

The Consumer Voice in Europe

ADDRESSING MEDICINES SHORTAGES DURING THE COVID-19 PANDEMIC AND BEYOND: THE CONSUMER CHECK LIST



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Why it matters to consumers

People need medicines to survive and to enjoy a better quality of life. As such, it is crucial to guarantee the constant supply of medicines at the pharmacy or the hospital. However, drug shortages are a major public health threat in Europe and affect supplies of all kind, from painkillers to cancer treatments. This is a longstanding problem, and the COVID-19 pandemic has highlighted the weak links in the supply chain. BEUC calls on the EU to step up action to ensure that medicines – to treat both COVID-19 and other diseases – are available when we need them.

Our Recommendations

The EU must step up action to address the causes of drug shortages, improve prevention and management, building on the initiatives put in place during the COVID-19 pandemic.

1. Urgent measures during the COVID-19 pandemic

- Ensure effective communication among Member States about anticipated or actual drug shortages, and available stocks. The single point of contact network (SPOC) should become an established monitoring system during and after the pandemic.
- Facilitate the re-allocation of excess stock to help those countries in short drug supply, and favour the rescEU stockpiling mechanism over national approaches.
- Make the most out of the Joint Procurement Agreement so it becomes the number one option to buy essential medicines to treat COVID-19 and other medical supplies.
- Support the set-up of a global mechanism to coordinate about medical supplies.

2. EU action needed beyond the COVID-19 pandemic

- Include common terminology for drug shortages and criteria for reporting by pharmaceutical companies in the EU legislation.
- Require pharmaceutical companies to submit drug shortage prevention plans to competent authorities. Ensure proactive monitoring of medicines supply.
- Ensure that pharmaceutical companies and distributors comply with medicines supply obligations, and explore how they could be strengthened.
- Ensure early notification by companies of drug shortages at least two months in advance as required by EU law. Map and promote best practices among Member States on earlier notification periods to achieve a harmonised approach.
- Enable consumers to report on drug shortages and their impact.
- Ensure effective public communication on drug shortages, through an EU database. Extend the use of electronic package information leaflets, in addition to paper leaflets.

3. Evidence-based policymaking

- Assess the impact of parallel trade on medicines (un)availability and consumer access; explore how supply robustness can be enhanced in Europe taking into account the need to ensure as well drug affordability; map and promote alternative (non-private) drug manufacturing models.

Context

- The COVID-19 pandemic and the response to it are causing important disruptions to the supply of medicines in the European Union. Some Member States are starting to experience shortage of medicines used in intensive care units.¹ In addition, the cost of basic drugs, such as painkillers, is driving up by as much as 30% due to raw material shortage.²
- This is not a recent challenge. In 2019, 95% of hospital pharmacists across Europe reported that drug shortages are a problem, compared to 92% in 2018 and 86% in 2014.³ Community pharmacists also report that the situation is worsening.⁴
- Consumer organisations have been raising the alarm for a long time. Already in 2015, Belgian consumer organisation Test Achats/Test Aankoop reported that among 500 surveyed consumers, one in five had faced a situation of drug shortage in the previous five years.⁵ A 2019 survey by consumer group Which? found that one in four people in the UK had experienced problems getting hold of the medicines they needed because of stock shortages in the previous year.⁶
- Medicines shortages have a negative impact on patient care.⁷ They risk causing delays or cancellation of care, and longer hospitalisations. Patients can end up receiving alternative treatments that do not work as well and increase the risk of suffering adverse events. These treatments are often, more expensive, and consumers get a higher bill at the pharmacy.
- Drug shortages are a public health threat, which has been exacerbated by the COVID-19 pandemic. The EU must step up action to address the causes of drug shortages and ensure effective response when this situation occurs. Strengthened cooperation and action must be based on strong solidarity to achieve equitable access to medicines.

1. Urgent measures during COVID-19 pandemic

The current pandemic and the response to it are affecting the provision of medicines used to treat COVID-19 patients and others. Factories in areas most affected by the pandemic have not been able to operate as usual and the closure of borders hinders the distribution chain of active pharmaceutical ingredients.⁸ In addition, governments around the world have introduced export bans and the uncoordinated stockpiling of medicines threatens equitable access. The sudden increase in demand adds up to a list of causes that are compromising access to medicines.

¹ European Medicines Agency. [Availability of medicines during COVID-19 pandemic](#). Accessed on 8 May 2020.

² The Guardian. [Coronavirus triggers sharp rise in price of pain relief medication](#). 12 March 2020.

³ European Association of Hospital Pharmacists (2020). [2019 EAHP medicines shortages report](#).

⁴ Pharmaceutical Group of the European Union (2020). [PGEU Survey on medicines shortages 2019](#).

⁵ Test Achats. [Grand temps de s'attaquer à la pénurie de médicaments](#). 01 October 2015.

⁶ Which? [Coronavirus and medicine shortages: what's going on?](#). 25 March 2020

⁷ See reference 3.

⁸ European Medicines Agency. [EU authorities agree new measures to support availability of medicines used in the COVID-19 pandemic](#). 06 April 2020

To ensure the availability of medicines, the European Commission, national governments, and regulatory agencies are working together on several fronts. BEUC welcomes this collaboration, and calls upon the newly established EU Executive Steering Group on shortages to ensure the effective implementation of some important measures:

1.1. Institutionalised system for rapid information-sharing on drug shortages and stocks

Member States must communicate effectively with each other about anticipated or actual drug shortages. Timely communication is essential to trigger early cooperation. They should also share information on available stocks. This is important for medicines used for the treatment of COVID-19 and for any other drug affected by the response to the pandemic.

The fast-track monitoring system that has been put in place by the EU Executive Steering Group is a welcome initiative. Given that its scope is limited to medicines used for treating COVID-19, BEUC calls for the single point of contact network (SPOC) to be adequately resourced to ensure it is an effective communication tool on other drug supplies affected by the response to the pandemic. The SPOC system, currently being piloted by the European Medicines Agency and the Heads of Medicines Agencies (HMA), should become an established monitoring system thereafter.

1.2. Equitable stock distribution across the EU

The European Commission in collaboration with Member States should facilitate the re-allocation of excess stock to help those countries in short supply. During the pandemic, the rescEU stockpiling mechanism used in emergency situations should be favoured over national stockpiling approaches to ensure equitable access. This is particularly important for essential medicines. The European Commission must ensure transparency around the functioning of this mechanism and the criteria to distribute stocks.

Looking ahead, the Commission should develop guidelines and a monitoring system to ensure that national initiatives on stockpiling are proportionate to their needs and do not create unintended consequences in other countries.

1.3. Joint procurement of medicines and medical supplies

The European Commission and national governments should make the most of the voluntary EU Joint Procurement Agreement, so it becomes the number one option by countries to buy essential medicines to treat COVID-19 and other medical supplies. Diversifying the number of suppliers should be considered to help ensure supply security.

Joint procurement increases governments' bargaining power, enabling them to buy medicines at lower prices and improve affordability and availability.⁹ Looking forward, the Commission should explore the option to expand the scope of the Joint Procurement Agreement so it can be used beyond situations of cross-border health threat (e.g. to ensure availability and affordability of new innovative medicines for other diseases).

⁹ In the Baltics, a joint tender for rotavirus vaccine resulted in a price 17-25% lower for each immunisation course than the participating countries had previously paid individually. In Cernuschi T, Gilchrist S, Hajizada A et al. (2020). Price transparency is a step towards sustainable access in middle income countries. *BMJ*; 368:I5375

1.4. Global cooperation on medical supplies

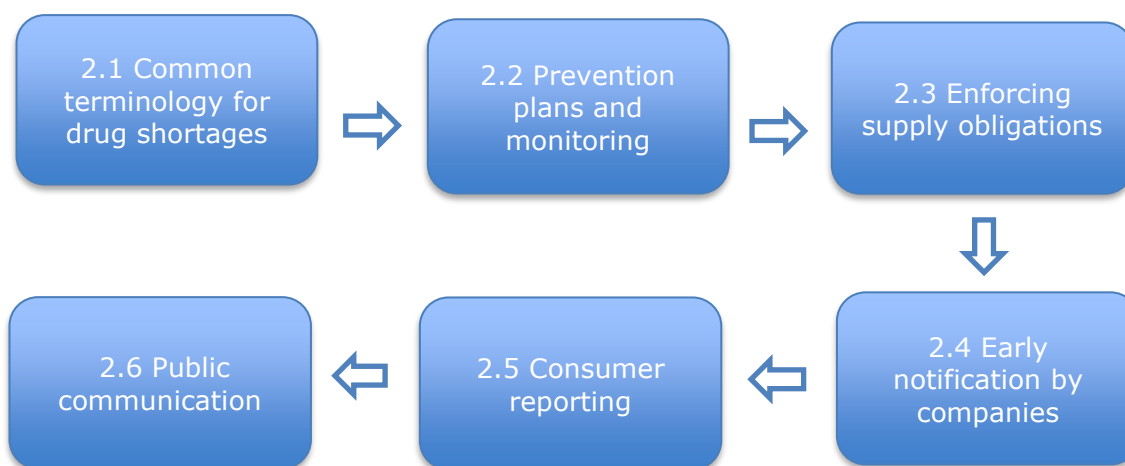
The EU should support the set-up of a mechanism to coordinate export curbs between countries at the global level, in which the WTO and WHO should play a central role. The COVID-19 crisis triggered an interest for an international trade negotiation on medical goods. Such an initiative could be a way to enable national authorities to share information, strengthen cooperation for effective shortage response and conduct joint investigations into shortages and price surges. The final agreement should include a provision to encourage such cooperation. It should also stress the importance of the coordinating role of the WHO.

2. EU action needed beyond COVID-19

In recent years, medicines shortages have become a recurring problem in Europe affecting old and new medicines across therapeutic areas. In France, in 2018 alone it affected 500 major drugs, ten times more than ten years before.¹⁰ In Spain, notifications on shortages have multiplied by 12 since 2009.¹¹

To tackle this problem, the EMA and HMA have undertaken some initiatives through a specific Task Force and there is ongoing dialogue at the Pharmaceutical Committee that brings together the Commission, Member States, the EMA and EEA countries. BEUC welcomes these efforts, but more needs to be done.

The EU must step up action to address the causes of drug shortages, improve prevention and management, building on the initiatives put in place during the COVID-19 pandemic. This requires strengthening the EMA's coordination role as already requested by the European Parliament,¹² and implementing several measures that are essential for a comprehensive, proactive policy approach and improved drug availability:



¹⁰ France Assos Santé. [CSA survey for France Assos Santé: the French want a stronger and more protective Europe in the health field](#) 14 May 2020

¹¹ Organización de Consumidores y Usuarios. [OCU alerta del desabastecimiento de medicamentos](#). 13 February 2020.

¹² European Parliament. Resolution of 2 March 2017 on EU options for improving access to medicines (2016/2057(INI)).

2.1. Common terminology for drug shortages

BEUC calls for a general definition and criteria that determine what constitutes drug shortages to be included in the EU pharmaceutical legislation.¹³ Common terminology is essential for effective joint action. The absence of formal and legally binding definitions in many Member States, as well as inconsistencies and incomparability of existing terminology across countries has likely hindered coordination, communication and comparative analyses of the scale and effects of shortages.¹⁴

Common criteria for harmonised reporting by marketing authorisation holders is particularly important. It should cover situations of withdrawals for economic reasons (see Aspen case).¹⁵ The results of the pilot project by the EMA and HMA on the notification of drug shortages by pharmaceutical companies, which uses a common definition, must be publicly discussed including with consumer groups.

2.2. Prevention plans and proactive monitoring

Pharmaceutical companies should be required to submit shortage prevention plans to competent authorities when they market a medicine.¹⁶ Such plans can help identify risks early on and promote mitigation measures (e.g. diversify the supply of active pharmaceutical ingredients, improve good manufacturing practices).

At present, whilst EU legislation requires pharmaceutical companies to ensure continued supplies of medicines, it does not mandate shortage prevention plans.¹⁷ Different countries have different approaches. For example, whilst such plans have been progressively requested in France since 2017 the same requirement is not in place in Belgium or in an EEA country like Norway.¹⁸ This must be reversed, and prevention plans become mandatory everywhere. Countries should start requiring pharmaceutical companies to take preventative measures, and this obligation should also be included in EU law in ways that ensure harmonised practices.

Based on these prevention plans and other information, competent authorities should proactively monitor the supply of those medicines that are at risk of shortage, particularly if they are essential (e.g. based on clinical need, added therapeutic value, reasonable price, narrow-therapeutic index¹⁹). The criteria to define 'priority monitoring lists' of medicines should be transparent.

¹³ It should be consumer-centric and cover the various causes of drug shortages, including supply issues due to parallel trade.

¹⁴ Bochenek T, Abilova V, Alkan A. et al. (2018), Systemic Measures and Legislative and Organizational Frameworks Aimed at Preventing or Mitigating Drug Shortages in 28 European and Western Asian Countries. *Front. Pharmacol.* <https://doi.org/10.3389/fphar.2017.00942>

¹⁵ In 2016, the Italian Competition authority fined Aspen with €5 million for inflating the price of several cancer medicines. Aspen had withdrawn these drugs from the market – creating shortages- and reintroduced them a few months later with a price tag between 300% and 1,500% higher. BEUC's Italian member organisation, Altroconsumo, played a key role in this case by denouncing Aspen's abuse of dominant position. The EC is conducting a pan-European investigation on the case and BEUC is engaged as an interested third party. See [BEUC to be involved in EU investigation on Aspen Pharma](#), 27 Nov. 2017

¹⁶ For medicines already on the market, competent authorities should at least require such plans for those medicines that are considered essential.

¹⁷ According to the European Commission 2018 Paper on the obligation of continuous supply to tackle the problem of shortages of medicines, this is at the discretion of Member States.

¹⁸ Latest update January 2020.

¹⁹ Medicines where small differences in dose or blood concentration could lead to serious therapeutic failures and/or adverse drug reactions.

2.3. Enforcing supply obligations

Member States must ensure that marketing authorisation holders and distributors comply with the requirement to ensure appropriate and continued supplies of medicines. Dissuasive sanctions should go hand in hand with strong enforcement in case of non-compliance with legal obligations.²⁰ In addition, we call on the European Commission to explore how the obligation on continued supplies could be strengthened, to better help prevent shortages.

Fines in case of non-compliance should help compensate for the additional expenses that shortages cause to public budgets and consumers' pockets. At the national level, governments and public insurers should find ways to **ensure that in a situation of drug shortage consumers do not end up paying more out-of-pocket**. It is important to ensure that alternative medicines that are prescribed or recommended are reimbursed at the same level as the standard treatment.

2.4. Early notification by companies and mapping best practices

All Member States must introduce obligations for pharmaceutical companies to notify drug shortages at a minimum two months in advance, as required in the EU legislation.²¹ Early notification about drug shortages is essential to search for alternative treatment and minimise any negative impact on patient care. However, a 2015 survey from the EMA found that some Member States did not have this requirement in their national legislation.²² Even in countries that do, compliance can be erratic.²³

At the same time, some countries require earlier notification periods by marketing authorisation holders. In Italy, companies should in principle notify shortages four months in advance. In Belgium and Spain, the notice period is six months if a (reimbursed) medicine is withdrawn from the market. Earlier notification periods are particularly relevant in these situations. The European Commission should map the different national reporting timeframes and identify best practices to achieve a harmonised approach.

EU legislation should also require other stakeholders involved in the supply chain, such as wholesale distributors and pharmacists, to report drug shortages in accordance with the national reporting system.²⁴

²⁰ In some countries the level of sanctions is not dissuasive enough. In Spain, consumer organisation OCU has requested tougher sanctions when big pharmaceutical companies breach the law. See [OCU alerta del desabastecimiento de medicamentos](#), 13 February 2020.

²¹ Article 23a, Directive 2001/83/EC consolidated version. "Such notification shall, other than in exceptional circumstances, be made no less than two months before the interruption in the placing on the market of the product".

²² European Medicines Agency. [Shortages survey 2015](#), Shortages Workshop 09 October 2015.

²³ A study conducted in Portugal showed that 71% of the 'raturas' (stockouts reported by MAHs) in 2018 were notified only one day before the shortage started. In New Angle (2019). Estudo da indisponibilidade do medicamento em meio ambulatório.

²⁴ Reporting requirements by law exist for example in Portugal for distributors and pharmacists, the latter having to report problems of medicines unavailability ('faltas') that go beyond 12 hours. In Italy, there are also reporting requirements for pharmacists in the law. It is important that such requirements go hand in hand with a system allowing pharmacists to report automatically, to reduce as much as possible workload on drug shortage management.

2.5. Consumer reporting

Competent authorities should enable medicines users to report on drug shortages. This should be embedded in EU legislation, like it was done with direct patient reporting of adverse events.²⁵ Patients and consumers are the main victims of drug shortages. As such, it is essential to capture their experience with shortages to better understand the health and societal impact. Reports from medicines users can also help identify problems with alternative treatments that have been prescribed.

To further enable reporting by consumers, the European Commission should support through the EU research framework programme the development of a mobile reporting app managed by the national medicines' agencies. It should include the possibility to activate, on a voluntary basis, notifications so consumers can be informed that the medicine they need is available again.

BEUC also calls for competent authorities to systematically engage consumer groups in initiatives and decisions on drug shortages at the national and EU level. For example, in the development of public communication strategies on drug shortages. Financial support from governments is important to maximise engagement by consumer groups.

2.6. Effective public communication

Consumers must be informed about (expected) shortages, start date and duration as well as alternative treatments to ensure continuity of care and minimise any potential adverse effects. BEUC calls for the EMA catalogue to be expanded,²⁶ and to evolve into a comprehensive user-friendly pan-European database connected to national public databases. A comprehensive database at the EU level is essential to get a better understanding on the extent of shortages.

It is important that information on medicines in short supply is published in the EU database using both, the brand name(s) and the INN (international non-proprietary name). In addition, full transparency must be ensured about the causes of shortages including when these occur due to economic reasons.

To ensure adequate information on the use of medicines, the electronic Product Information (ePI) should be implemented across the EU. ePIs can help consumers access information on the correct use of medicines in their own language when packages are imported from other countries in response to a situation of shortage.²⁷ Pharmacist should print out a paper leaflet in the local language for consumers with low digital literacy.

In general, it is important that ePIs complement, but not replace, paper leaflets in the packages. BEUC [calls for ePIs](#) to be developed and managed by regulatory authorities, and to comply with EU's data protection and security framework.

²⁵ The EU pharmacovigilance legislation, which came into effect in 2012, expanded direct patient reporting of adverse drug reactions across Member States.

²⁶ It should include cases of drug shortages reported at national level across EU/EEA, for all reasons. At the national level, all Member States should also have user-friendly, searchable, and comprehensive databases. At present, however some national registers include a list of PFDs (e.g. Greece), do not appear to be available online (e.g. Cyprus, Luxembourg) and important information such as alternative treatment or the estimated duration of the shortage is not systematically reported everywhere. See HMA/EMA [Good practice guidance for communication to the public on medicines' availability](#), 14 July 2019 and [EMA shortages catalogue](#) for the list of national registers (accessed 7 May 2020).

²⁷ To facilitate uptake, and avoid medication errors, it is important to aim at having medicines marketed across countries in similar packages and dosages.

To ensure consistency in their communications, national competent authorities should follow the EMA/HMAs Good practice guidance for communication to the public on medicines availability issues.²⁸

3. Evidence-based policymaking

We call upon the European Commission to have a closer look at these issues:

- **Impact of intra-EU parallel trade:** Parallel imports and exports of medicines can facilitate access in some countries but also create shortages in others.^{29,30} The European Commission should conduct a comprehensive study on the extent and scope of parallel trade in the internal market, and its impact on medicines' (un)availability and consumer access. Such an assessment can help identify the need for additional measures and guidance to address any adverse effects on access to medicines. Consumer groups must be involved in these discussions.
- **Need to ensure availability and affordability:** Given the industry's dependence of global pharmaceutical supply chains, we urge the EU to explore how our supply robustness can be enhanced in the medium-term. Current discussions between the Commission and Member States focus on the need to provide incentives to the industry to relocate production in Europe. BEUC calls for any incentives to safeguard medicines' affordability.
- **Alternative drug production models:** In addition, we call for the European Commission to conduct a study mapping alternative (non-private) drug manufacturing models in Europe and beyond. Scaling-up these initiatives at the national and EU level, in full compliance with quality requirements, can help improve the availability of medicines that are in short supply (including old medicines for which there is no commercial interest).

ENDS

²⁸ European Medicines Agency and Heads of Medicines Agencies (2019). Good practice guidance for communication to the public on medicines' availability issues.

²⁹ Mixich V, Voinea S, Mardale S et al. (2019). Magnitude of cancer drugs parallel trade from Romania to European Union countries in 2017. *Value in Health* DOI: <https://doi.org/10.1016/j.jval.2019.04.732>

³⁰ European Commission. Infringement: Parallel trade of medicines: Commission closes infringement proceedings and complaints against Poland, Romania and Slovakia, 17 May 2018.



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