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COMMUNICATION FROM THE COMMISSION

Guidelines on the optimal and rational supply of medicines to avoid shortages during the COVID-19 outbreak

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1. Objective and Scope

These guidelines aim to protect public health and preserve the integrity of the single market, whilst ensuring that Europe has the supply of affordable medicines it needs during the COVID-19 outbreak.

They focus on the rational supply, allocation and use of medicines to treat COVID-19 patients. They also cover any medicine at risk of shortage due to the COVID-19 pandemic.

The guidelines outlined below are addressed to the EU Member States and are also relevant for European Economic Area (EEA) countries. The guidelines recognise the competency of Member States to organise the delivery of healthcare and retail sales of medicinal products. It should be stressed that they rely on the EU pharmaceutical industry acting responsibly and with solidarity.

The unprecedented nature of the outbreak may require Member States to take exceptional measures to protect public health. These guidelines have been developed based on best practices in the Member States shared with the Commission.

2. Introduction

The current crisis has highlighted many challenges in ensuring the supply of medicines needed in the EU during the COVID-19 outbreak. There are different ways to bridge the gap between supply and demand.

Demand side

The COVID-19 pandemic has led to a significant increase in the demand for certain medicines.

In EU/EEA countries with available data, around 30% of diagnosed COVID-19 patients are hospitalised[1], many of them needing oxygen therapy. For patients in critical care who need intubation, a concomitant therapy with anaesthetics, antibiotics, muscle relaxants, resuscitation medicines and anti-diuretics is essential. This has resulted in a considerable surge in the demand for these medicines and medical oxygen. Additionally, respiratory and cardiac medicines, analgesics, anti-clotting medicines, medical nutrition and large-volume parenterals are needed for intensive and supportive care of those COVID-19 patients. There has also been stockpiling of non-prescription painkillers by citizens in reaction to the pandemic. The increase in demand for medicines to treat COVID-19 can also, in some cases, threaten their availability for patients using them to manage their chronic and/or rare diseases.

The Commission, with the support of the European Medicines Agency (EMA), has been collecting data to monitor, assess and anticipate EU level shortages, notably in hospital settings. They have also collected information on overall demand from Member States and the

[1] ECDC report: Coronavirus disease 2019 (COVID-19) pandemic: increased transmission in the EU/EEA and the UK – seventh update of 25.03.2020

potential impact of third country export bans. At a technical level, EMA chairs a regular exchange with Member States on shortages in the single point of contact network ('SPOC'). The SPOC network has been used to collect information on current or expected shortages of intensive care medicines. A similar process is in place to collect direct reports, from supply chain stakeholders, of actual and anticipated shortages of critical medicines used in context of COVID-19, both for centrally authorised and nationally authorised medicines.

Supply side

The Commission has been closely monitoring the situation since the onset of the crisis. Weekly meetings with the EU associations representing the different actors of the pharmaceutical supply chain aimed to encourage industry to share information, report shortages and anticipate any disruption in the supply of critical products. The Commission has formally called on the pharmaceutical industry to increase production capacity for all medicines for which there is an increased demand as a result of COVID-19, and in particular for those for which there is a risk of supply shortages.

It has become apparent that protectionist measures are affecting the global pharmaceutical supply chain. Export bans and national stockpiling, within and outside the EU, can easily lead to inequitable supply and shortages in the EU and worldwide. Total export bans for medicines are not in line with the Treaty and impede the functioning of the single market. The European Commission is calling on all Member States to lift unjustified export bans for medicines within the internal market.

Stockpiling practices in anticipation of possible shortages can further contribute to the actual appearance of such shortages. While a certain level of stockpiling of essential medicines for emergency use is understandable, generally speaking, the more localised the stockpiling, the greater will be the tendency towards an unsustainable increase in aggregate anticipatory demand which, if supply cannot follow suit, will lead to shortages in places where needs have materialised. Stockpiling at EU level (e.g. through RescEU) is therefore the optimal solution for all Member States, and any stockpiling by Member States should be at national level and for moderate quantities based on epidemiological indications.

Decreased production capacity, closure of raw material/active pharmaceutical ingredients (API) suppliers, logistics issues in affected countries, as well as transportation barriers between countries also have a direct impact on the availability of medicines, as well as on the development of new treatments against COVID-19. Worldwide confinement measures have led to disruptions and increased prices for air freight and shipping.

It is important to acknowledge that no country is self-sufficient in the raw materials, intermediates, APIs and finished medicines required to ensure a well-functioning healthcare system.

The elements outlined above all contribute to an increased risk of shortages of essential COVID-19 medicines (referred to here as *essential medicines*). It is therefore critical to optimise and rationalise supply, allocation and use to ensure the optimal availability of the essential medicines needed to respond to the pandemic.

3. Showing solidarity

a. Lifting export bans and restrictions

Member States are expected to protect public health in a spirit of European solidarity.[2] In order to achieve this objective, 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. Measures leading to requisitioning of medicines, intermediates or APIs, or their production, should not be considered as an option. These measures, especially as far as they are applied to APIs or intermediates, endanger supply since they lead to a slowdown in industry output.

b. Avoiding national stockpiling

The COVID-19 pandemic affects all Member States. They must ensure that essential medicines are available in the hospitals and pharmacies that need them most, regardless of their location. Preventive stockpiling by Member States puts supply at risk for all countries. A fortiori, more localised stockpiling can be even more harmful - Member States should therefore ensure that stockpiling by wholesalers and pharmacies (including by hospital pharmacies) is prevented.

c. Avoiding that misinformation leads to improper use and unnecessary stockpiling

In order to prevent panic buying or irrational consumption by citizens and excessive purchasing by wholesalers and pharmacists, national authorities should ensure that supply chain actors have access to reliable information on the use of medicines in the context of COVID-19. Member States should inform citizens of the actions taken to address actual and potential problems of availability and correct any misinformation concerning shortages. Member States should also take account of communication by the European Medicines Agency.

4. Ensuring supply

a. Increasing and reorganising production

The current crisis requires a significant increase of production. It might also require to re-organise supply chains and production lines and tap on existing stocks to increase output as quickly as possible. Where such temporary measures of pharmaceutical companies require cooperation or coordination with other companies in order to ensure continued care for COVID-19 patients, the Commission is ready to provide guidance and legal certainty to these companies on their compliance with EU competition rules.[3]

The Member States, with the support of the Commission and the European Medicines Agency should continue:

[2] Communication to the European Parliament, the European Council, the Council, the European Central Bank, the European Investment Bank and the Eurogroup on coordinated economic response to the COVID-19 outbreak of 13.03.220, COM(2020)112 final

[3] See also: Communication from the Commission on the Temporary Framework for assessing antitrust issues related to business cooperation in response to urgency situations related to the current COVID-19 pandemic of 8 April 2020, C(2020)3200

- to request that actors in the supply chain monitor their stocks and production capacity, share information with authorities, report shortages and monitor any potential disruptions in the supply of essential medicines;
- to request, facilitate and coordinate, as need be, joint industry efforts to find effective measures and resources to reduce shortages and meet the demand for COVID-19 medicines; and,
- to implement, as need be, demand support and procurement initiatives to encourage appropriate supply to patients (EU level tools such as RescEU and the EU joint procurement agreement can be considered, as well as the Emergency Support Instrument when approved by the budgetary authority).

b. Ensuring manufacturing continues at full capacity

Pharmaceutical manufacturing (including all necessary raw materials and components) should be designated as an essential activity and allowed to continue operating. In particular, manufacturing of essential medicines should be increased, where possible or at least maintained at their current level. Member States should support industry increasing their manufacturing capacity, in particular through fiscal incentives and State aid.[4] It is of utmost importance to ensure that products considered essential to protect public health remain available at competitive prices.[5]

Additionally, the following measures are fundamental to ensure that production capacity can function optimally:

- Member States should ensure access to personal protective equipment (PPE) for actors in the pharmaceutical supply chain as they are not only required by applicable EU legislation on occupational safety and health but are also necessary to prevent cross contamination and ensure the quality of medicines.
- Employees working in manufacturing sites should be allowed to continue to travel to their place of work. Particular flexibility should be granted to cross-border workers in line with Commission guidelines.[6]

c. Implementing regulatory flexibility

To ensure sufficient supply and optimise manufacturing capacity, it is recommended that Member States grant regulatory flexibility to the pharmaceutical industry in the context of variations to marketing authorisation according to the relevant guidance.

Taking into account the current unprecedented crisis, the procedures for changes in suppliers of APIs, the designation of new manufacturing sites or the extension of expiry dates should be accelerated as long as quality is ensured.

Simplified control procedures could also be introduced for controlled substances that fall under international rules against the illicit traffic of drugs and psychotropic substances and

[4] Communication from the Commission on Amendment to the Temporary Framework for State aid measures to support the economy in the current COVID-19 outbreak of 3.04.2020, C(2020) 2215 final

[5] Joint statement by the European Competition Network (ECN) on application of competition law during the Corona crisis of 23 March 2020 (https://ec.europa.eu/competition/ecn/202003_joint-statement_ecn_corona-crisis.pdf)

[6] Commission Communication concerning the exercise of the free movement of workers during COVID-19 outbreak of 30.03.2020, (2020/C 102 I/03)

that are used to manufacture many intensive care medicines. In some cases, administrative procedures slow down movement of these substances cross-border within the EU. The processing of import permits should, therefore, be accelerated and facilitating the movement of medicines containing controlled substances across Member States should be considered in compliance with International Narcotic Control Board advice.

d. Monitoring available stocks at national level

Member States should share information with marketing authorisation holders (MAHs), wholesalers and hospital pharmacies, such as epidemiological forecasts[7], that help them to better plan for increased demand and respond to that Member State's needs. Contacts between national authorities and industry should be organised via a single contact point. Information received from industry should be shared at EU level via the SPOC network coordinated by EMA. The European Commission should be directly informed of any supply issues due to third country export bans that require political outreach. On their side, marketing authorisation holders should ensure that Member States authorities are promptly informed of any potential or expected shortages and other relevant information.

e. Ensuring necessary support to the wholesale sector

Medicines wholesalers are responsible for distributing medicines within the EU/EEA. They must be allowed to continue operating at full capacity and supply medicinal product to hospitals and pharmacies. Their employees should have access to the necessary PPE. In order to ensure deliveries, vehicle drivers should also receive permits to travel without restriction and access hospitals, pharmacies and other dispensing sites (especially in quarantined areas).

f. Fully enforcing the green lanes

Pharmaceutical production and distribution is multinational and vulnerable to border control delays. It is important to fully implement green lanes, established to facilitate transport of all goods, as they will allow for smooth transport of not only medicinal products, but also raw materials, intermediates, APIs, substances of human origin (e.g. plasma), and related materials such as packaging.[8] In order to effectively facilitate transport, trucks travelling to/from manufacturing sites after or before pick-up must also be allowed to cross borders without delays.

g. Facilitating air freight and other forms of transport

The current confinement measures have led to a decrease in air freight capacity and price increases. The pharmaceutical industry relies mainly on small volume shipments by air. Member States should consider actions to ensure air cargo capacity for transport of medicines, APIs, intermediates and raw materials in line with Commission guidelines.[9] Member States should encourage cargo and express airlines to exceptionally reserve capacity for the supply of essential goods, in particular medical and emergency supplies, and to apply reasonable shipping rates for such supplies.

[7] One example are the EPI forecasts: https://epiforecasts.io/covid/posts/global/

[8] Guidelines for border management measures to protect health and ensure the availability of goods and essential services adopted on 16 March 2020, (COM (2020) 1753final) and Communication on the implementation of the Green Lanes, C(2020) 1897 final

[9] Communication from the Commission on facilitating air cargo operations during COVID-19 outbreak adopted on 26.03.2020, C(2020) 2010 final

Similarly, maritime cargo services need to run smoothly and without unnecessary delays to ensure the continuity of supply chains.[10] In order to effectively facilitate transport, inland vessels travelling to manufacturing sites after or before pick-up must also be allowed to cross borders without delays.

h. Ensuring fair distribution of supply

Member States should ensure that wholesaler distributors, community pharmacies and hospitals receive their usual stocks of medicines. Supplementary demand (voluntary stockpiles) must be justified according to the number of COVID-19 patients in the affected area. In situations of high demand, national coordination between authorities, procurers and industry should be put in place to guarantee an equitable distribution of medicines. In order to ensure adequate supply, and especially in case of urgent demand, the flexibilities outlined in the Commission guidance on using the public procurement framework in the emergency situation related to the COVID-19 crisis should be taken into account.[11]

It is recommended that procurement is organised regularly at short intervals to avoid shortages and prevent stockpiling. As much as possible, in order to increase efficiency, purchases for hospitals should be bundled and organised by central purchasing bodies active in the healthcare sector.

5. Optimal use of medicines in hospitals

a. Equitable distribution of available medicines

National authorities should be able to reallocate stock between hospitals depending on needs. The supply of essential medicines to hospital pharmacies must be coordinated at the appropriate level that allows an efficient and equitable distribution of the available medicines, depending on Member State's organisation and structure. National authorities should monitor stocks and demand by organising an efficient reporting system that allows hospital pharmacies to communicate available and required stocks of essential medicines once or even several times per week. This should allow the reallocation of stocks to the hospitals most in need. Coordinated or aggregated purchasing also helps to allocate supplies depending on hospital needs.

b. Exchanging hospital protocols to treat patients

The use of the medicines in the hospitals should follow validated hospital protocols that optimise the amount of medicines used to treat patients. Such protocols should be based on evidence and adapted following experiences in treating COVID-19 patients. Member States should encourage exchange of those experiences. Optimised protocols with confirmed outcomes should be made available to share between hospitals EU wide. Hospitals may

[10] Commission Communication concerning Guidelines on protection of health, repatriation and travel arrangements for seafarers, passengers and other persons on board ships adopted on 8 April 2020, C(2020)3100
[11] Guidance from the European Commission on using the public procurement framework in the emergency situation related to the COVID-19 crisis (2020/C 108 1/01)

benefit from the COVID-19 Clinicians network[12] established by the Commission to adjust their protocols for better clinical outcomes and in order to optimise the use of medicines.

c. Considering alternative medicines on the basis of hospital protocols and national guidelines

In case of confirmed medicines shortages, hospitals should adapt their existing protocols or establish new validated protocols that identify the optimal alternative. This information should be shared with the marketing authorisation holder and wholesalers, as appropriate, to facilitate their ability to supply alternative medicines in case of shortages of first-line treatments.

d. Extending the expiry dates of medicines

Hospital pharmacies may have stocks of medicines close to or past their expiry dates. Marketing authorisation holders should be invited to request the extension of the expiry dates of batches of essential medicines where possible, based on stability data to the relevant national authorities.

e. Considering the use of magistral preparations or veterinary medicines

Magistral preparations should be used to replace unavailable medicines. In case of critical shortages of essential authorised human medicines, using equivalent medicines (the same active substance, strength and pharmaceutical form) authorised for veterinary use should also be considered. Substitution should always be carefully assessed and authorised by the appropriate national authority taking into account the possible specificities of the veterinary sector. Special attention should be given to ensure appropriate dosing and additional reporting of adverse reactions. Where regular sources are exhausted, essential medicines should be allowed to be sourced outside the EU/EEA under the supervision of national authorities or the European Medicines Agency.

f. Using medicines off label and in clinical trials

For medicines under development or medicines currently authorised for other diseases and used to treat COVID-19 patients outside their authorised indications ("off-label") used under national early access programmes or in clinical trials, it is important that a complete forecast can be made of the supplies needed taking into account the needs of patients using these medicines on-label. Preference needs to be given to setting up large, as much as possible European, clinical trials as these are necessary to generate the robust data required to establish evidence of their efficacy and thus to provide appropriate advice to healthcare professionals and patients and enable regulatory decision-making.

6. Optimisation of sales in community pharmacies to avoid hoarding

a. Introducing measures to reassure persons reliant on medication

Patients may be tempted to hoard medicines to avoid visiting pharmacies and being exposed to coronavirus during the pandemic. Member States should therefore encourage alternative

[12] COVID-19 Clinical Management Support System: https://ec.europa.eu/eusurvey/runner/COVID19CENTRES

delivery measures to prevent excessive purchasing by citizens, at least limited to patients in risk groups (e.g. home delivery services set up by local community pharmacies).

b. Introducing restrictions on sales in community pharmacies

Member States should limit dispensing and sales of certain prescription and non-prescription medicines (for example only allowing a one-month supply of prescription medicines, or a maximum of one package per customer of non-prescription medicines). Member States should apply these limits for medicines at risk of shortages or subject to increased demand.

c. Limiting online sales of products at risk

Limitation of online sales of essential medicines may be temporarily considered to better control the supply of essential medicines to patients. Members States should also consider strengthening information regarding the common EU logo that identifies legally operating on-line retailers to avoid that patients buy falsified medicines from unauthorised sellers.

d. Reassuring patients

Member States should promote the rational use of medicines and reassure the public of the availability and safe use of medicines. Member States should also inform citizens of any European Medicines Agency recommendations.[13]

[13] Such as the European Medicines Agency (EMA) recommendation on the use of non-steroidal anti-inflammatories for COVID-19: https://www.ema.europa.eu/en/documents/press-release/ema-gives-advice-use-non-steroidal-anti-inflammatories-covid-19_en.pdf