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COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Addressing medicine shortages in the EU

1. INTRODUCTION

Continued availability of medicines is essential: shortages put the health and well-being of citizens at risk. The COVID-19 pandemic and the Russian military aggression against Ukraine exposed Europe's supply chains dependencies and the risk that economic dependency could be weaponised. This has also heightened awareness of the risk of medicine shortfalls, experienced across all Member States[1] and involving both original and generic medicines[2]. During the winter of 2022-2023 shortages of key medicines, such as antibiotics, triggered particular public and political concern.

A new approach is needed to better tackle medicines shortages in the European Health Union. This was highlighted in the call from the June 2023 European Council for urgent measures to ensure sufficient production and availability of the most critical medicines and components[3]. This feeds into a broader strategic agenda, confirmed by EU leaders at their meeting in Granada in October 2023, of putting in place a concerted approach to boost the EU's resilience and sustainable competitiveness through diversification and risk management in the spirit of open strategic autonomy[4].

The EU has a strong and competitive pharmaceutical sector, a global leader in the production of medicines and a major contributor to the EU economy, directly employing some 800.000 people. It is particularly strong in the research and development of innovative medicines. However, the landscape for pharmaceutical manufacturing has evolved in recent decades. Production of inputs for generic medicines has increasingly moved outside Europe, in particular to China and India. Pharmaceutical production in the EU has focused on more complex products, which require high-tech infrastructure, a skilled workforce and sophisticated processes[5]. At the same time, almost 70% of the medicines dispensed in Europe are generics.

Ensuring that this strong basis carries through into a secure medicines supply meeting patients' needs means addressing the vulnerabilities affecting supply chains. The delocalisation of the manufacturing of Active Pharmaceutical Ingredients (API) to a limited number of locations outside the EU has accentuated concerns about security of supply inside the EU. Addressing vulnerabilities in the supply chain of critical medicines is key as a springboard for enhanced resilience of EU healthcare systems. In addition to labour shortages that may hamper ambitions to increase local production, demographic changes are also having an impact on access to certain critical medicines, by raising demand for medicines tailored to age-related conditions and geriatric care, thus influencing pharmaceutical R&D priorities.

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1 A Commission study confirmed that the problem was widespread: "Future-proofing pharmaceutical legislation – Study on medicine shortages (2021)".

2 A generic medicine is a medicine that is developed to be the same as a medicine that has already been authorised. A company can only market a generic medicine once the regulatory and intellectual property protections of the original medicine have expired.

3 June 2023 European Council conclusions.

4 See Commission Communication "Towards a more resilient, competitive and sustainable Europe" (COM(2023) 558) and https://www.consilium.europa.eu/en/press/press-releases/2023/10/06/granada-declaration/.

5 Impact assessment report and executive summary accompanying the revision of the general pharmaceutical legislation, annex 5, 2023.

The EU market for medicines remains fragmented, despite the EU having a single market and being the second largest market for pharmaceuticals in the world. The organisation of healthcare systems is a national competence of Member States: this allows decisions closer to the patient, but also brings major divergences in both pricing and patient access. Better and closer coordination between national authorities opens the door to a more efficient and effective supply of medicines throughout the EU.

The continued availability of safe, effective and affordable medicines for patients is a foundation of the strong European Health Union now being built[6]. The reinforced mandate of the European Medicines Agency (EMA) has already strengthened the coordinated and collaborative EU level management of critical shortages. The Commission's Health Emergency Preparedness and Response Authority (HERA) is supporting with foresight and emergency preparedness to ensure the availability of medical countermeasures. The Union Civil Protection Mechanism is providing stockpiles of critical medical countermeasures that can be quickly deployed when Member States cannot cope with a health emergency. The upcoming HERA review will further look into reinforcing HERA's capacity to act in this area, in order to reinforce security of supply and ensure the availability of medicines for healthcare systems and patients in the EU at all times.

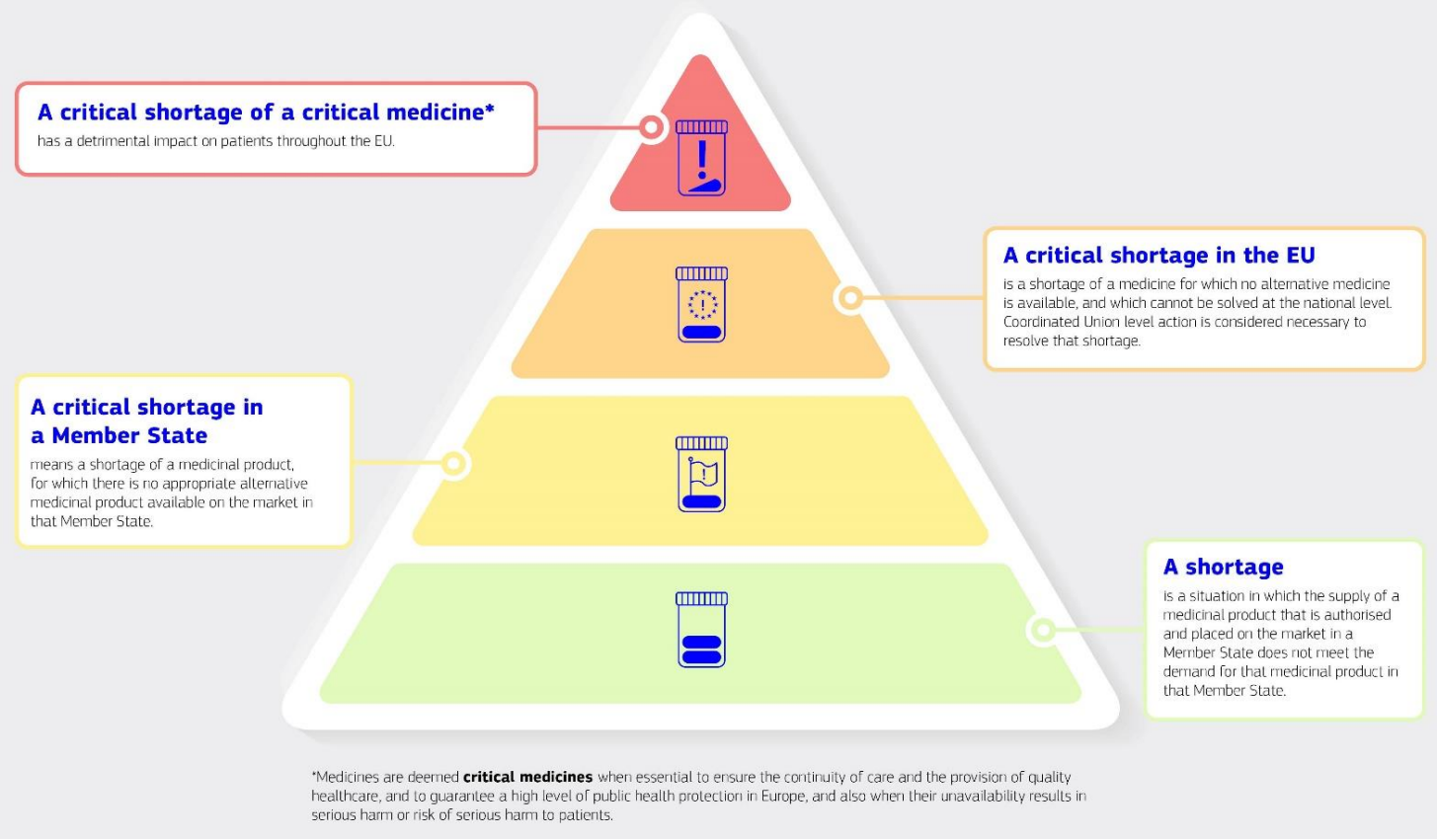
The reform of the EU pharmaceutical legislation[7] is essential to take the work on critical shortages and security of supply forward, building a pharmaceutical ecosystem that is competitive, future-proof and with a single market in medicines benefitting all Europeans. **The Commission therefore calls on the European Parliament and the Council to ensure its swift adoption, as did the European Council**[8]**.**

This Communication builds on the work under way and sets out steps the EU can take to make a difference in the availability of medicines to patients across the EU, for the coming winter and more structurally. This work will cover both generic and innovative medicines, as well as their ingredients. The Communication puts forward a broad set of short-term and longer-term actions to address shortages of medicines and enhance their security of supply in the EU, by providing predictability and a comprehensive and coordinated approach with stakeholders at EU and global level. The key goals are to prevent or mitigate ***critical shortages*** at EU level and to assure a particular focus on the most ***critical medicines*** for which security of supply needs to be assured in the EU at all times, in normal times, and in times of crisis.

6 Commission Communication on Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats

7 COM(2020) 761; COM(2023) 193 and 192.

8 June 2023 European Council conclusions.



The EU system today: supporting Member States' efforts to address shortages

Member States are responsible for the supervision of medicines supply in their territory and most shortages are managed and resolved at national level. However, the EU has been building tools to address critical shortages which require EU-level coordinated action, as well as to bring more structural support to security of supply of critical medicines:

- ***Obligations on suppliers****:* companies have a legal obligation to "ensure appropriate and continued supplies", so that the needs of patients in the Member State in question are covered[9]. In addition, companies should notify any interruption of supply to the competent authority. This has not prevented shortages arising due to unforeseen events outside of the control of the companies (such as manufacturing issues or natural disasters) or commercial decisions (including, most obviously, a lack of profitability).
- ***EU-level coordination****:* over recent years, the EU has improved coordination between Member States to better respond to critical shortages in a timely and coherent manner. Under the European Health Union, the ***EMA***'s mandate has been reinforced, so that it can more effectively monitor and mitigate shortages by coordinating, in cooperation with Member States, EU-level management of critical shortages, as well as the response to specific public health emergencies[10]. The added value of this enhanced

9 Article 81(2) of Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67.

10 This is coordinated through an Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), composed of representatives of Member States, the Commission, EMA and observers from patients and healthcare professionals' organisations.

cooperation has been shown in recent cases of shortages of a medicine dissolving blood clots and a medicine against vision loss. Joint policies and guidance on shortage prevention, management and communication to the public, including to avoid the risk of hoarding by citizens, have been also developed[11]. In addition, ***HERA*** plays a key role in ensuring availability of medical countermeasures, as shown by the EU Vaccines Strategy and joint procurements of COVID-19 therapeutics.

- ***Dialogue with industry***: for critical shortages, regulators consult with a broad range of industry through the EMA, working with Member States to assess the situation and decide whether specific recommendations should be adopted. The coordination with industry beyond regulatory context is now complemented by HERA, including by the Joint Industrial Cooperation Forum.
- ***Joint procurement****:* the joint procurement of medicines or the procurement of medicines on Member States' behalf (e.g. in the case of the COVID-19 pandemic) provided a powerful tool to improve access, affordability, and security of supply, of particular benefit in smaller EU markets.
- ***Stockpiling****:* the work of the Union Civil Protection Mechanism (UCPM) to coordinate in-kind assistance extends to cross-border health threats[12]. Strategic reserves at EU level under rescEU were created during the COVID-19 pandemic and have been further developed as a safety net in the event that national stocks do not suffice. With the creation of HERA, EUR 1.2 billion has been devoted to this work.

These steps have provided vital experience for building a more comprehensive and effective EU approach to address critical shortages and secure supply of critical medicines.

2. MITIGATING CRITICAL SHORTAGES IN THE IMMEDIATE AND SHORT TERM

During the winter of 2022-2023, many Member States experienced critical shortages of certain antibiotics, endangering the health of patients and risking the development of antimicrobial resistance. These critical shortages were the result of changing infection patterns, which strongly increased demand. On the supply side, the long lead times needed to boost production made it difficult to respond quickly. This experience underlined the need for a dedicated effort – from the industry, as well as from Member States and the EU level to address the issue of critical shortages.

There are many ways in which the EU can already act to prevent and tackle critical shortages. Further implementing these measures represents a major enhancement of the EU's ability to address the risk of medicine shortages in a coordinated manner.

Avoiding critical shortages of key antibiotics over the coming winter

To better prepare for winter 2023-2024, the EMA and HERA have identified a subset of key antibiotics (including specific paediatric formulations) for which they have simulated

[11] Through the coordinated work of the Heads of national medicines agencies and the EMA and Based on the EU Medicines Agencies Network Strategy to 2020 (europa.eu).

[12] Examples of support from the UCPM in the case of medicine shortages include Doxycyline in Brazil (2021) and immunoglobulin in Romania (2018, 2022). Health emergencies managed through the UCPM include Ebola (DRC 2021, Guinea 2020, West Africa 2014), and the UCPM has delivered medicines in many other emergencies, including the Russian military aggression against Ukraine.

the planned supply and estimated demand, to anticipate the risk of critical shortages. This work has been conducted in close collaboration and with the support of Member States and the industry.

The following measures aim to improve availability of certain key antibiotics in 2023-24:

- Continuous monitoring of forecasts of supply and demand, in cooperation with companies and national authorities.
- Interaction between Commission, EMA and companies, so that measures to prevent potential shortages through, for example, increased manufacturing capacity have been put in place.
- Deploying regulatory flexibilities (see below) where needed to prevent and manage critical shortages.
- Deploying, where needed, the Voluntary Solidarity Mechanism for medicines (see below).
- Intensified exchange of information with international regulators, as a channel for early warning of critical shortages identified elsewhere in the world.
- Targeted joint procurement or procurement on Member States' behalf of medical countermeasures enabling prevention[13].
- International solidarity through work to establish two-way donation channels of antibiotics with countries in the Southern Hemisphere (as the winter peak occurs there at another time of the year).
- Information to the public on measures taken at EU level to prevent shortages of antibiotics in the EU, also promoting the prudent use of antibiotics and highlighting the need to avoid hoarding by all relevant stakeholders.
- Deploying the available rescEU stockpile of antibiotics, in case of critical shortage[14].

Together with EMA, the Commission continues to closely monitor the situation as it evolves, keeping day-to-day contact with the relevant companies and other stakeholders to detect early any unexpected shortfall of supplies of certain key antibiotics, and to monitor the continued supply of other medicines commonly used in the autumn/winter season such as cough syrups, ibuprofen and paracetamol.

The information available today suggests that – if demand in the coming winter season does not differ significantly from the demand of recent years – the supply to the EU of key antibiotics seems to generally match demand. However, this depends on the compliance by relevant companies with their legal obligation to ensure supply and their ability to adapt.

Sharing medicines between Member States

A "***Voluntary Solidarity Mechanism for medicines"*** is being launched in October 2023 to support Member States experiencing critical shortages[15]. The scheme allows Member States to flag needs for a given medicine in critical shortage at national level to other Member States, so that they can indicate the availability of stock that could be redistributed.

In cases when Member States are overwhelmed and in urgent need of a given medicine, the Union Civil Protection Mechanism, via its 24/7 available European Response

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13 Involving vaccines and therapeutics for respiratory syncytial virus (RSV) to prevent aggravation of shortages due to increased demand of antibiotics to treat co-infections between RSV and bacteria.

14 When a Member State has triggered the Union Civil Protection Mechanism.

15 https://www.ema.europa.eu/en/documents/other/mssg-solidarity-mechanism_en.pdf

Coordination Centre (ERCC) can be activated to coordinate and logistically support the voluntary transfer of medicines. This requires good coordination between health and civil protection authorities at national level. Such a redistribution of stocks, drawing on national reserves, will build on existing examples of European solidarity, and will further strengthen cooperation among Member States in the European Health Union.

Building on this work and on the experience of the COVID-19 Clearing House for medical equipment[16], the Commission will also establish by Q2 2024 a *matchmaking platform*, where economic operators and developers will be able to flag their capabilities and collaboration needs. The Commission will also foster networking and business relationships through the HERA Industry Days[17], dedicated to medicines and medical countermeasure.

Defining a Union list of critical medicines

Medicines are deemed critical medicines[18] when essential to ensure the continuity of care and the provision of quality healthcare, and to guarantee a high level of public health protection in Europe, and also when their unavailability results in serious harm or risk of serious harm to patients.

The Commission will publish ***a Union list of critical medicines ,*** building on work with EMA and the Member States, as a first step to ensure the security of supply. This work is under way[19], and a first version of the Union list of critical medicines will be available by the end of 2023. The list will be updated to ensure coverage of all relevant critical medicines, including possibly paediatrics and antibiotics, based on continued analysis of all types of medicines.

The Commission, together with Member States, and based on information from other stakeholders, will analyse the vulnerabilities in the supply chain of a first tranche of critical medicines on the future list by April 2024. This will provide the basis for decisions on further remedial action, such as recommendations that companies diversify suppliers or increase production within the EU, investment incentives, additional regulatory obligations for companies, and procurement with strong contractual obligations for delivery.

Improving demand and supply forecasting to prevent risks of critical shortages

The ***forecasting of demand*** by industry - as part of their existing regulatory obligation to ensure continuous supplies -, but also by public authorities, plays a major role in providing early warning of potential critical shortages, alongside supply and production capacity information.

The Commission, EMA and national medicine agencies have provided a set of practical recommendations to support the demand forecasting at national level, drawing on experience under the COVID-19 pandemic[20]. This could be complemented by a best practice model to help the comparability of demand forecasts. The Commission is also

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16 In April 2020, the Commission set up a Clearing House for medical equipment to facilitate the timely availability of the medical supplies needed to fight the virus.

17 HERA Work Plan 2022 (europa.eu)

18 See also article 2 (13) of COM (2023) 193.

19 A draft methodology to identify critical medicines was put forward in the 2022 Commission Staff Working Document on vulnerabilities of the global supply chains of medicines.

20 https://www.ema.europa.eu/en/documents/other/reflection-paper-forecasting-demand-medicinal-products-eu/eea_en.pdf

working on an EU Mechanism for Demand Signalling to pull the information together to empower the collective EU public sector in its decisions. Better knowledge of longer-term demand trends could help in specific cases to directly support research, facilitate market launches in the EU and make the EU market even more attractive for companies. The Commission will also work with the European Centre for Disease Prevention and Control on building reliable forecasts of potential threats beyond the current short-term horizons.

The ongoing development of new IT tools will also help to harness the data behind the monitoring of demand and supply of medicines. A new ***European Shortages Monitoring Platform*** for reporting information regarding available stocks and shortages of medicines is expected to become operational in 2025[21]. Artificial intelligence will also be used to provide information about trends in demand and supply from existing data[22]. The future European Health Data Space would offer additional opportunities for European and national authorities of using existing health data to analyse trends. The interoperability of databases, at EU and with national level, as well as cybersecurity measures[23] is critical to maximise the potential of this data for the benefit of healthcare systems in Member States and ultimately EU citizens.

Accelerating and anticipating the pharmaceutical reform to enhance security of supply

The proposed ***reform of the pharmaceutical legislation*** introduces structural measures to improve availability of medicines.

Key elements include a new European alert system with earlier notification of shortages and withdrawals by companies, harmonised reporting criteria, mandatory shortage prevention plans and coordinated management of shortages by EMA[24]. The reform would reinforce and strengthen companies' obligation to ensure appropriate and continued supply.

In addition, the reform brings a major overhaul of the incentives provided to companies and would reward, for newly authorised medicines, continuous supply in sufficient quantity in all Member States[25]. Administrative burden has also been reduced, making the marketing authorisation process faster and easier. The proposed reform would also facilitate earlier market entry of generic medicines, once the exclusivity period of the originator ends.

The benefits will only be felt in full when the new legislation is in place. However, Member States, EMA and the Commission have already started actions that go in the

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21 Established by Regulation 2022/123 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.

22 Through two systems (EU-MED and ATHINA) currently under development by HERA. ATHINA will support the monitoring and the analysis of supply chains of crisis-relevant medical countermeasures and, thus, guide national and EU-level actions to increase supply chain resilience.

23 ENISA Threat Landscape 2022.pdf

24 The revision was informed by the Commission's Structured Dialogue with actors in the pharmaceutical manufacturing value chain and public authorities. In October 2022, the Commission published a Staff Working Document summarising the findings of the Structured Dialogue. This work complemented the results of the study analysing the root causes of medicine shortages and the analysis fed into the reform of the pharmaceutical legislation.

25 Supplying all Member States within two years after the marketing authorisation would bring an additional two years of regulatory protection for medicines authorised after the pharmaceutical revision becomes applicable.

direction of the proposed reform to coordinate on preventing and mitigating critical shortages risks[26]. This process should be accelerated.

Elements of the new pharmaceutical legislation that could be anticipated include:

- Earlier notification of the risk of a shortage by companies;
- Shortage prevention plans for all medicines by all companies;
- Increased information sharing on critical shortages amongst Member States and with EMA to help the EU to use existing systems and processes to the full. This would include information on planned measures or measures already taken, including unilateral actions by Member States, such as export bans or prohibition of parallel trade;
- Recommendations from the Commission/EMA to manage critical shortages and improve future security of supply (such as maintaining contingency stocks);
- Continuous consultation by EMA of all relevant industry stakeholders during a critical shortage;
- To limit the impact of medicines withdrawals from the market, facilitate the transfer of the marketing authorisation to a third party.

This could be complemented by other steps, such as proactive communication on critical shortages. For example, Member States could launch information campaigns to discourage hoarding or take actions to avoid waste[27], at any level of the supply chain, from wholesalers to patients.

National capacity in the area of shortages is being supported through a €10 million Joint Action on shortages under EU4Health, including a 'best practice' IT concept model for use at national level. Participating authorities can also benefit from EU support to enhance national capacity with respect to shortages management.

Making use of all flexibilities

Regulatory flexibilities can be an important tool to manage and mitigate shortages of critical medicines. This includes measures to facilitate the quick authorisation and roll-out of alternatives; the upscaling of production or approval of alternative suppliers of raw materials or finished products; temporarily extending shelf-life; or measures to facilitate redistribution between Member States.

Over recent years, EU regulators have gained experience with those flexibilities, especially during the COVID-19 pandemic. This offers confidence that they can be used without compromising safety and quality standards[28]. A new Joint Action will promote effective use of regulatory flexibilities and other flexibilities that could be applied at national level, such as how the magistral preparations of local pharmacies might be used to mitigate certain shortages.

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[26] Guidance from the EMA and national medicines agencies has already been issued to support the anticipation of some of these elements: Good practice guidance for patient and healthcare professional organisations on the prevention of shortages of medicines for human use (europa.eu) and Good practices for industry for the prevention of human medicinal product shortages (europa.eu)

[27] Some countries introduced measures requiring pharmacies to sell the exact quantity of prescribed medicines, instead of whole packages that would require subsequent disposal.

[28] Supported by MSSG toolkit and recommendations on regulatory flexibility, published on 24 October 2023.

Pricing and reimbursement policy

While ***pricing and reimbursement policies*** for medicines are a national competence, cooperation in this area is essential in order to avoid that decisions in one Member State create shortages in other Member States. While the price paid within a given Member State reflects the preference of a national health system, more coordination on pricing and procurement could contribute to more equal and timely access to medicines, including for Member States with lower purchasing power. Voluntary collaboration will be further facilitated by the Commission, including in the group of National Competent Authorities on Pricing & Reimbursement and public healthcare payers ("NCAPR"). In this group, Member States share experience from national pricing, reimbursement and procurement policies, which are relevant for affordability and security of supply.

In the longer run, evaluation of the existing Transparency Directive[29] gives the opportunity to look at an important tool for cooperation on pricing and reimbursement.

Using procurement to enhance security of supply

Practices in procurement procedures for medicines differ between Member States and long-term availability is rarely a primary consideration. The 2014 Procurement Directive encourages a more strategic approach through award criteria, including criteria *beyond* price. Using the lowest price as the main selection criterion may reduce incentives for the industry to build for long-term supply in the EU. At the same time, vulnerability may be increased when ***public procurement procedures*** award contracts to a single company. Where challenges with access to a critical medicine and related affordability may be an issue, Member States can work together to increase buying power: existing examples include the Baltic Procurement Initiative and the Nordic Pharmaceutical Forum.

Joint procurement between Member States can act as a powerful tool to improve access, affordability and security of supply, of particular benefit in smaller EU markets. This can improve the negotiating position of Member States to incentivise production capacities, as well as diversifying supply chains. In specific cases, those instruments could also support enhanced predictability through multi-annual contracts. The Commission will look at using joint procurement for antibiotics and treatments for respiratory viruses ahead of winter 2024-25.

Public procurement practices supporting security of supply of medicines:

There are a variety of tools which can already be used in relation to availability of critical medicines:

- Preliminary market consultation;
- Awarding contracts to multiple winners, to reduce the risk of supply disruptions and maintain a competitive environment;
- Increased use of most economically advantageous tender (MEAT) award criteria in public tenders, using qualitative criteria such as security of supply and production in the EU/EEA or in countries with which the EU has concluded an agreement on government procurement;

[29] Directive 89/105/EEC on the transparency of measures regulating the prices of medicines for human use and their inclusion in the scope of national health insurance systems. A study has been commissioned with the purpose to analyse the functioning of Council Directive 89/105/EEC (better known as the "Transparency Directive") and the results are expected in November 2023.

- Joint procurement (group procurements and cross-country procurements) to overcome access challenges of smaller market sizes. This would increase scale and negotiating power, while also opening the door to steps fostering competitive markets and disincentivising supply chain consolidation;
- Ensuring that the duration of contracts is tailored to favour predictability of demand and long-term availability.

Through continued work with experts and national authorities, the Commission will issue **EU *guidance on procurement*** by early 2024. The focus will be on procurement practices that can make a direct contribution to security of supply and availability through effectively integrating supply security as an award criterion[30], whilst having regard to the EU's international commitments. This will further support Member States and procurers in their procurement practices.

More generally, the Commission proposal to recast the ***Financial Regulation***[31] would ensure further options as regards procurement instruments at EU level beyond crisis situations. Where there is Member State interest and there is a specific legal basis, the Commission could not only procure medicines jointly with Member States, but also procure medicines on their behalf, on the basis of a mandate. This could cover critical medicines and ancillary products beyond the current scope of the Joint Procurement Agreement to procure medical countermeasures.

One issue to be looked at in the forthcoming review of HERA is the extent to which action should cover response beyond serious cross-border health threats across the full range of medicines.

The Commission, together with the EMA and the Member States, will intensify work ahead of the forthcoming winter to prevent critical shortages:

- Deploy the new Voluntary Solidarity Mechanism for medicines;
- Use regulatory flexibilities where appropriate;
- Deploy the rescEU stockpile of antibiotics if UCPM is triggered.

In addition, the Commission, together with the EMA and the Member States, will deliver in a short to mid-term the following actions to support long-term security of supply of critical medicines in the EU:

- Publish the Union list of critical medicines by the end of 2023 and analyse the vulnerabilities of a first tranche of critical medicines by April 2024;
- Anticipate proposed measures under the pharmaceutical reform to ensure more systematic and coordinated notification and mitigation of critical shortages;
- Set up communication tools for better supply and demand forecasting, such as a matchmaking platform (by Q2 2024); an EU Mechanism for Demand Signalling; and the European Shortages Monitoring Platform;
- Prepare to launch in 2024 a Joint Action on regulatory flexibilities, including magistral preparations;

[27] For example, in Germany, a law of July 2023 stipulates the production of the active pharmaceutical ingredient in the EU or the European Economic Area as a mandatory criterion in tenders for the purchase of certain medicines (https://dserver.bundestag.de/btd/20/068/2006871.pdf).

[31] COM(2022) 223 final; Proposal for a Regulation on the financial rules applicable to the general budget of the Union (recast), 16 May 2022.

- Develop a best practice guidance for the public procurement of medicines by early 2024, as part of wider efforts to leverage procurement to better support security of supply.

Member States are invited to:

- Monitor and fully enforce the supply obligations of companies;
- Develop effective communication plans to inform and reassure about availability of medicines[32];
- Consider how national procurement rules and criteria can increase security of supply.

Pharmaceutical industry stakeholders are invited to:

- Assure to the full the supply obligation for companies under EU law
- Continuously monitor the evolution of demand and supply of critical medicines and provide complete information to regulatory authorities as early as possible; Implement recommendations, both on regulatory flexibilities and on the elements of the pharmaceutical revision that could already be applied, such as earlier notifications of shortages and withdrawals.

3. STRUCTURAL MEASURES FOR THE MID AND LONG-TERM

Ensuring that Europeans receive the medicines they need, when they need them, regardless of where they live in the EU is a central objective of the European Health Union. Boosting the competitiveness of the European pharmaceutical industry and assuring better availability of medicines and more equal and timely access for patients is a key deliverable of the proposed EU pharmaceutical reform. While the reform foresees structural measures to strengthen the security of supply in the EU, including for generic medicines, it will not address the industrial dimension of medicines shortages.

In addition to existing and planned policy, legislative and regulatory measures[33], the EU needs a strategic and coordinated industrial approach to enhance security of supply of the most critical medicines. Strengthening the EU's security of medicines supply may require new legislation. A legislative initiative for an EU *"**Critical Medicines Act**"* would require thorough preparation, including the assessment of economic dimensions. The Commission will, to that end, launch a dedicated, preparatory study by the end of 2023, paving the way for an impact assessment.

A Critical Medicines Alliance: Working together to boost security of supply

The EU and Member States have many tools which can be used to promote a coordinated industrial approach**,** bringing together public and private actors from the European health and industrial ecosystem.

[32] https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/good-practice-guidance-communication-public-medicines-availability-issues_en.pdf

[33] Based on the learnings of the Structured Dialogue and concrete MSSG recommendations on critical medicines set out in the pharmaceutical reform.

The Commission intends to set up a "***Critical Medicines Alliance***" by early 2024. This would allow national authorities, industry, civil society representatives, the Commission and EU agencies to come together to develop coordinated action at the EU level against the shortages of medicines, in compliance with the competition rules and EU's international commitments.

The starting point would be the shared vulnerability analysis of supply chain bottlenecks of the critical medicines on the Union list (over-dependency on a limited number of external suppliers, limited diversification possibilities, limited production capacities, etc). This evidence-based process would result in ***identifying a limited number of critical medicines with the highest risk of shortages and impact*** on healthcare systems. Through this process, the Alliance would be able to identify the most appropriate tools to respond to these vulnerabilities in the most optimal way.

This work could draw on a varied toolbox, including a set of actions to mitigate these structural risks, notably reinforcing supply by making demand more predictable, encouraging diversification and increased manufacturing for the most critical medicines, as well as EU stockpiling if needed:

- ***Public procurement***

Coordination at EU level could offer a strategic frame to enhance security of supply of the identified critical medicines through ***public procurement***. This could draw on Commission guidance and common criteria for the procurement of critical medicines, such as green production and prioritisation of supplies in Europe at times of critical shortages.

Such an approach could also help in defining adequate supply in relation to critical medicines and, thereby, compensate and incentivise industry, and support the application of these criteria in a coordinated way, at EU level. Predictability of supply would also be helped by ***medium-term contractual incentives*** to diversify and attract the next generation of manufacturing investments in Europe. More generally, it would explore common approaches on how to encourage security of supply, on which Member States could draw when taking forward joint procurements at EU level. Another possibility could be to use ***capacity reservation contracts,*** using the model of EU FAB.

- ***Diversification of global supply chains***

The Alliance could also help in exploring how to ***diversify global supply chains*** for critical medicines. Identifying priority countries for strategic partnerships with third countries concerning the security of supply of critical medicines would help coherence and potential synergies between Member States' and EU cooperation with third countries.

- ***Boosting innovation and manufacturing capacity***

Another strategic focus of the Alliance would be how to help to boost Europe's capacity to produce and innovate in the manufacturing of critical medicines and ingredients in coordinated and competitive way. This would enhance security of supply, strengthen availability and reduce some of the EU's supply chain dependencies.

All the national and EU support should be compatible with the state aid framework. The Alliance would coordinate efforts to identify security of supply needs for critical medicines, based on the identified vulnerabilities. In this context, ***Services of General Economic Interest*** (SGEI), coordinated at EU level and covering several criteria, including priority rated order for EU market, could be envisaged by Member States to limit the risk of critical medicines shortages at the EU level. The Alliance could play a role in promoting a harmonised approach across the EU.

Furthermore, Member States in the framework of the Alliance could discuss whether to support the development of advanced and innovative green technologies, including for off patent medicines production, possibly as part of a new ***Important Project of Common European Interest (IPCEI) focusing on critical medicines***. It could complement the ongoing work of the existing IPCEI in the health area, which aims to support the development of innovative treatments on antimicrobial resistance, rare diseases and cancer, as well as innovative production processes and products. A new IPCEI could focus on developing innovative and sustainable manufacturing and production technologies and processes for generic medicines. This would both enable to increase innovative domestic production and foster environmental standards. It would also be an opportunity for the EU to lead in the greening of generic medicines production.

- ***EU stockpiling of critical medicines***

Several Member States already have provisions in national legislation obliging the different actors in the supply chain to maintain a contingency stock, in order to have a buffer when short-term shortages occur.

When stockpiles are already built up before shortages occur, they can help to bridge the supply gap before production increases or provide the input materials in shortage, needed to boost the quantities that can be manufactured. However, national stockpiling can impact availability of medicines in other Member States, be costly and potentially wasteful, particularly if not used in tandem with mitigation measures to address the shortage itself.

The Commission and Member States should develop a common strategic approach to ***medicines stockpiling*** in the first half of 2024. Building upon experience under the Union Civil Protection Mechanism (UCPM) and its existing rescEU stockpile, this would look at the conditions required for stockpiling to be an appropriate and cost-effective option. A first step would be to define the needs for stockpiling of critical medicines at the EU level, based on the vulnerability analysis of supply chains. To complement the strategy, the Commission intends to launch a Joint Action on stockpiling in 2024, which will support Member States to enhance and/or improve national stockpiling strategies in an efficient and coordinated manner.

The speed with which the UCPM can act will mean that it will continue to be a key part of the EU approach. If the UCPM is to be complemented with a long-term stockpiling system, this would require sustainable financing.

- ***Skills for the pharmaceutical industry***

European pharmaceutical producers face rapidly evolving skills needs. The digitalisation of the industry puts the emphasis on artificial intelligence, robotics, and big data processing. The health industrial ecosystem is highly regulated, and compliance with standards requires professionals well-versed in regulatory frameworks, quality assurance and control. The green transition calls for skills, including green chemistry, sustainable engineering, life cycle assessment, sustainable sourcing and energy management.

The pharmaceutical industry is also characterised by jobs for highly skilled workers and a high density of cross-national collaborations. It is therefore highly dependent on labour mobility, with the free movement of workers an enabler of innovation and growths. Pharmacists are among the regulated professions, allowing for an easier adjustment of the curricula for this profession and benefiting from EU measures to facilitate free movement.

The ***EU Skills Agenda*** addresses the widespread issue of skills gaps across the EU. More specifically, it aims to contribute to the increase of STEM (Science, Technology, Engineering and Mathematics) graduates, by raising the attractiveness of STEM studies and careers, with focused actions to attract girls and women, and by encouraging a cross-disciplinary and innovative teaching and learning approach in schools, VET and higher education. The 'Pact for Skills' aims to tackle the most pressing industry skills gaps with active involvement of industry and key actors in education and training. A strong emphasis is put on a complementary skills partnership for the health industry, including pharmaceuticals, with a partnership agreement expected by the end of 2023, with active involvement of the members of the Joint Industrial Cooperation Forum. One area for cooperation would be better common identification of skills needs, as an encouragement to pooling of training.

- ***Financial support***

An important benefit of a common strategic approach as part of an Alliance would be to better leverage and align ***EU and national funding***. This would offer more long-term investment predictability for the private sector, as well as avoiding unnecessary duplication and ensuring that other horizontal priorities be factored in (such as facilitating the participation of SMEs).

There is already substantial EU funding support for medicines. Around EUR 4 billion are dedicated to supporting medicines, including research under Horizon Europe[34], development and production of medicines under the European Regional Development Fund[35], support for the development and production of anti-microbials and other medical countermeasures under the EU4Health Programme[36], as well as the funding for medical stocks under the Union Civil Protection Mechanism. Broader support to health systems as a whole comes through EUR 43 billion under Recovery and Resilience Facility.

The Strategic Technologies for Europe Platform (STEP)37, proposed as part of the mid-term review of the Multiannual Financial Framework, aims at boosting investments in critical technologies in Europe, either to promote innovation or to contribute to reduce or prevent strategic dependencies of the Union. The STEP seeks to reinforce and leverage existing EU instruments for a quick deployment of financial support for the development or manufacturing in the Union of critical technologies in several fields, including biotech. More specifically, the Commission proposal covers pharmaceuticals and medical technologies vital for health security as examples of biotechnologies that should be covered by STEP. STEP projects could be supported through several programmes, such

[34] For example, more than EUR 180 million is devoted to clinical trials and support research in new anti-microbials, anti-virals or vaccines that could be used in case of a new pandemic. In addition, the Innovative Health Initiative with a total budget of EUR 2.4 billion for the period 2021-2027, funded jointly by the EU and by industry associations representing Europe's life science industries aims to translate health research and innovation into tangible benefits for patients and society. Its activities include but are not restricted to medicine research and development.

[35] The European Regional Development Fund supports mostly SMEs in projects linked to medicines development and production through over EUR 200 million for research, upskilling, investments in fixed capital/immaterial assets of enterprises, greening of production processes and infrastructure.

[36] HERA Invest is a EUR 100 million top-up to the InvestEU Programme that supports sustainable investment, innovation and job creation in Europe. In addition, EUR 160 m are dedicated to EU-FAB, which aims to support ever-warm capacities that could also be extended to critical medicines. In addition, over EUR 100 m are dedicated under the EU4Health Programme for the development of and access to innovative technologies and critical medicines, including antibiotics.

[37] https://commission.europa.eu/strategy-and-policy/eu-budget/strategic-technologies-europe-platform_en;

as cohesion policy programmes, the Recovery and Resilience Facility, EU4Health, Horizon Europe or InvestEU. Moreover, the STEP also proposes to create a Sovereignty Seal, with the objective to promote synergies amongst existing programmes.[38]

The Technical Support Instrument could also be used to enhance the administrative capacity of Member States in managing shortages and producing critical medicines.

Actions for the medium and long-term

The Commission will discuss with Member States the establishment of a Critical Medicines Alliance to provide a strategic frame to promote structural support for critical medicines supply. It should aim to be up and running by early 2024.

The Commission will also:

- Launch a study by the end of 2023 on whether legislation could help to offer long-term structural support to critical medicines supply;
- Develop a common strategic approach on medicines stockpiling with Member States, to be completed by June 2024;
- Conclude strategic partnerships with third countries for production of critical medicines, reflecting both local demand and needs at the EU and global level.

Member States are invited to:

- Use available funds to invest in priorities identified by the Alliance, in line with State aid rules when applicable;
- Develop national stockpiling approaches consistent with an overall EU stockpiling approach for medicines;
- Support the launch of a partnership for skills, with a focus on needs of the pharmaceutical sector.

4. INTERNATIONAL PARTNERSHIPS FOR SUPPLY

The EU, acting as Team Europe, has been at the forefront of forging a global approach to health: this was set out in full in the November 2022 Global Health Strategy[39]. A key aspect of this has been through support to those in need, shown most strikingly with the large-scale donation[40] of COVID-19 vaccines from the EU to international partners. The COVID-19 pandemic also illustrated the critical importance of global supply chains to ensuring essential medical supplies. International cooperation and the genuine integration of the global pharmaceutical industry is a key determinant for the availability of medicines in the EU and across the world: many partners have their own difficult experience of shortages and recognise the value of a collective approach.

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38 STEP can also become a powerful instrument to support the production of critical medicines. In line with the need to reduce EU's strategic dependencies, including on critical medicine shortages, STEP will be able to promote a more coordinated approach at EU level for the financing and of such actions, in particular with the Sovereignty Seal that will increase synergies between programmes like EU4Health, Horizon Europe on the one hand and cohesion policy funds and the RRF on the other hand.

39 https://health.ec.europa.eu/system/files/2023-03/international_ghs-report-2022_en.pdf

40 If needed, through the European Humanitarian Response Capacity (EHRC)

Diversification of supply chains

Diversification helps to reduce supply chain vulnerabilities resulting from dependencies. Given the complexity of pharmaceutical supply chains, EU industry needs to have access to a broad range of essential inputs. Trade policy and partnerships aim at opening new markets and diversifying sources of supply and complement enhanced efforts to reduce excessive dependencies for critical supply chains. Identifying risks and vulnerabilities, especially for critical medicines, gives a focus for mitigating measures and to build resilience in the global trading system and global pharmaceutical market. This is one of the goals of the EU's 42 preferential trade agreements with 74 different trading partners, as well as of the work within international fora such as the G20, the G7 and the WTO.

The EU also works with key trading partners at bilateral level to avoid disruption of supply chains. The EU is currently negotiating a free trade agreement with India, and the existing Trade and Technology Council also offers a forum to discuss how to enhance the value chains in the pharmaceutical sector, given India's key strategic importance. Bilateral meetings with China provide a platform to raise issues affecting access to medicines supply chains. Dialogue with Latin America reflects an increasingly important trade relationship. The Commission will seek to set up ***strategic partnerships*** with third countries for production of critical medicines and APIs. These could define commitments on concrete actions of mutual interest. These actions could be tailor-made to reflect the potential of different partners to help secure supply or whether a third country requires additional monitoring, prevention and minimisation of environmental, social or legal impacts.

International cooperation to ensure regulatory convergence and a level playing field

Regulatory convergence can help to reduce obstacles and bottlenecks to supply. Compliance with good manufacturing practice was a goal of the Pharmaceutical Strategy,[41] to ensure the highest quality for products marketed in the EU and produced in third countries.

Regulatory convergence and harmonisation of standards for pharmaceuticals is achieved and promoted through active engagement in relevant multilateral fora, such as ICH (the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) and ICMRA (International Coalition of Medicines Regulatory Authorities). It is also important to support the World Health Organisation work in this area to strengthen regulatory convergence.

Harmonisation can also be promoted through Free Trade Agreements, with an obligation that both parties take into account international provisions/practices and guidelines for pharmaceuticals[42]. This enhances the quality of products worldwide and ensures that differing standards do not become an obstacle to trade. Another key tool is mutual recognition agreements (MRAs) with third-country authorities concerning the conformity assessment of regulated products, allowing for mutual confidence in inspections and exchange of information. Such agreements facilitate the trade of medicines with Australia, Canada, Israel, Japan, New Zealand, Switzerland and the United States.

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41 The European Medicines Agency has led this dialogue for the EU, notably through the Global Regulatory Working Group on Drug Shortages and the International Coalition of Medicines Regulatory Authorities, focused on G7 partners and the World Health Organisation.

42 Notably those elaborated by WTO, OECD, ICH, and IMDRF, and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/s)

Bilateral arrangements with the United States and the Republic of Korea also enable the sharing of non-sensitive market knowledge to anticipate possible problems.

Subject to applicable State aid and antitrust rules, the Commission will broaden this work by creating and fostering a ***network of international partners***, aiming to address supply chain resilience, and to boost access to medicines and critical medical countermeasures. The network could be established within a year, bringing together manufacturers and key consuming countries. Its goal would be to foster general knowledge sharing and crisis preparedness, with a focus on supply diversification including through local manufacturing capacities.

Support production capacity at global level

More sustainable and more diverse production worldwide will benefit people around the world, including in the EU. Under the Global Gateway, the EU is supporting local manufacturing of health products. Team Europe has mobilized EUR 1.1 billion for the flagship initiative on ***manufacturing and access to vaccines, medicines and health technologies in Africa***. This allows for increased and equitable access to high-quality health products, by focusing on supporting local and regional demand and supply, and also contributes to diversification and strengthening of international supply chains. The Commission is setting up another Team European Initiative in Africa on health security, using the One Health Approach, working closely with African partners to improve pandemic preparedness, prevention and response. An ***EU-Latin America and Caribbean Partnership*** on manufacturing and access to vaccines, medicines and health technologies and strengthening health systems has also been set up. Supporting more diverse production is also one of the EU's goals in the current negotiations to develop the global health architecture.

Lastly, the EU will continue to support the provision of critical medicines in humanitarian contexts, through the UCPM and the European Humanitarian Response Capacity and working closely with its humanitarian partners on the ground.

Action to support availability on the global level

The EU should:

- Establish a network of international partners and companies to boost the exchange of information on supply issues;
- Develop further Team Europe initiatives to support production capacity and access in low- and middle-income countries, and reinforce cooperation on prevention and preparedness;
- Conclude strategic partnerships with third countries for production of critical medicines, reflecting both local demand and needs at the EU and global level.

5. CONCLUSION

Availability of medicines in the EU is at the core of the strong European Health Union. Securing supply of critical medicines is part and parcel of building up a resilient and sustainable basis for the future that saves lives and brings benefits beyond the EU.

Building a sustainable single market for medicines in the interests of all patients entails supporting a strong and competitive pharmaceutical sector.

The experience of the COVID-19 pandemic showed what is possible with collective unity of purpose: EU action can make an important difference in ensuring the availability of critical medicines and softening the impact of critical shortages when they occur. This requires solidarity and a high degree of coordination, with the Commission, EMA, national governments and regulators, and also with industry, patients and healthcare professionals. It also requires a whole of government approach at national and European level, and a deep engagement with the international community. This Communication shows that further action can be taken to prevent shortages this winter and beyond, but also to ensure the long-term supply of critical medicines in the EU. Reinforcing security of supply of critical medicines means acting at every stage, from essential inputs to the finished medicine.

A Critical Medicines Alliance is the opportunity to develop coordinated action at the EU level on shortages of medicines through the range of tools available at EU and national level. It would be a direct policy response to the need to enhance security of supply and it could pave the way for a possible future Critical Medicines Act.