

Strengthening the Health Systems Response to COVID-19

Technical guidance #3

Supply of essential medicines and health technologies (6 April 2020)

This paper is one of a set of technical guidance papers developed by the WHO Regional Office for Europe to provide practical information and resources for decision-makers on measures to strengthen the health system response to COVID-19.

The purpose of this paper is to provide WHO Regional Office for Europe Country Offices and Member States with guidance on how to maintain supplies of medicines and health technologies, including devices, diagnostics and blood products, during the COVID-19 outbreak.

This paper supports the operationalization of the policy recommendations for the WHO European Region on strengthening the health system response to COVID-19, focusing on policy recommendation No. 11 (Table 1).

Table 1 Summary of 16 health system policy recommendations to respond to COVID-19

1. Expand capacity for communication and pro-actively manage media relations.	2. Bolster capacity of essential public health services to enable emergency response.	3. Clarify first point of contact strategy for possible COVID-19 cases: phone, online, physical.	4. Protect other potential first contact health system entry points.
5. Designate hospitals to receive COVID-19 patients and prepare to mobilize acute and ICU surge capacity.	6. Organize and expand services close to home for COVID-19 response.	7. Maintain continuity of essential services while freeing up capacity for COVID-19 response.	8. Train, repurpose and mobilize the health workforce according to priority services.
9. Protect the physical health of frontline health workers.	10. Anticipate and address the mental health needs of the health workforce.	11. Review supply chains and stocks of essential medicines and health technologies.	12. Mobilize financial support and ease logistic and operational barriers.
13. Assess and mitigate potential financial barriers to accessing care.	14. Assess and mitigate potential physical access barriers for vulnerable groups of people.	15. Optimize social protection to mitigate the impact of public health measures on household financial security.	16. Ensure clarity in roles, relationships and coordination mechanisms in health system governance and across government.

The guidance will be updated on a regular basis using best available evidence and emergent country practices in response to the COVID-19 outbreak in the WHO European Region, including knowledge and evidence generated through the joint WHO Regional Office for Europe/EU Commission/European Observatory platform.

During the COVID-19 outbreak, regular supply chains of essential medicines and health technologies may be disrupted. Countries will want to procure the same products at the same time; therefore, ensuring sustainable access to medicines and health technologies during this period will be challenging. Within each country, it will be important that an effective and collaborative supply process is maintained. Communication channels should be established between all those involved, including between ministries of health, national medicines agencies, procurement agencies, and those involved in distribution and logistics. Good communication, including with the private sector, is essential to maintain supplies to the population.

In summary and order to ensure emergency access to medicines and health technologies, countries should ensure that they have in place:

- Emergency standard operating procedures (SOPs) for logistics/fast track procurement
- Operationalized mechanisms to deploy and receive medical countermeasures and other supplies
- An effective procurement system for distribution of essential medicines, and ensure that other medical materials, including personal protective equipment (PPE) (as defined in the WHO commodity package), are in place for timely and equitable access to life-saving interventions
- Emergency market authorization for new essential medicines

1. Key issues

Delays: Significant numbers of shipments of active pharmaceutical ingredients (API), other components and finalized pharmaceutical products (FPPs), health products and vaccines are being delayed due to the abrupt limitation of flights coming in and out of European airports, as many supplies rely on cargo space in passenger flights. Bans established by countries in the Region on passenger flights from Asia, European Member States and the USA would affect timely deliveries. Most generic antiretrovirals and medicines are sourced from India. However, their APIs and/or excipients of these products are manufactured in affected countries, such as China. The impact on the production capacity of these countries will change over time.

High prices: It is anticipated that prices may rise where additional sources/freight arrangements must be made, but procurers should be vigilant against price hikes and ask for justification where there are concerns.

Shortages: The international pharmaceutical industry and generics associations are reporting that members have stocks on hand for 2–3 months and are not reporting shortages of medicines, except for paracetamol and chloroquine products. Companies are being requested to provide early notification to WHO of potential shortages. National suppliers should also be requested to provide early notification.

2. Recommendations and strategic actions

Strategic actions	What may this involve?
Selection	<ul style="list-style-type: none"> • Ensure that there is a priority list of medicines and health products to focus resources on those whose supply should be maintained. For example, medicines against COVID-19, priority medical conditions and types of medicine that should not be stopped abruptly or changed; for example, medicines for HIV, tuberculosis, noncommunicable diseases, epilepsy or mental health medicines. • Standard WHO guidance is that countries should only be procuring medicines listed on their national essential medicine list (NEML). Where this list exists, it should be updated or emergency exception provisions should be put in place to allow for acceptable alternatives/substitutes where medicines are in short supply. • Medicines procured for COVID-19 should be aligned with the guidance in Clinical management of severe acute respiratory infection when novel coronavirus (nCoV) infection is suspected (WHO, 13 March 2020): https://www.who.int/publications-detail/clinical-management-of-severe-acute-respiratory-infection-when-novel-coronavirus-(ncov)-infection-is-suspected • All guidance documents and lists should refer to medicines by their international nonproprietary name (INN) rather than brand name alone. • Identify, validate and expand (when needed) the list of prequalified potential suppliers and manufacturers. In emergency situations, do not stockpile as this will threaten the global supply. However, increase buffers in accordance with lead times, which should be monitored and increased where necessary. Medicines that are being purchased from a single supplier are particularly vulnerable; these medicines should be identified and other routes sourced to protect suppliers, including purchase from alternative sources, such as UN agencies or wholesalers. Investigate local production of critical products to reduce reliance on foreign sources. • Consult WHO guidance for local production of handrub formulations: https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf (The link below gives the legislation in France for the production of handrub in community and hospital pharmacies: https://www.legifrance.gouv.fr/affichTexte.do;jsessionid=452B07D28542E0FEA2EE E45F3E930FB6.tplgfr25s_3?cidTexte=JORFTEXT000041697126&dateTexte=&oldAction=rechJO&categorieLien=id&idJO=JORFCONT000041697001)

Strategic actions	What may this involve?
Legislation	<ul style="list-style-type: none"> • A review of existing legislation and regulations should be undertaken to identify any potential barriers to maintaining supply and implementing the guidance given below. For example, identify what impediments exist to purchasing from international agencies, centralizing procurement or provision of packaging and documents in local languages. Emergency mechanisms for procurement should be in place. • Where available, Trade-Related Aspects of International Property Rights (TRIPS) flexibilities to enable local production should be considered to override patents of key medicines and health products in cases in which they become in short supply.
Registration and marketing authorization	<ul style="list-style-type: none"> • In some circumstance, please check options and documentation required to obtain a waiver for importing medicines and health technologies. Most countries have legislation requiring that all medicines in circulation need to be registered in the country. In exceptional circumstances, waivers to this requirement can be obtained to allow importation of alternatives or new products. These routes are likely to be needed, and procedures and documentation requirements should be clarified. • All medicines and health products supplied during an emergency should comply with the existing national quality standards. Where capacity is limited, it is acceptable if those products are demonstrated to comply with external quality standards. This WHO document (http://apps.who.int/medicinedocs/en/m/abstract/Js23326en/) provides additional and specific guidance to the National Regulatory Authorities (NRAs) of non-vaccine-producing countries when dealing with pandemic influenza emergencies; this can be expanded to include all medicines (including vaccines) and health technologies in the case of emergency situations.
Quantification	<ul style="list-style-type: none"> • If possible, explore the existing provision of medicines and medical products in the country (expiry dates etc.) and what is in the pipeline. • Determine the appropriate quantity of medicines and health products to procure. Adjust for past shortages, surpluses and programme growth. Start with accurate past-consumption data from all units being supplied. • Some online tools exist to evaluate the quantity of medical products being ordered: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/covid-19-critical-items https://www.iplusacademy.org/course/view.php?id=98 • Increase procurement volume by aggregating demand and centralizing the purchase of medicines and health products on the essential lists to avoid duplications and internal competition for limited supplies. This could be facilitated by emergency legislation or ministerial orders. In addition, larger volumes could attract more potential suppliers and could lower prices. • Consider increasing the buffer stock/stockpile for essential medicines, including for chronic diseases at all levels. Depending of the lead time, the buffer stock can be adjusted.
Procurement	<ul style="list-style-type: none"> • Develop transparent and written procedures for all emergency procurement actions. • It is anticipated that prices may rise where additional sources/freight arrangements have to be made; procurers should be vigilant for unjustified price hikes and ask for justifications where there are concerns. Consider mandatory reporting and publishing of prices of key products so that procurers and the public can check.

Strategic actions	What may this involve?
	<ul style="list-style-type: none"> • Promote the use of centralized request management and procurement to avoid duplication of stock. • Approach potential suppliers and distributors directly. Only reliable sources for procurement should be considered. Allow only prequalified suppliers to compete in restrictive tenders. • Usual lead times may vary in pandemic situations; this should be checked, including from international procurement agencies. • For products at risk of short supply, particularly where a contract is held with a single source, the Ministry of Health should identify additional suppliers; for example, those that submitted unsuccessful bids during previous tendering exercises. • Check if foreign language packages can be imported. • Consider procuring medicines with shorter shelf lives. • Consider procuring Emergency kits (from WHO online catalogue, only available for WHO staff). http://intranet.who.int/tools/wcat/QuickSearch.aspx
Distribution	<p>Transport and logistics:</p> <ul style="list-style-type: none"> • WHO is in close communication with suppliers and global partners, including regulators, and is continuously monitoring the market situation and logistics challenges to procure and deliver vaccines, syringes, essential medicines and diagnostics kits. • Ensure sufficient certified transport capacity for transporting health products in good conditions, with respect to temperature, humidity, exposure to light etc. • Take steps to ensure efficiency of transport for example, avoid travelling half empty • Ensure good planning in the light of the increased difficulties faced by all countries. <p>Storage:</p> <ul style="list-style-type: none"> • Ensure sufficient capacity to store health products in good conditions, with respect to temperature, humidity, exposure to light etc. • Keep stock moving. • Improve efficiency (reduce number of warehouses, contract-out transport). • Assess the storage capacity of primary, intermediate and health facility stores.
Shortages	<ul style="list-style-type: none"> • A mechanism should be created to provide information to professional societies, health care providers and the public notifying of anticipated shortages and the substitutes that should be used. • For antimicrobials, substitutes should be made within the same Access, Watch and Reserve category. Reserve categories should only be substituted when absolutely necessary and within their licensed indications. • National treatment guidelines should be developed to help health workers follow the recommended treatment. • To maintain stocks, it is particularly important to ensure that medicines are supplied only by prescription, unless in emergency situations in which prescriptions cannot be obtained. • Some countries are banning parallel export and putting restrictions on exports by national manufacturers. This is limiting the availability of products available for procurement and may put existing contracts at risk. For example, this is the case with ventilators.

Strategic actions	What may this involve?
	<ul style="list-style-type: none"><li data-bbox="462 275 1344 348">• Identify additional suppliers and explore for products at risk other options, as repurpose local manufacture and repair.

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3. Helpful resources

Supply of tests: With the sharply increased demand for in vitro diagnostic tests to detect SARS-CoV2, the causative agent of COVID-19 disease, supply of sufficient quantities of reliable tests is becoming problematic.

For a list of diagnostics approved for clinical use, more information can be found at:

- WHO Pre-qualification Webpage on Emergency Use Listing for Diagnostics (https://www.who.int/diagnostics_laboratory/EUL/en/)
- Link to all regulators approving diagnostics (https://www.who.int/diagnostics_laboratory/200326_imdrf_collated_table_26_march_2020.pdf)
- US FDA: an emergency use authorization (EUA) has been issued to authorize the emergency use of specific test kits (<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd>)
- FIND: COVID-19 diagnostics (<https://www.finddx.org/covid-19/>)
- Australia: diagnostic tests included on the Australian Register of Therapeutic Goods (ARTG) for legal supply in Australia (<https://www.tga.gov.au/covid-19-diagnostic-tests-included-artg-legal-supply-australia>)

Medical devices: WHO has developed technical specifications for devices to be used for Covid-19 response (<https://www.who.int/emergencies/what-we-do/prevention-readiness/disease-commodity-packages/en/>).

Solidarity trial: Research is ongoing into vaccines and treatments for COVID-19, including repurposing existing medicines. A COVID-19 Core Protocol for clinical trials has been produced to compare the effects of management outcomes.

Please see here for updates: <https://www.who.int/thailand/news/detail/20-03-2020-thailand-joins-the-who-solidarity-trial-global-testing-of-effective-treatments-of-covid-19-across-8-countries-an-aggressive-effort-to-save-lives-from-the-pandemic>.

Blood safety: WHO's interim guidance on "Maintaining a safe and adequate blood supply during the pandemic outbreak of coronavirus disease 2019 (COVID-19)" provides guidance on the management of the blood supply in response to the pandemic, including the possible support of the blood services for the collection of convalescent plasma for treatment of COVID-19 patients (https://www.who.int/bloodproducts/brn/2017_BRN_PositionPaper_ConvalescentPlasma.pdf).

Oxygen therapy devices: WHO-UNICEF technical specifications and guidance for oxygen therapy devices

(https://www.who.int/medical_devices/publications/tech_specs_oxygen_therapy_devices/en/)

Laboratories: COVID-19 technical guidance: Laboratory testing for 2019-nCoV in humans

(<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance>).