

Medicine shortage in the EU during the novel coronavirus outbreak

The novel coronavirus outbreak is an unprecedented public health crisis with far-reaching consequences. It has highlighted the EU's long-existing structural problems related to the supply of medicines, and the dependency on third-country import for certain essential and critical medicines and ingredients.

While public health policy, including the organisation of the delivery of healthcare and the sales of medicines remains in the competence of the Member States, it has also become clear that cooperation with the pharmaceutical industry, amongst the Member States, and with the Commission and the European Medicines Agency, is key in resolving the problems of medicine shortages in these extraordinary times.



This paper looks into the causes of medicine shortage during the novel coronavirus pandemic in the Union, and the responses and solutions at European level.

Context

Though there is no legal **definition of medicine shortage**, in the context of preparing a recent guidance document on shortage notification, the European Medicines Agency (EMA) and the Heads of Medicine Agencies (HMA), in consultation with stakeholders, agreed on a common definition. According to that, 'shortage of a medicinal product for human or veterinary use occurs when supply does not meet demand at a national level'¹.

Directive 2001/83² requires **the marketing authorisation holder (MAH) and the distributor** of a given medicinal product to ensure, within the limits of their responsibilities, appropriate and continued supply to pharmacies and other persons authorised to supply medicines so that patients' needs are met (Article 81, subparagraph 2). MAHs are also obliged to notify the competent authority of the given Member State in good time in case of shortages, i.e. if the medicine 'either temporarily or permanently, ceases to be placed on the market' of the given Member State (Article 23a, subparagraph 2). If the shortage concerns a centrally authorised medicine, EMA should also be notified.



Glossary

Centralised procedure: A European authorisation route, resulting in a centrally authorised product with a single marketing authorisation. If a product has been authorised using the centralised procedure, it has been assessed on an EU-wide basis and approved by the Commission. EMA organises the process of evaluation, using scientific expertise from the Member States.

Mutual recognition procedure, MRP: A European authorisation route, resulting in a mutually recognised product. Mutual recognition must be used when a product is already authorised in at least one Member State on a national basis, and the Marketing Authorisation Holder wishes to obtain a marketing authorisation for the same product in at least one other Member State.

Decentralised procedure, DCP: For authorising medicines in more than one European Union Member State in parallel. While the product must already be authorised in at least one Member State on a national basis in order for *MRP* to be used, *DCP* may be used if the product is not already authorised in any Member State.

National authorisation procedure: For authorising a medicine in a single Member State, in accordance with its national authorisation procedure. Run by the national competent authority.

Marketing authorisation holder, MAH: The company or other legal entity that has the authorisation to market a medicine in one, several or all EU Member States.

National competent authority, NCA: The medicines regulatory authority in a EU Member State.

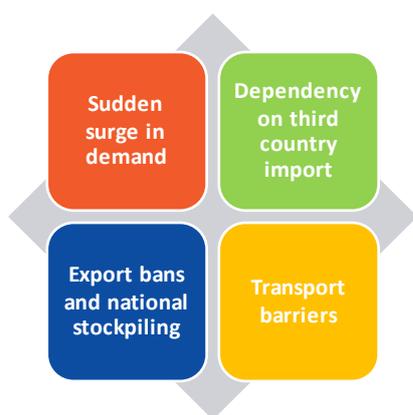
Source: [European Medicines Agency - Glossary](#)
[Heads of Medicine Agencies - Glossary](#)

MAHs should be particularly vigilant for medicines for which the manufacturing process or part of it is dependent on a single facility (e.g. a single starting material source, active ingredient manufacturer, finished product manufacturer or batch release site); and for those medicines for which no or only limited alternatives are available, and the shortage would result in a potential risk for public health (e.g. medicines for life threatening conditions, critical or essential medicines³). For those medicines, competent authorities may require MAHs to develop a shortage prevention plan, as part of their obligation to ensure continuous supply⁴. Wholesale distributors also have a responsibility. They should ensure continuous supply to pharmacists and the person entitled to supply to the public, to cover the needs of the patients on the territory where the distributor is established. Full-line wholesalers are required to supply all, other wholesalers a set of, pre-defined medicinal products at regular intervals for a specific geographic area. Most medicine shortages are dealt with at national level, by the national competent authorities; EMA can be involved e.g. when the shortage affects several Member States or when it is linked to a safety concern.

The Commission and EMA have been working closely together and with the Member States, under the umbrella of the **European medicines regulatory network**⁵, to prevent shortages and limit their impact. Recognising the importance of the issue and the need for further cooperation, the Heads of the Medicine Agencies and EMA established a **Task Force on the availability of authorised medicines** in 2016⁶. Between April and August 2019, the task force ran the pilot phase of a single point of contact (**SPOC**) network⁷. SPOC had the objective of improving information sharing between Member States, EMA and the Commission on important medicine shortages (both human and veterinary medicines); and coordinating actions to help to prevent and manage shortages, including information sharing on alternative medicines that are available in other Member States. A very timely initiative, which generated experience and prepared the ground for an even more enhanced cooperation during the coronavirus outbreak.

The causes of medicine shortage during the coronavirus pandemic

Root causes of medicine shortage during the pandemic



Source: Authors's own elaboration

The availability of medicines is affected by several factors, ranging from economic causes to manufacturing and supply chain issues and regulatory aggravating factors⁸. The pandemic brought these issues into a new dynamics, worsening the situation by a sudden surge in demand amid severe supply disruptions worldwide. We could observe increased demand for certain medicines, for the same type of medicines from all over Europe, in the same time and in large quantities, among severely disrupted manufacturing and transport capacities.

1. Sudden surge in demand during the pandemic

Approximately 40% of the diagnosed COVID-19 cases require hospitalisation; and while not all critical cases are admitted to intensive care units (ICU), and ICU admissions are dependent on the severity of illness and the ICU capacity of the health-care system, on average 2% of the

total cases are treated in ICUs and/or requiring respiratory support⁹. The demand for **medicines used in intensive care units** has therefore increased substantially. That includes anaesthetics, antibiotics, muscle relaxants, resuscitation medicines and anti-diuretics; as well as medical oxygen. Respiratory and cardiac medicines, analgesics, anti-clotting medicines are also needed for intensive and supportive care of COVID-19 patients.

Currently there is no effective treatment for COVID-19, but a number of medicines which were authorised for treating other diseases, are now being examined as potential treatment for COVID-19 (**off-label and compassionate use**). These include remdesivir (investigational medicinal product, used so far in clinical trials only); lopinavir/ritonavir (currently authorised as an anti-HIV medicine); chloroquine and hydroxychloroquine (currently authorised at national level as treatments for malaria and certain autoimmune diseases); systemic interferons β (currently authorised as treatment for multiple sclerosis); and monoclonal antibodies with activity against components of the immune system¹⁰.

Chloroquine and hydroxychloroquine were amongst the first medicines which got known to the general public as a promising potential cure for COVID-19; and a number of large, randomised clinical trials are currently ongoing to assess the benefits and risks of this medicine for COVID-19 treatment. Remdesivir is used in certain Member States in compassionate use programmes, and is also under a rolling review of data by EMA. **The increasing demand for these medicines for COVID-19-treatment has threatened their availability for patients using them for the authorised indications**, i.e. to treat their chronic or rare illnesses.

Glossary

Compassionate use: The use of an unauthorised medicine outside a clinical study in individual patients, under strictly controlled conditions. This helps to make medicines that are still under development available to patients. Compassionate use programmes are set up at the level of the Member States.

Off-label use: The use of a medicine for an unapproved indication or in an unapproved age group, dosage, or route of administration.

Rolling review of data: It enables EMA to assess data as they become available on a rolling basis, while development is still ongoing. This way EMA can speed up the evaluation of a promising treatment in the times of the pandemic.

Source: [European Medicines Agency - Glossary](#)

Finally, in reaction to the pandemic, panic-buying, and stockpiling of **over-the-counter painkillers** by citizens was also commonly observed in the Member States.

2. Dependency on third country import for medicines and ingredients used in the context of COVID-19 treatment

Medicine shortages in the EU is not a new phenomenon brought on by the pandemic. The dependency of the European pharmaceutical industry on third-country imports has been a long-standing issue, which was recognised as a potential threat to the EU's strategic autonomy already before the pandemic, and has now been exacerbated by the crises. While 'it is important to acknowledge that no country is self-sufficient in the raw materials, intermediates, APIs (*active pharmaceutical ingredients*) and finished medicines that are required to ensure a well-functioning healthcare system'¹¹, the fact that 90% of APIs for generic medicines have been sourced from India and China has been an alarming fact for long. Europe is India's biggest buyer of paracetamol APIs and imports around 12000 tonnes annually; while India is dependent on China, which supplies almost 70% of the APIs for Indian drug-makers. Though for innovative medicines many APIs are produced in Europe, and 31% of the US supplies of APIs comes from Europe, 'even when APIs are produced in the EU, most of the raw materials, for both generics and innovative medicines, are sourced from China'¹².

The coronavirus crises has exposed the **EU's dependence on China and India for imports of crucial ICU drugs** such as narcotic pain relievers, muscle relaxant ingredients and some older anaesthetics; **as well as for paracetamol**, whose export India restricted in the beginning of March 2020¹³.

3. Export bans and national stockpiling in response to the pandemic

As mentioned in the above section, export bans in supplying third countries, such as the restrictions by India on the export of 26 APIs, including the API and formulations of paracetamol, had a substantial impact on the global supply chain. Export bans were introduced within the EU by the Member States as well, in the anticipation of shortages and to create national stockpiles, hampering the functioning of the internal market.

'Member States may take measures to prevent or address shortages of medicines by restricting the free movement of goods within the EU (Joined Judgments C-468/06-C-478/06, para. 75). Member State authorities may restrict supply of medicinal products to operators in other EU Member States by wholesale distributors (...) as long such restrictions are justifiable as appropriate, necessary and proportionate to protect the life and health of humans by preventing the occurrence of shortages of medicines'¹⁴. The Commission, while noting that a certain level of stockpiling of essential medicines for emergency use was understandable, assessed that **COVID-19-related export restrictions within the EU went beyond of what were justifiable, and were not compatible with the principle of solidarity**. It therefore called on the Member States to lift export bans and restrictions, and end preventive national and localised (by wholesalers or pharmacies) stockpiling.

4. Transport barriers

The worldwide confinement, which resulted in temporary lockdowns or decreased production capacity in production sites, raw material or API suppliers, had a severe impact on the availability of essential medicines and ingredients. A decrease in air freight capacity and price increases due to the grounding of air transport, border closures within the EU and other transport barriers worsened the situation further; those caused **substantial delays in, and made expensive the transport of, medicines and ingredients**.

Selected responses to tackle the pandemic-related medicine shortage

1. Enhanced cooperation and coordination at EU level

Ensuring the continuity of supply of medicines remains the primary responsibility of pharmaceutical companies, and Member States continue to be responsible for the regulatory oversight. However, it has become clear that a more coordinated approach was needed at European level. The Commission issued comprehensive guidelines on the optimal and rational supply of medicines to avoid shortages during the COVID-19 outbreak¹⁵; EMA and the Commission brought together key figures in an executive steering group to tackle shortages; and EMA moved its cooperation with NCAs and the pharmaceutical industry to a new level.

To respond to the needs of closer cooperation and coordination, the '**EU Executive Steering Group on shortages of medicines caused by major events**'¹⁶ was launched. The Steering Group is chaired by the Commission, and composed of

representatives of the Commission, HMA, EMA, the chairs of the Coordination Groups for mutual recognition and decentralised procedures, and risk communication specialists. It is working to identify and coordinate EU-wide actions in case of supply shortage risk and ensure consistent and transparent information about the risks and the remedial actions. Since its establishment, it holds weekly virtual meetings.

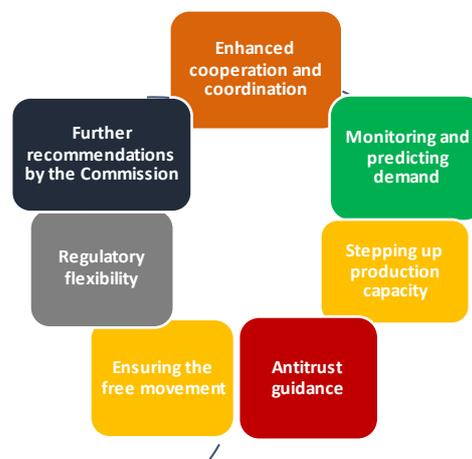
Under normal circumstances it is the NCAs who deal with most medicine shortages, but during the COVID-19 pandemic EMA acts exceptionally as a **central coordinator, and supports Member States in monitoring the supply chain**. **SPOC**, the 'Single Point of Contact' network remains in play after last year's pilot stage, ensuring direct and stable communication between EMA and the national authorities concerning shortages of all essential COVID-19 medicines, centrally and nationally authorised ones. **i-SPOC**, the 'industry Single Point of Contact System' is a newly established network, launched in mid-April 2020 for a direct communication between pharmaceutical companies and EMA on the availability of crucial COVID-19 medicines, both centrally and nationally authorised ones. In the starting phase, the system is focusing on the priority group of medicines, namely ICUs medicines across Europe, and will be extended to a broader group of medicines later¹⁷. That does not affect the reporting obligation of the pharmaceutical companies to the national authorities, and the communication between national authorities and EMA via SPOC; i-SPOC complements that flow of information, allowing EMA to gain direct insight in a timely manner from the industry.

Commissioners Kyriakides and Breton also monitor closely how the situation evolves, and hold weekly phone meetings with the pharmaceutical industry to exchange first-hand information on bottlenecks, supply and production issues.

2. Monitoring and predicting demand, matching supply and demand

The European medicines regulatory network is compiling a list of the medicines used for COVID-19 treatment, comprising **active substances identified by the national competent authorities as crucial**,

Responses to tackle the pandemic-related medicine shortage



Source: Authors's own elaboration

particularly in ICUs. These medicines, used in ICUs and are at greater demand, will be closely monitored for any possible supply problems via i-SPOC.

Pharmaceutical industry associations have taken steps to develop a **forecasting model based on industry data** that would help to predict and match demand and supply of medicines used in ICUs. **National data models** for the estimation of future needs, based amongst others on feedback from hospitals on the use of ICU medicines, are also a valuable tool in making supply matching the demand. In their last meeting the Steering Group and the heads of the NCAs agreed that **developing joint principles for modelling demand at national level**, and sharing this demand data by the NCAs, would not only contribute to short and medium-term supply and demand equilibrium, but could also help to prevent possible shortages of medicines during the expected second wave of the pandemic. The discussion on how to bring this project further will continue in their next meeting¹⁸.

3. Increasing production capacity

In the beginning of April 2020, in the wake of imminent shortage of essential ICU medicines and the export ban of paracetamol from India, Commissioner Kyriakides turned directly to the pharmaceutical companies and asked them to increase production of those medicines¹⁹. This call was reiterated a few days later in the Commission's guidelines as well, which called not on the industry but on the Member States to request, facilitate or coordinate joint industry efforts to find effective measures and resources to reduce shortages.

Stepping up the production of essential medicines by **moving their production lines and making use of free (buffer) production capacity, and increasing stocks** were amongst the most important steps that pharmaceutical companies took. **Dual sourcing** of products or materials, i.e. making use of a qualified second manufacturing site in addition to the disruption-torne primary site, where it was possible, also features on the list of measures. Being able to take these steps required that the pharmaceutical companies had already put **shortages preparedness plans** in place, and followed up on them as the public health emergency unfolded²⁰. This situation has clearly tested the resilience of the pharmaceutical supply chain²¹.



4. Antitrust guidance for securing the supply of hospital medicines

When stepping up production or switching production lines, pharmaceutical companies may need to coordinate e.g. on stock management or distribution, to avoid that all companies focus on the production of same medicines while certain essential ones are overlooked. In normal times such coordination would be contrary to antitrust rules; but in the current pandemic it can have a substantial added value from public health point of view.

In the beginning of April 2020 the Commission therefore published a 'Temporary Framework', providing **antitrust guidance to companies who wish to cooperate and coordinate their activities temporarily, in order to optimise supply of essential, in particular, urgently needed hospital medicines**²².

The Commission is giving a helping hand to companies and trade association with **assessing the legality of their arrangements, and putting in place safeguards** against longer-term anticompetitive effects; this would normally be up to the companies themselves. As yet another exceptional measure, a '**comfort letter**' (written comfort) is issued concerning specific cooperation projects that need to be swiftly implemented.

The first comfort letter was issued on the day of the publication of the temporary framework to 'Medicines for Europe'²³, related to a specific voluntary cooperation project among pharmaceutical producers. It concerns generic medicines, injectable forms of ICU medicines, which are the largest part of the critical hospital medicines urgently needed in large quantities. The Commission explained that in the pandemic such temporary cooperation was justifiable under EU antitrust law, given that it was Commissioner Kyriakides herself who requested pharmaceutical companies to work together to respond to the increased demand; and the cooperation was necessary to achieve the increases in production, and supply the medicines in the most efficient way. Granting comfort was made subject to a set of safeguards, such as keeping the cooperation open to anyone who wishes to join; working in a transparent manner; limiting exchange of confidential business information to the most indispensable pieces; maintaining the cooperation only until the risk of shortage (including a possible second wave) is overcome. The letter emphasised that any discussion of prices is out of the scope, and participating undertakings may not unduly increase prices beyond what is justified by possible increases in costs. The Commission also made very clear that it would not tolerate any conduct opportunistically seeking to exploit the crisis.

5. Ensuring the free movement of ingredients and medicines into, and within the EU

Given export restrictions and border closures, pharmaceutical companies relied on the Member States to lift the barriers to the free flow of ingredients and medicines. Ensuring '**green lanes**' for transport within the EU²⁴, **temporary easing of the entry conditions for medical goods and the use the temporary admission procedure at the external borders** of the EU²⁵ are essential in that aspect. The guidelines issued by the Commission in the beginning of April 2020 ensured that Member States apply these extraordinary measures at a uniform manner. The Commission also made all possible efforts via diplomatic channels to **ask Indian authorities to lift the export ban on paracetamol** and other active pharmaceutical ingredients.

6. Regulatory flexibility

EMA, HMA and the Commission issued a joint document, providing clarity on those issues where regulatory flexibility could help to ensure the continuous supply of essential medicines. This is a 'living document', subject to updates²⁶.

To overcome supply chain/manufacturing disruptions that MAHs experience and thus, ensure the continuity of supplies of essential medicines for COVID-19 treatment, certain regulatory flexibility is allowed. That enables MAHs to exceptionally source materials and ingredients from **suppliers not specifically mentioned in the marketing authorisation**, and use **manufacturing sites or sites responsible for quality control that are not specifically mentioned in the marketing authorisation**.

There is easing as well with regard to **Good Manufacturing Practice (GMP) certificates and GMP on-site inspections**. That does not affect, of course, the obligation of GMP-compliance; manufacturers and importers must continue to adhere to GMP, that is paramount for the safety of medicines. The flexibility concerns the validity of GMP certificates, which might be extended until the end of 2021; and GMP on-site inspections for new sites, which might be done via distant assessment. Similar flexibility applies to **Good Distribution Practice (GDP) certificates and on-site inspections** for wholesale authorisations. Guidance is also made about the conditions of the work of the so-called **Qualified Person (QP)** for remote batch inspections, batch releases and remote audits of the active substance manufacturer.

MAHs must comply with quality requirements during the pandemic as well, but there is possibility to request **adaptation of the quality control scheme**. **Individual case safe reporting (ICSR)** might also be eased, and a reporting hierarchy is established to help with prioritising reporting obligations.

Flexibility applies to **labelling and packaging**, if this helps with making available medicines in those Member States where they are needed the most. Zero-day mutual recognition procedures, compassionate use programmes and authorisation of the distribution of an unauthorised medicinal product feature among the solutions which provide flexibility with the **marketing of medicines**.

7. Further recommendations by the Commission

The comprehensive guidelines, issued by the Commission on 8 April 2020 on the optimal and rational supply of medicines, include **a broad range of recommendations to the Member States**, from reinforcing solidarity, ensuring supply, to ensuring the optimal use of medicines in hospital and optimising the sales in community pharmacies²⁷. The guidelines were developed on the basis of good practices that Member States shared with the Commission. Given their non-binding nature, and the fact that the primary competence for these issues lies with the Member States, there is no follow-up on to what extent Member States adhere to the guidelines.

- ¹ EMA guidance on shortage detection and notification https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-detection-notification-shortages-medicinal-products-marketing-authorisation-holders-mahs_en.pdf.
- ² Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02001L0083-20190726&from=EN>.
- ³ The definition of critical or essential medicines varies across the Member States; each has their own list, sometimes based on the EMA-developed criteria for critical medicines and the WHO essential medicines list. https://www.ema.europa.eu/en/documents/other/criteria-classification-critical-medicinal-products_en.pdf, <https://www.who.int/publications-detail/who-model-list-of-essential-medicines>.
- ⁴ Paper on the obligation of continuous supply to tackle the problem of shortages of medicines (European Commission, DG SANTE), agreed by the Ad-hoc technical meeting under the Pharmaceutical Committee on shortages of medicines on 25 May 2018 https://ec.europa.eu/health/sites/health/files/files/committee/ev_20180525_rd01_en.pdf.
Summary report by the European Commission, DG SANTE, for the ad-hoc technical meeting of the Pharmaceutical Committee on medicine shortages https://ec.europa.eu/health/sites/health/files/files/committee/ev_20180525_summary_en.pdf.
- ⁵ European medicines regulatory network <https://www.ema.europa.eu/en/about-us/how-we-work/european-medicines-regulatory-network>.
- ⁶ HMA/EMA Task Force on the availability of authorised medicines <https://www.hma.eu/522.html>.
- ⁷ EU-level coordination of the availability of medicines – SPOC network <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/availability-medicines#eu-level-coordination-on-medicines-availability-section>.
- ⁸ European Parliamentary Research Service (EPRS) briefing: Addressing shortages of medicines [https://www.europarl.europa.eu/RegData/etudes/BRIE/2020/649402/EPRS_BRI\(2020\)649402_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2020/649402/EPRS_BRI(2020)649402_EN.pdf).
The Economist Intelligence Unit: Addressing medicine shortages in Europe <http://graphics.eiu.com/upload/topic-pages/medicine-shortages/Addressing-medicine-shortages-in-Europe-EIU.pdf>.
- ⁹ ECDC rapid risk assessment, 9th update of 23 April 2020, Table 1 <https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-rapid-risk-assessment-coronavirus-disease-2019-ninth-update-23-april-2020.pdf>.
- ¹⁰ Treatment and vaccines for COVID-19, EMA overview <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines-covid-19#potential-treatments-under-investigation-section>.
- ¹¹ Guidelines by the Commission on the optimal and rational supply of medicines to avoid shortages during the COVID-19 outbreak (2020/C 116 I/01) [https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52020XC0408\(03\)&from=EN](https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52020XC0408(03)&from=EN).
- ¹² Note by the European Commission, DG SANTE to the Pharmaceutical Committee https://ec.europa.eu/health/sites/health/files/files/committee/ev_20200312_795_en.pdf.
- ¹³ Financial Times: Covid-19 exposes EU's dependence on drug imports <https://www.ft.com/content/c30eb13a-f49e-4d42-b2a8-1c6f70bb4d55>.
Reuters: India says will allow export of formulations of pain reliever Paracetamol <https://www.reuters.com/article/health-coronavirus-india-pharmaceuticals/india-says-will-allow-export-of-formulations-of-pain-reliever-paracetamol-idUSFWN2C5013>.
- ¹⁴ See endnote 4.
- ¹⁵ See endnote 11.
- ¹⁶ Establishment and first actions of the Steering Group <https://www.ema.europa.eu/en/news/update-eu-actions-support-availability-medicines-during-covid-19-pandemic>.
- ¹⁷ Setting up the i-SPOC network <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/availability-medicines-during-covid-19-pandemic#enhanced-monitoring-system-for-medicines-used-for-treating-covid-19-section>.
- ¹⁸ EU actions to support availability of medicines during COVID-19 pandemic

<https://www.ema.europa.eu/en/news/update-eu-actions-support-availability-medicines-during-covid-19-pandemic>;
<https://www.ema.europa.eu/en/news/eu-actions-support-availability-medicines-during-covid-19-pandemic-update-4>;
<https://www.ema.europa.eu/en/news/eu-actions-support-availability-medicines-during-covid-19-pandemic-update-6>.

- ¹⁹ Letter from Commissioner Kyriakides to the pharmaceutical companies <http://www.oeb.org.cy/wp-content/uploads/2020/04/Letter-from-Commissioners-Kyriakides-to-the-pharmaceutical-industries.pdf>.
- ²⁰ European Federation of Pharmaceutical Industry Association, EFPIA: Update on the supply of medicines to the patients that need them <https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/09042020-europe-s-covid-19-battle-update-on-the-supply-of-medicines-to-the-patients-that-need-them/>.
- ²¹ Lucker, F. & Seifert, R. W., Building up resilience in a pharmaceutical supply chain through inventory, dual sourcing and agility capacity https://openaccess.city.ac.uk/id/eprint/19503/1/FL_Main_Document.pdf.
- ²² 'Temporary framework': Commission provides guidance on allowing limited cooperation among businesses, especially for critical hospital medicines during the coronavirus outbreak https://ec.europa.eu/commission/presscorner/detail/en/ip_20_618.
- ²³ Comfort letter to 'Medicines for Europe' https://ec.europa.eu/competition/antitrust/medicines_for_europe_comfort_letter.pdf.
- ²⁴ Commission presents practical guidance to ensure continuous flow of goods across EU via green lanes https://ec.europa.eu/commission/presscorner/detail/en/IP_20_510.
- ²⁵ European Commission, DG TAXUD: Guidance on customs issues related to the COVID-19 emergency, update of 20 May 2020; sections on "Entry of goods" and "Special procedures" https://ec.europa.eu/taxation_customs/sites/taxation/files/covid-19-customs-guidance-for-trade.pdf.
- ²⁶ Questions and answers on regulatory expectations during the COVID-19 pandemic https://ec.europa.eu/health/sites/health/files/human-use/docs/guidance_regulatory_covid19_en.pdf.
- ²⁷ See endnote 11.

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IP/A/ENVI/2020-7; Manuscript completed: May 2020; Date of publication: May 2020

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This document is available on the internet at: www.europarl.europa.eu/supporting-analyses

Print ISBN 978-92-846-6732-1 | doi:10.2861/788214 | QA-04-20-283-EN-C

PDF ISBN 978-92-846-6733-8 | doi:10.2861/27241 | QA-04-20-283-EN-N