislation banning parallel exports to accommodate the pharmaceutical industry.** While it is not only contrary to the EU Treaty to use supply quotas with the aim to limit competition in the Internal Market, rejection of such legislation has also been confirmed by national courts.⁴⁰ However, as this trend continues it should be clear to Member States, that the introduction of parallel export bans based on a wish to find an ‘amicable’ end to supply quota systems introduced by pharmaceutical manufacturers is unacceptable and unlawful under the EU Treaty.⁴¹

On the matter of supply quotas, the Greek Court of Appeal posed a number of questions to the ECJ (Syfait II case) in the form of a preliminary reference. At the outset, the ECJ stated that:

“Parallel imports enjoy a certain amount of protection in Community law because they encourage trade and help reinforce competition.”⁴²

The ECJ stated that the practices of an undertaking in a dominant position which aim at avoiding parallel exports from one Member State to other Member States by partitioning the national markets - thus neutralising the benefits of effective competition in terms of the supply and the prices that those exports would obtain for final consumers in the other Member States - are caught by the prohibition laid down in Article 102 TFEU.⁴³

In sum, the ECJ held that a dominant pharmaceutical manufacturer which, in order to prevent parallel exports by certain wholesalers, refuses to meet ‘ordinary orders’ from those wholesalers is abusing its dominant position, thus breaching Article 102 TFEU.

In Belgium, supply quota practises of manufacturers lead to shortages which is why a law was introduced in 2019 with the aim to reduce shortages caused by supply quotas.⁴⁴ According to the Federal Agency for Medicines and Health Products (FAMHP), manufacturers apply quotas and artificially reduce the supply to wholesalers which then leads to shortages:

“Another cause is the failure to respect the principle of quotas. Applying quotas is a practice used by some pharmaceutical companies to deliver their stocks in a controlled manner. (...) In such cases of unavailability, the company still has lots of stock available, but the pharmacist is unable to order it via the wholesaler-distributor. In practice, such cases are not notified to the FAMHP because they rarely last more than 14 days, usually only occur at the end of the month and the drug is available again at the beginning of the following month.”⁴⁵

³⁹ <https://m.apotheke-adhoc.de/nachrichten/detail/apothekenpraxis/trotz-rezept-novartis-verweigert-jakavi-kontingentierung/>.

⁴⁰ Judgment of the Belgian Constitutional Court no. 146/2019 of 17 October 2019.

⁴¹ *Ibid.*

⁴² Joined Cases C-468/06 to C-478/06 *Sot. Lelos kai Sia and Others*, EU:C:2008:504, para. 37.

⁴³ *Ibid.*, para. 66.

⁴⁴ <https://www.dekamer.be/FLWB/PDF/54/3599/54K3599001.pdf>, page 3.

⁴⁵ FAMHP website, accessed 22 May 2020: https://www.famhp.be/en/items-HOME/unavailability_of_medicinal_products.



The practice to apply strict supply quotas which lead to shortages and provoke an export ban is highly problematic. This happened in Belgium. However, the Belgian Constitutional Court in its ruling of 17 October 2019 on the law could find no evidence that exports were the cause of the existing shortages on the Belgian market. Moreover, shortages even continued to grow when the law on export restrictions was in force.⁴⁶

As laid out above, Article 81 of Directive 2001/83/EC stipulates that Member States have to impose PSO's both on manufacturers and wholesalers in order to ensure appropriate and continued supplies of medicines. **According to the European Commission and Member States, manufacturers fulfil their obligation to ensure adequate quantities to cover the demand from patients by ensuring continued supply that covers the need of wholesale distributors.**⁴⁷ The PSO should therefore be understood as the right of wholesalers to be supplied. The right to be supplied applies to all orders of wholesalers that are not out of the ordinary. It should be monitored and enforced by national authorities.

Recommendation 19:

Affordable Medicines Europe proposes that wholesalers who are under a PSO obligation themselves should have a right to be supplied in order to meet patient needs and ensure sufficient buffer stocks and a competitive internal market.

When supply quotas are applied, they should have a justified reason, e.g. production problems justifying rationing. Such quotas must be sufficiently transparent and flexible. Quotas imposed on wholesale distributors have to be adjusted according to market fluctuations such as changes in prescribing practice or changes in the number of pharmacy customers of a wholesaler. So-called 'black-box' quotas, where wholesalers do not know how much stock they will receive per week or month, should not be allowed. Finally, new entrants on the market need to be granted distribution quotas so as to be able to start their business activity in satisfactory conditions.

Recommendation 20:

Affordable Medicines Europe proposes that supply quotas must always be sufficiently transparent, flexible, and justified, and that 'black-box' quotas be banned.

⁴⁶ Judgment of the Belgian Constitutional Court no. 146/2019 of 17 October 2019.

⁴⁷ European Commission, May 2018, 'Paper on the obligation of continuous supply to tackle the problem of shortages of medicines of 25 May 2018', bottom of page 1; https://ec.europa.eu/health/sites/health/files/files/commit-tee/ev_20180525_rd01_en.pdf.





WORKING IN PARALLEL FOR A BETTER DEAL

Affordable Medicines Europe represents Europe's licensed parallel distribution industry, an integral part of the European pharmaceutical market that adds value to society by introducing price competition for patented medicines and a supplementary layer of product safety. We represent 125 companies in 23 EU/EEA Member States. These members account for approximately 85% of the total parallel import market volume in the EU/EEA. Membership in Affordable Medicines Europe is exclusive to companies holding a wholesale (GDP) license (export and import). All importing members furthermore are GMP licensed.
