EUROPEAN
COMMISSION

Brussels, 2.9.2025
SWD(2025) 263 final

COMMISSION STAFF WORKING DOCUMENT

Summarising evidence supporting the legislative proposal laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability of, and accessibility of, medicines of common interest and amending Regulation (EU) 2024/795

CONTENTS

Glossary

Acronyms	Meaning or definition
API	Active Pharmaceutical Ingredient
CDMO	Contract Development and Manufacturing Organization
CEP	Certificate of Suitability
CHESSMEN	Coordination and Harmonisation of the Existing Systems against Shortages of Medicines – European Network) – EU Joint Action on shortages
CMA	Critical Medicines Act
CRMA	Critical Raw Materials Act
DG COMP	DG Competition
DG GROW	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
DG HERA	Health Emergency Preparedness and Response Authority
DG SANTE	Directorate-General for Health and Food Safety
eAF	electronic Application Form
ECDC	European Centre for Disease Prevention
EDQM	European Directorate for the Quality of Medicines & HealthCare
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EMVS	European Medicines Verification System
ESG	Environmental, Social and Governance
ESMP	European Shortages Monitoring Platform
GVA	Gross Value Added
MAH	Marketing Authorisation Holder
MS	Member State
MSSG	Executive Steering Group on Shortages and Safety of Medicinal Products

PO	Policy Option
SPOC	Single Point of Contact
SPP	Shortage Prevention Plans
SU	Standard Units
SWD	Staff Working Document
Terms	Definitions
Medicinal product	Medicinal product as defined in Article 4 point (1) of Directive (EU) …/… of the European Parliament and of the Council – [*reference to be added to corresponding Article after adoption of cf. COM(2023) 192 final*];
Key input	Input material other than an active substance required in the manufacturing process of a given medicinal product, including primary packaging materials, excipients, solvents and reagents;
Active substance	Active substance as defined in Article 4 point (3) of Directive (EU) …/… of the European Parliament and of the Council [*reference to be added to corresponding Article after adoption of cf. COM(2023) 192 final*];
Critical medicinal product	Medicinal product for which insufficient supply results in serious harm or risk of serious harm to patients as defined in Article 4 point (13) of the Regulation (EU) …/… [reference to be added after adoption of cf. COM(2023) 193 final];
Medicinal product of common interest	Medicinal product, other than a critical medicinal product, for which in three or more Member States the functioning of the market does not sufficiently ensure the availability and accessibility to patients in the quantities and presentations necessary to cover the needs of patients in those Member States;
Vulnerability in the supply chains	Risks and weaknesses within the supply chains of critical medicinal products, identified at the aggregated level taking into account all authorised medicinal products in the EU and grouped under a common name with the same route of administration and formulation, that compromise the continuous supply of such medicinal products to patients in the Union;
Vulnerability evaluation	Evaluation of the supply chains of critical medicinal products to identify their vulnerabilities performed by the MSSG in accordance with Regulation (EU) …/… of the European

	Parliament and of the Council *[reference to be added after adoption cf. COM(2023) 193 final],*
Contracting authority	Contracting authority as defined in Article 2(1) of Directive 2014/24/EU;
Strategic Project	Industrial project identified pursuant to the criteria set out in Article 5 of the Commission proposal for a Critical Medicines Act.
Project promoter	Undertaking or consortium of undertakings developing a Strategic Project
Permit granting process	Process covering all relevant permits to build and operate a strategic project, including building, chemical and grid connection permits and environmental assessments and authorisations where those are required and encompassing all applications and procedures;
Innovative manufacturing process	Novel manufacturing process and technology or novel application of an existing technology, including, but not limited to, decentralised manufacturing, continuous manufacturing, Artificial Intelligence, platform techniques, 3D manufacturing;
Member States' cross-border procurement	Procurement procedure initiated between the contracting authorities from different Member States on the basis of Article 39 of Directive 2014/24/EC;
Procurement on behalf of or in the name of the Member States	Procurement procedure initiated at the request of Member States and mandating the Commission to act as a central purchasing body on behalf of, or in the name of, the requesting Member States, as provided for in Article 168(3) of Regulation (EU) 2024/2509;
Joint procurement	Procurement procedure carried out jointly by the Commission and Member States, as provided for in Article 168(2) of Regulation (EU) 2024/2509;
Supplier	Manufacturer or marketing authorisation holder of finished dosage forms, key inputs or active substances;
Strategic partnership	Commitment between the Union and a third country, group of third countries or international organisations to increase cooperation related to one or more critical medicinal products that is established through a non-binding instrument and which facilitates beneficial outcomes for both the Union and the relevant third country, group of third countries or international organisation.

1. INTRODUCTION

This Staff Working Document (SWD) summarises the analysis and evidence supporting the Commission legislative proposal for a Regulation laying a framework for strengthening the availability and security of supply of critical medicinal products as well as the availability and accessibility of other medicinal products of common interest ([1]). The proposal for the so-called Critical Medicines Act (CMA) was adopted on 11 March 2025.

The growing issue of medicines shortages poses a serious threat to patients and public health. Healthcare systems in the EU face increasing challenges to secure a stable and resilient supply of medicines that are critical to ensure a high level of care to EU patients. Recent global events, including the COVID-19 pandemic and Russia's war against Ukraine, have exposed vulnerabilities in the EU's pharmaceutical supply chains. In addition, the strong reliance on non-EU suppliers and lack of diversification of global supply chains exacerbate the risk of shortages. Without swift action to address these vulnerabilities, in addition to regulatory measures on shortage management and security of supply of critical medicines introduced with the reform of the pharmaceutical legislation, disruptions could have severe consequences for patient care, including delayed treatments for life-threatening conditions.

The proposed Regulation delivers on the political commitment by President von der Leyen ([2]) to propose a Critical Medicines Act to address the severe shortages of medicines and reduce dependencies relating to critical medicines and ingredients, as well as to ensure the supply of affordable medicines. In this regard, the Act is an important element of the European Health Union and complements (1) the regulatory provisions proposed in the context of the ongoing revision of the pharmaceutical legislation of the EU ([3]); (2) the reinforced mandate for the European Medicines Agency on crisis preparedness and management for medicines ([4]); (3) key actions in relation to the completion of a European Health Union in which all EU Member States prepare and respond together to health crises and in which medical supplies are available, affordable and innovative ([5]); and (4) new industrial policy measures that recently came into force in other 'critical' domains ([6]).

The proposed Regulation also aims to improve access to and availability of other medicines of common interest where a market failure exists, complementing the regulatory measures proposed in the revision of the pharmaceutical legislation.

([1]) Critical medicines Act - European Commission

([2]) Political guidelines 2024-2029

([3]) Reform of the EU pharmaceutical legislation - European Commission

([4]) A stronger role for EMA | European Medicines Agency (EMA)

([5]) European Health Union

([6]) European Critical Raw Materials Act and Net-zero Industry Act

2. BACKGROUND

2.1. Political and legal context of shortages of medicines

The EU has a strong and competitive pharmaceutical sector, which is a global leader in the production of medicines and a major contributor to the EU economy and directly employs around 800,000 people ([7]). The sector is particularly strong in the research and development of innovative medicines. The landscape for pharmaceutical manufacturing has evolved in recent decades. Pharmaceutical production in the EU has increasingly focused on more complex products, which require high-tech infrastructure, a skilled workforce and sophisticated processes. Production of inputs for generic medicines has increasingly moved outside Europe. At the same time, almost 70% of the medicines dispensed in Europe are generics ([8]).

In September 2020, the European Parliament adopted a resolution on the shortages of medicines ([9]), calling for rapid action to ensure security of supply of medical products, reduce the EU's dependence on third countries and support local pharmaceutical manufacturing for medicines of major therapeutic interest.

More recently, 23 Member States submitted a non-paper calling for a Critical Medicines Act ([10]). The European Council reiterated this call for urgent measures to ensure sufficient production and availability of the most critical medicines and components in June 2023 ([11]). In June 2024, the Council approved Council Conclusions on the future of the European Health Union ([12]), which invited the Commission and the Member States to continue the work on addressing vulnerabilities in the supply chains of critical medicines and, where appropriate, make suggestions to improve their security of supply. In these conclusions, the Council also invited the Commission to consider proposing a Critical Medicines Act to provide a legal framework to address supply chain vulnerabilities of critical medicines, with the aim to strengthen EU production and diversify vulnerable supply chains.

Furthermore, several Member States raised the potential impact of stockpiling and contingency stock requirements on supply in other member states at the EPSCO (Health) meeting in June 2024 and called for a coordinated approach at EU level to ensure transparency, proportionality and solidarity ([13]). At the EPSCO meeting in December 2024, several Member States called for a voluntary cooperation of Member States on joint

([7]) Impact assessment report and executive summary accompanying the revision of the general pharmaceutical legislation, annex 5, 2023

([8]) IQVIA White paper. Beneath the Surface: Unravelling the True Value of Generic Medicines April 2024

([9]) European Parliament resolution on the shortages of medicines

([10]) Non-paper on improving the security of medicines supply in Europe

([11]) Council conclusions adopted in June 2023

([12]) Council conclusions on the future of the European Health Union

([13]) Employment, Social Policy, Health and Consumer Affairs Council (Health), 21 June 2024

procurement of medicinal products ([14]). The discussion referred to the need of providing a legal basis under EU law for this type of actions.

In addition to this, the existence of market failures for *other* medicines of common interest ([15]) persist in several countries, leading to challenges of availability and accessibility of medicines. This is due to certain structural market failures that prevent some medicines from being launched in specific national markets or cause delays in their launching. These failures may arise from factors such as a limited patient population, as it is often the case with orphan medicines, or the small size of a country's market. Additionally, some medicines, such as novel antimicrobials, are intended to be used only in exceptional cases, resulting in very low expected sales volumes. These conditions contribute to an uneven presence of medicines across Member States.

2.2. Relevant existing EU legislation and related initiatives

Shortages of medicines have been on the EU's political agenda for many years ([16]). The **pharmaceutical strategy for Europe** in 2020 ([17]) acknowledged the need to create a future-proof regulatory pharmaceutical framework and give additional support to the pharmaceutical industry in promoting research, innovation and technologies that meet the therapeutic needs of patients while ensuring affordable access to medicines.

The pharmaceutical strategy also included the launch of a **structured dialogue** ([18]) on the industrial policy dimension of security of supply in a public health context. Starting in 2021, this initiative brought together stakeholders from the pharmaceutical industry (including manufacturers of active substances), wholesalers, academia, healthcare professionals and patients, and Member State authorities.

Subsequently, the Commission published a **staff working document on vulnerabilities of the global supply chains of medicines** in 2022 ([19]) which presented the main findings of the structured dialogue with the aim of informing further actions to improve the security of supply and the availability of critical medicines, active substances and raw and starting materials for pharmaceuticals.

Additional steps have been taken since to address the above-mentioned challenges, including the challenge of ensuring supply-chain security of critical medicines. These steps relate in particular to the proposed **revision of the EU general pharmaceutical**

([14]) Employment, Social Policy, Health and Consumer Affairs Council (Health), 3 December 2024

([15]) According to Article 3(5) of the CMA proposal, a medicinal product of common interest means "*a medicinal product, other than a critical medicinal product, for which in three or more Member States the functioning of the market does not sufficiently ensure the availability and accessibility to patients in the quantities and presentations necessary to cover the needs of patients in those Member States*".

([16]) See for instance the European Parliament resolution of 2 March 2017 on EU options for improving access to medicine and the EPSCO Council Conclusions (2021/C 269 I/02)

([17]) A pharmaceutical strategy for Europe - European Commission (europa.eu)

([18]) Structured dialogue on security of medicines supply - European Commission (europa.eu)

([19]) Staff working document on vulnerabilities of the global supply chains of medicines - European Commission (europa.eu)

legislation ([20]), which is currently under discussion by the co-legislators, and the extended mandate of the European Medicines Agency (EMA) ([21]).

The **revision of the EU general pharmaceutical legislation** introduces several regulatory measures to prevent and mitigate critical shortages through EU coordinated actions, and to strengthen the security of supply of critical medicines in the EU. It also aims to improve access to medicines across the EU by clarifying responsibilities, streamlining regulatory processes for the approval of medicines, fostering the competitiveness of the EU regulatory system as well as incentivising equitable access to medicines in all Member States.

In addition, the **new regulation on Health Technology Assessment** ([22]) that entered into force in 2022 and applies from 2025 onwards, aims to ensure a fair, transparent, and evidence-based assessment of medical technologies. This legislation is also expected to reduce delays in access to innovative medicines, such as new cancer treatments, advanced therapy medicinal products and orphan medicines. By establishing a framework for joint clinical assessments among EU Member States, the new HTA regulation aims to enhance national decision-making processes, reduce duplication of efforts and promote equitable access to innovative medical technologies across the Union.

In 2023, the Commission published a Communication on addressing medicine shortages in the EU ([23])**, setting out a number of actions to better prevent and mitigate critical medicine shortages in the EU.** While pharmaceutical companies are responsible for ensuring sufficient supply of medicines to cover the needs of patients, Member States ensure the supervision of medicines supply in their territory. Most shortages are managed and resolved at the national level. However, to prevent and mitigate critical shortages where no alternative medicines are available and that cannot be solved at the national level, coordinated action is needed to address supply challenges and to make Europe's medicine supply chains more resilient in the long run. This coordinated work had already been established at EU level in the context of crisis preparedness and management and was codified in legislation with the introduction of the **EMA extended mandate**, Regulation (EU) 2022/123.

The 2023 Communication therefore put a particular focus on the need for preventative measures to ensure the security of supply of the most **critical medicines** at all times. It highlighted the need to publish a **Union list of critical medicines prior to the adoption of the revised EU pharmaceutical legislation.** The first Union list of critical medicines, identified by combining the criteria of seriousness of the disease and the availability of alternative medicines, was published by the European Commission, the EMA and the Heads of Medicines Agencies of the Member States in December 2023. A second version was published in December 2024 ([24]). The list includes 276 individual active substance

([20]) Reform of the EU general pharmaceutical legislation (europa.eu)

([21]) Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

([22]) Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU

([23]) Communication on addressing medicine shortages in the EU – European Commission (europa.eu)

([24]) Union list of critical medicines | European Medicines Agency (EMA)

groups, covering treatments for various illnesses such as infections, cardiovascular diseases, mental health conditions and cancer. It provides a first list of medicines whose supply chain vulnerabilities should be analysed and where further actions may be needed to reinforce supply chains. In 2024, the Commission conducted a **vulnerability assessment pilot** on 11 critical medicines included on the Union list. The technical report published in July 2024 provides a summary of the main findings as well as the lessons learnt on the data management, methodology and stakeholders' engagement ([25]).

As an additional measure towards boosting the security of supply of critical medicines, the Commission also announced in its Communication the creation of a '**Critical Medicines Alliance**' in preparation of a proposal for a Critical Medicines Act ([26]). This Alliance was formally launched in April 2024 ([27]). The main objective of the Alliance was to 'identify challenges resulting from vulnerabilities and the most appropriate actions and instruments to address the vulnerabilities in the supply chains of critical medicines, with the primary public health goal of reducing the risk of shortages of those critical medicines'. It brought together over 300 organisations, including industry, patient organisations, scientific researchers, healthcare providers and public authorities. The work of the Alliance culminated with its Strategic Report including a set of recommendations on 28 February 2025 ([28]).

In 2024, the Commission organised several *ad hoc* meetings of the **Pharmaceutical Committee** ([29]) in response to Member States' call for further coordinated actions on contingency stocks ([30]). These meetings aimed at sharing information between Member States on existing or planned national measures on contingency stocks to increase transparency and at discussing common principles of proportionality, solidarity and transparency for these national contingency stock requirements.

In recent years, the EU has also been actively working to improve our emergency preparedness and response capacity. This includes not only possible future pandemics, but also natural disasters or conflict scenarios arising from growing geopolitical instability. With the Emergency Framework Regulation ([31]), the EMA and the Commission will be empowered to gather information related to availability of medical countermeasures from Member States and economic operators, in case of a declared emergency. Furthermore, strengthening supply chains, where medical countermeasures are concerned, will also contribute to the crisis preparedness strategy.

([25]) Commission assessment shows the need to reinforce resilience of critical medicines supply chains - European Commission, 2024

([26]) Critical Medicines Alliance - European Commission

([27]) Launch of the Critical Medicines Alliance

([28]) Strategic Report of the Critical Medicines Alliance

([29]) Human Pharmaceutical Committee - Meetings - European Commission

([30]) Contingency stock requirements refer to obligations imposed by Member States on supply chain actors to hold buffer stocks of certain medicines to mitigate the risk of supply chain disruptions.

([31]) Council Regulation (EU) 2022/2372 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level

Collaborative procurement

Prior to the COVID-19 pandemic, there was the possibility for joint procurement of medicines at EU level under the Joint Procurement Agreement for which the legal basis was Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health ([32]). The use of this instrument had been limited so far to procurements of pandemic influenza vaccines.

The COVID-19 pandemic saw major developments in the area of joint procurement. The Joint Procurement Agreement was used to procure a wide range of medical countermeasures ([33]) and equipment. An entirely separate temporary legal basis was created by the Commission and Member States on the basis of the Emergency Support Instrument for the urgent procurement of COVID-19 vaccines by the Commission on behalf of the Member States which at the time was not provided for in the Financial Regulation. While the COVID-19 vaccines procurement remains a unique example of the Commission's procurement on behalf of Member States, from 2020 onwards, the amount of joint procurement carried out at EU level has increased significantly and is still used to improve the preparedness of participating countries by securing medical countermeasures against any cross-border threat to health (e.g. procurement of the mpox vaccine ([34])).

Since the end of the COVID-19 pandemic, the Joint Procurement Agreement's legal basis has been revised and replaced by Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health. Moreover, Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level has provided a permanent legal basis for procurement in a crisis scenario.

In addition, national governments have established different forms of regional collaboration for cross-border procurement of medicines or related activities such as joint price (or reimbursement) negotiations. Member States have the possibility to initiate procurement procedures between contracting authorities from different Member States on the basis of Article 39 of Directive 2014/24/EU of the European Parliament and of the Council on public procurement. Successful examples of such cross-border procurement include the Baltic Procurement Initiative (joint procurement of vaccines included in the national immunisation schedules of at least two of the three member countries Estonia, Latvia, and Lithuania) or the joint Nordic tenders conducted by some of the members of the Nordic Pharmaceutical Forum (Denmark, Iceland, Norway, Sweden) to jointly purchase mainly "old" (well-established) hospital medicines. Differently to these two initiatives, the Beneluxa Initiative - which brings together Belgium, the Netherlands, Luxembourg, Austria and Ireland - focuses on high-cost, potentially innovative medicines

([32]) Joint Procurement Agreement – European Commission

([33]) Medical countermeasures encompass vaccines, therapeutics, diagnostics, and personal protective equipment (PPE). They play a vital role to enhance our protection from current and future health emergencies, including those arising from infectious disease outbreaks, antimicrobial resistance (AMR), chemical, biological, radiological or nuclear (CBRN) threats, or other large-scale cross-border emergencies.

([34]) Procurement of vaccines for Africa Mpox outbreak

and does not conduct joint procurement. However, member countries have conducted joint price negotiations.

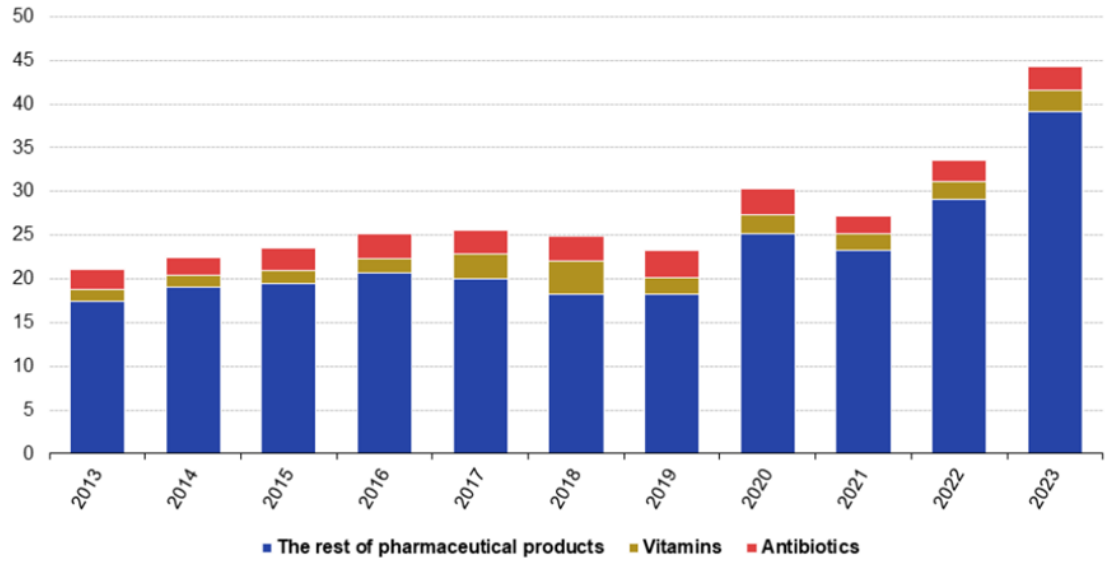
2.3. Critical medicines and other medicines of common interest

2.3.1. The EU pharmaceutical industry

The pharmaceutical industry is of significant importance to the EU, not only for its critical role in developing treatments that improve health and quality of life for patients, but also for its substantial contribution to the EU economy.

According to the exploratory study dedicated to the Critical Medicines Act ([35]), the total production value of basic pharmaceutical products ([36]) fluctuated between EUR 21 billion and EUR 26 billion between 2013 and 2018. Over 2018-2023, the basic pharmaceutical production in the EU experienced significant growth, driven in part by the increased demand during the COVID-19 pandemic, reaching a record high of EUR 44bn in 2023. This was in line with global trends that saw the demand for prescription medicines worldwide steadily increasing by about 13% per year.

Figure 1 - Sold production of basic pharmaceutical products, EU, 2013-2023 (in EUR billion)



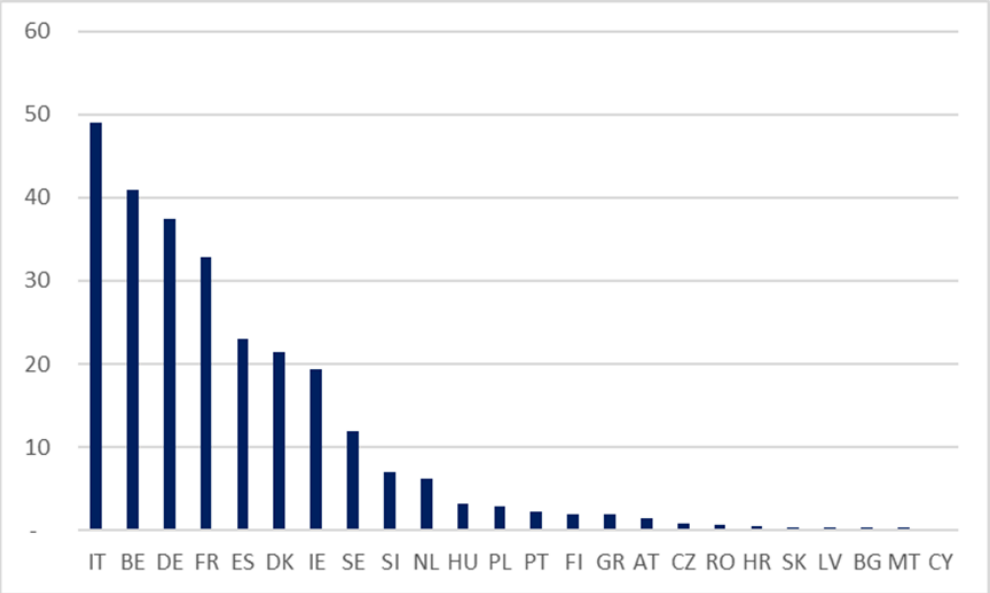
Source: Eurostat (available here) Note: EU except Cyprus, Luxembourg and Malta.

([35]) Exploratory study in view of a Critical Medicines Act by Ecorys (forthcoming study).

([36]) This class comprises medicinal active substances to be used for their pharmacological properties in the manufacture of medicines such as antibiotics, basic vitamins, salicylic and O-acetylsalicylic acids etc but also processing of blood (here) and non-medical products, such as the manufacture of chemically pure sugars.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) reports that the total pharmaceutical production, beyond basic pharmaceutical products, in the EU reached EUR 266bn in 2022, with an estimated value of EUR 285bn in 2023. This reflects a consistent upward trend in output over the past decade. In absolute terms, the largest EU production markets are Italy, Belgium, Germany, and France, which together account for 60% of total pharmaceutical production (see Figure 2). However, when measured relative to GDP (data not shown), key production markets include Slovenia, Belgium, Denmark and Ireland, highlighting their significant contribution to the pharmaceutical sector compared to their overall economic size. This growth has been driven by various factors, such as the increased demand for medicines due the rising healthcare needs, especially during the COVID-19 pandemic, or the growing focus on high-value products like biologicals and advanced therapies.

Figure 2 – Total EU pharmaceutical production, 2022 (EUR bn)



Source: Ecorys calculations based on EFPIA (2024), available here. Data not available for Luxembourg, Estonia and Lithuania.

2.3.2. Critical medicines: a diverse set of pharmaceuticals

Critical medicines are defined as medicines for which insufficient supply results in serious harm or risk of serious harm to patients ([37]). These medicines are identified using the EU methodology outlined in the proposed pharmaceutical legislation. They span a diverse spectrum of medicines (for human use) for which continued supply is considered a priority in the EU. Overall, these medicines are necessary for the normal functioning of healthcare systems and avoidance of serious harm to patients.

([37]) See Article 2(13) of the proposed pharma Regulation (COM(2023) 193) final) and Article 3(4) of the Critical Medicines Act proposal

A first version of the **Union List of Critical Medicines ([38])** has already been prepared in anticipation of the implementation of the revised EU pharmaceutical legislation and the Critical Medicines Act. This list has been compiled using the expertise of the Heads of Medicines Agencies of the Member States, the European Commission, and the EMA, in consultation with key stakeholders, including healthcare professional and patient organisations and industry associations. It includes medicines that are widely used such as antibiotics (e.g. amoxicillin), but also orphan medicines, which target rare diseases (affecting ≤5 in 10,000 people in the EU ([39])) or speciality medicines like biologicals for treatment of cancer or autoimmune diseases.

Published for the first time in December 2023 and updated one year later, the most recent list contains 276 active substances used in medicines for human use that are deemed critical using an agreed methodology, based on two key criteria: 1. the medicine's therapeutic indication; 2. the availability of appropriate alternatives ([40]). It represents currently 18700 medicinal products on the EU market.

Medicines are included on the Union list if they meet the above-mentioned criteria on their critical status and if they meet additional conditions, such as the number of Member States considering the medicine critical or the marketing status of the medicine ([41]). It is important to note that inclusion on the list does not necessarily indicate an imminent shortage, rather it prioritises prevention efforts for these critical medicines.

According to the exploratory study on a Critical Medicines Act ([42]), critical medicines represent a significant and essential segment of the EU pharmaceutical market. Sales of critical medicines accounted for over EUR 30bn in 2023, based on IQVIA MIDAS data ([43]), with a steady increase since 2019. Critical medicines can be dispensed either in hospitals or in pharmacies (retail). Hospital sales accounted for slightly more than half (52%) of total EU sales of critical medicines in 2023 (see Figure 3). Such distinction is important as the distribution channels are different for the two sectors: certain procurement practices are particularly relevant in the hospital sector.

([38]) Union list of critical medicines | European Medicines Agency (EMA)

([39]) Orphan medicinal products - European Commission

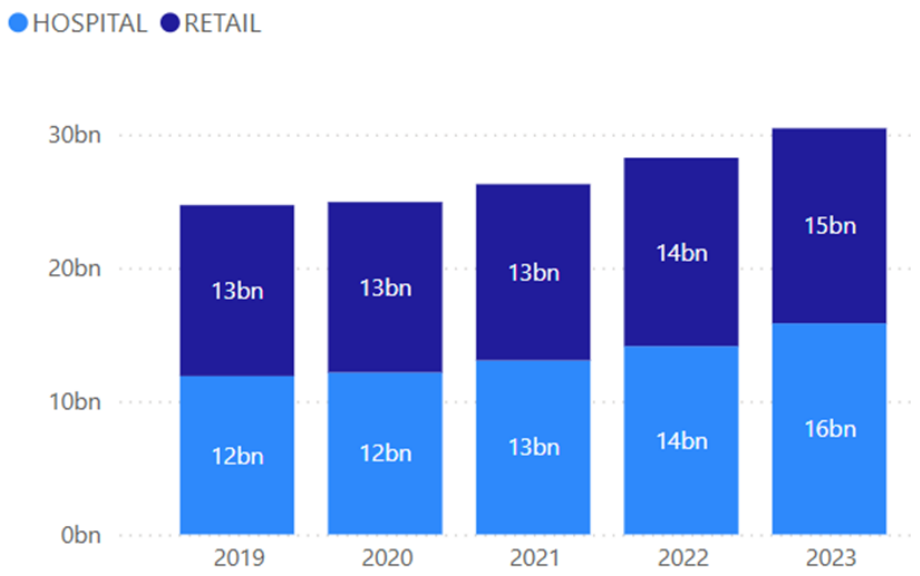
([40]) Union list of critical medicines | European Medicines Agency (EMA)

([41]) Member States carry out the criticality assessment according to an agreed matrix. The outcomes for each medicine are processed by EMA and reviewed according to the agreed conditions to identify medicines as critical for inclusion in the Union list. As part of this assessment, targeted consultations with stakeholders, including patients, consumers and healthcare professionals, may take place.

([42]) Exploratory study in view of a Critical Medicines Act by Ecorys (forthcoming study).

([43]) Use of the WHO ATC Level 5 codes to identify medicinal products listed on the Union List of Critical Medicines (updated version published in December 2024). While an exact match with ATC codes was possible for most products, certain products were instead identified by matching their active substances (leading possibly to a slight overestimation of the market size/volume of critical medicines).

Figure 3 - Sales (EUR) of critical medicines in the EU, by year and distribution channel

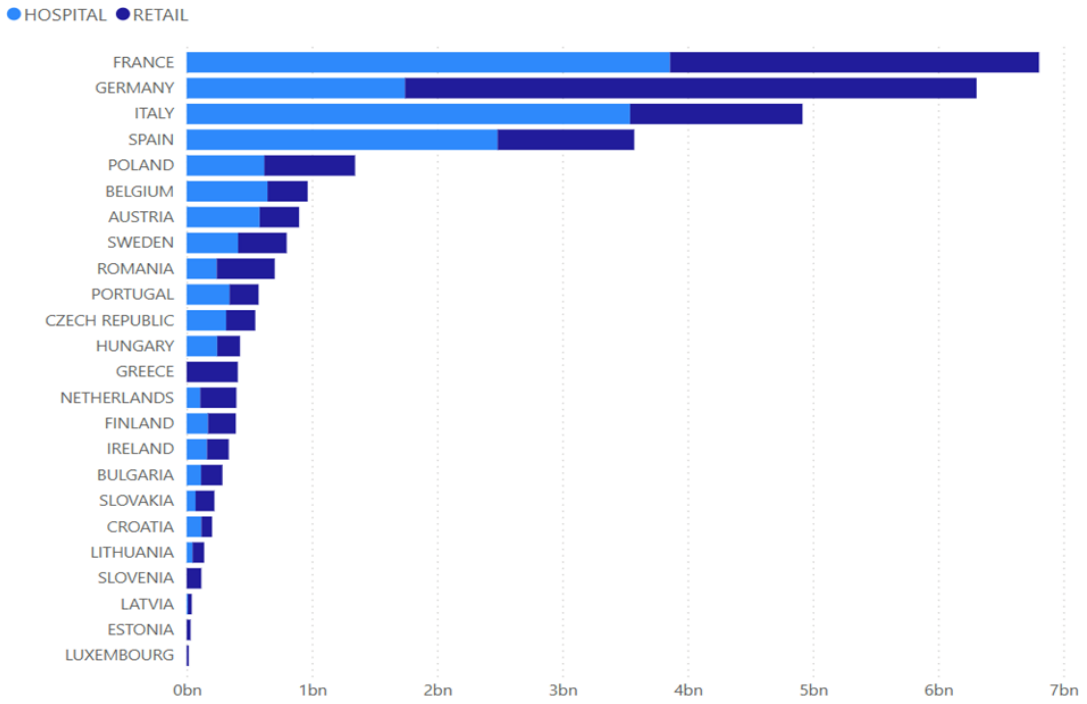


Source: Ecorys based on IQVIA MIDAS®: value sales data of critical medicines in the EU for period January 2019 to December 2023 reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved.

Figure 4 further breaks down the sales of critical medicines in the EU by country and distribution channel for 2023. It highlights substantial disparities in market size and sectoral distribution across Member States, reflecting the varying roles of healthcare systems and retail distribution channels in different countries.

France, Germany, Italy, and Spain dominate the sales landscape of critical medicines, accounting for more than 70% of the EU market. This reflects their large national healthcare markets for critical medicines and may also be driven by price differentials across Member States. In these countries, with the exception of Germany, *hospital* sales surpass *retail* sales, highlighting the critical role of hospitals in the distribution of these medicines. In France, the distribution is relatively more balanced, with 57% of sales through hospitals and 43% through retail. In contrast, Italy (72% hospital, 28% retail) and Spain (69% hospital, 31% retail) demonstrate a significant dominance of the hospital sector. Conversely, Germany stands out with retail as the primary distribution channel, accounting for 72% of total sales. Mid-sized markets, including Belgium, Austria, and Sweden, display similar trends with a prevalence of hospital sales. Overall, the data reflects the significant variations in healthcare infrastructure and market dynamics across the EU.

Figure 4 - EU sales (EUR) of critical medicines, by country and distribution channel (2023)

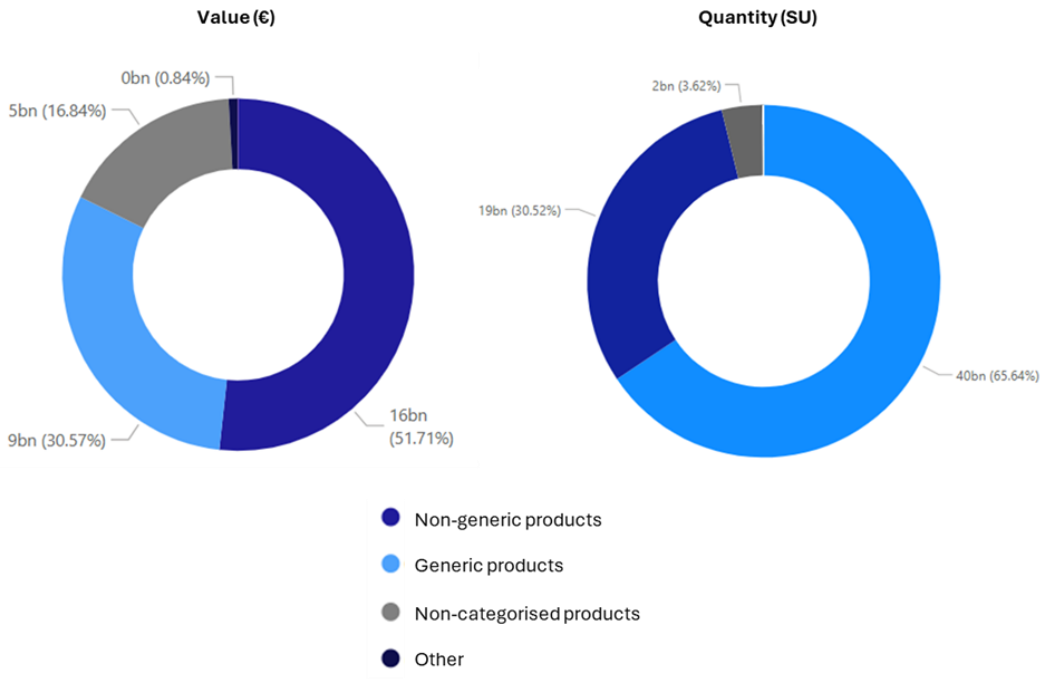


Source: Ecorys Study based on IQVIA MIDAS®: value sales data for period January 2023 to December 2023 reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved. *Note: for Greece and Estonia only retail data are available.

Figure 5 illustrates the *distribution* of EU sales for critical medicines in 2023 ([44]). Non-generic products represent the largest share in terms of value of critical medicines, amounting to EUR 16 billion (51.7%). Generic products, while contributing a substantial EUR 9 billion (30.6%), represent a comparatively smaller share of the value. This disparity appears to be driven by the relatively higher prices of non-generic medicines. However, when considering volumes of sales, generic products account for over 65% of total sales of critical medicines within the EU, although non-generic products still maintain a significant share, slightly below one-third.

([44]) Critical medicines are categorised by legal status into non-generic products (also known as innovator or reference products), generic products (medicines with same qualitative and quantitative composition in active substances and same pharmaceutical form as the reference medicine – they are marketed after the patent and exclusivity rights of the reference product has expired) and non-categorised products (when the legal status of is not specified in the database)

Figure 5 - EU sales of critical medicines, by legal status (2023)



Source: Ecorys study based on IQVIA MIDAS®: value and volume sales data for period January 2023 to December 2023 reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved. Note: Quantities are expressed in Standard Units (SU), which is a unit of measure designed to standardise comparisons across different markets, formulations, and packaging. It is agnostic to pack size and represents the smallest measurable dose of a product, such as a single tablet capsule, vial or millimetre of liquid medication.

2.3.3. Medicines of common interest

Medicines of common interest are defined as medicines, other than critical medicines, for which in three or more Member States the functioning of the market does not sufficiently ensure the availability and accessibility to patients in the quantities and presentations necessary to cover the needs of patients in those Member States ([45]). Medicines of common interest can comprise all types of medicines - novel medicines, off-patent molecules, or others - if a market failure prevents the medicine from being available and accessible to patients in affected Member States. Similarly to critical medicines, the medicines of common interest span a wide range of therapeutic areas, from orphan medicines to novel antibiotics.

The category of medicines of common interest could include any of the approved medicines in Europe, other than critical medicines, including newly authorised medicines at EU-level, providing that a market failure exists ([46]).

([45]) See Article 3(5) of the Critical Medicines Act proposal

([46]) In 2024, EMA recommended 114 medicines for marketing authorisation, including 46 with new active substances. Over the past years, on average 45 new medicines were authorised by the Commission through the centralised procedure. From the impact assessment underpinning the general pharmaceutical legislation (section 5.1.1, page 30), it is noted that the life sciences sectors continue to invest in and

Policy actions related to medicines of common interest are restricted to those medicines where there is a need for EU intervention. Market failures may arise from various structural factors, such as limited population sizes (as seen with orphan medicines), or the nature of some medicines that are intended to be used only sparingly, such as novel antimicrobials. Estimating the probabilities of market failures leading to access and availability issues requires assumptions on the likelihood of arising market failures, the likelihood of addressing the problem by the affected Member States, and the probability of Member States agreeing on a set of actions. Making highly uncertain assumptions about the future state of markets and policy actions is outside the scope of this document.

To illustrate the problem of access, and as a proxy for the problem of availability of medicines, the unequal access of EU Member States to innovative medicines can be considered. While most likely only a fraction of innovative medicines are only marketed in a few Member States due to market failures, figures about the lack of access of EU Member States can give an upper bound estimate for the problem as follows:

The impact assessment underpinning the general pharmaceutical legislation ([47]) has shown that approximately 90 million of EU citizens or 20% of the EU population lack complete access to the average new medicine 5 years after that new medicine received marketing approval in the EU. This estimate is a rather conservative approximation of the possible scope of medicines of common interest because it does not include medicines which are available but hardly or not affordable, for example when not dispensed due to price constraints.

The lack of access has been illustrated more recently in a case study of medicines approved in 2011 reported in the Draghi's report ([48]) (see below). Figure 6 displays, by Member State, the number of medicines brought to the market between 2011 and 2022 from the group of medicines for human use (excluding generics and biosimilars) that received central marketing authorisation in 2011. The graph highlights that a maximum of 30 medicines ("products") of that sample were launched in Germany (DE) between 2011 and 2022. In 2022, after 11 years, a maximum of 20 new medicines of the same sample were launched in the countries with the least newly launched medicines (LT, HR, LV). The graph illustrates with the sample of 2011 authorised medicines, that 10 medicines, or around 30% of all newly launched medicines, were not available in at least three countries after 11 years ([49]).

Figure 6 also shows that, even after 11 years, in 2022, a group of 8 Member States (approx. 19% of the EU population) lacked access to at least 20% of medicines that were approved in 2011. The Member States which lacked access to at least 20% of the approved medicines

advance innovative therapeutics and vaccines, the total number of products that are in active development globally exceeds 6,000, up 68% over the 2016 level. ('Global Trends in R&D: overview through 2021,' IQVIA Institute for Human Data Science, February 2022.) Rich pipelines translate to more medicine authorisations, and it is assumed that the current annual 30-40 authorisations of medicines with new active substances in the EU will expand to 50-60 in the next 15 years. In a dynamic baseline, the IA considers the middle value at the middle of the next 15-year period, 45 innovative medicines per year.

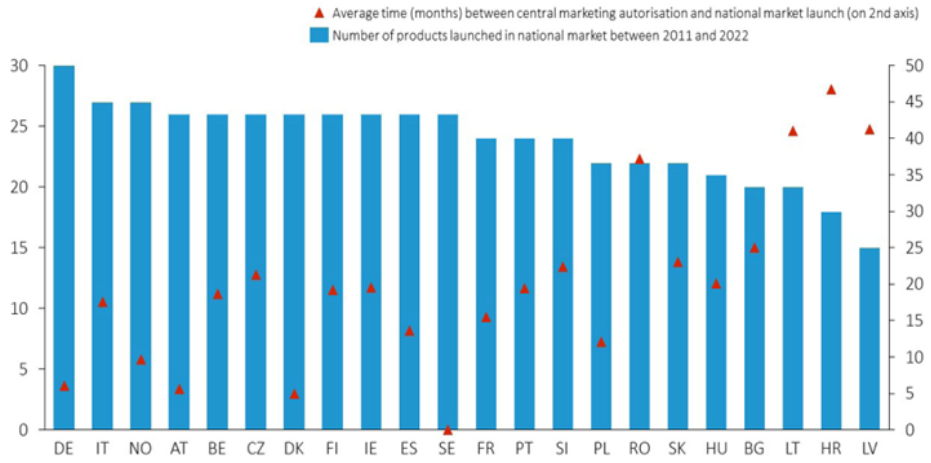
([47]) Impact assessment underpinning the general pharmaceutical legislation - Annex 4, Figure 3, page 48.

([48]) Draghi's report on "The future of European competitiveness, part B", figure 7, p. 194.

([49]) The graph does not inform us whether the 10 medicines which are not available in at least three MS were actually the same medicines.

after 11 years (Figure 7, Draghi report) miss out access to 8 medicines (26% of all approved medicines in 2011) on average. Even for the medicines that were ultimately launched in the group of 8 Member States, the average delay to the date of the marketing authorisation was up to 4 years and in many Member States more than 3 years.

Figure 6 – Wide differences in national market launches



Source: European Commission. Based on IQVIA MIDAS quarterly volume sales data for period 2012 – 2022 reflecting estimates of real-world activity. Copyright IQVIA All rights reserved

3. PROBLEM DEFINITION

3.1. Problem 1: Shortages of medicines affecting the security of supply and availability of critical medicines

The main problem that the CMA proposal aims to tackle is the increasing challenge to secure a stable and resilient supply of medicines that are critical to ensure the health of EU patients. The potential consequences of medicine shortages are significant for both EU citizens and society. They include:

- reduced quality of life for patients, particularly for those with chronic or life-threatening conditions and potential deterioration of their health status due to delays in treatment and suboptimal care;
- increased healthcare costs, as alternative treatments or medicines may be more expensive; and,
- additional burden on healthcare systems, as the management of medicines shortages leads to substantial costs for public authorities while healthcare providers are spending significant time and resources managing shortages and finding alternative treatments instead of dispensing care to their patients.

In 2024, among the 1214 shortage notifications received by EMA from marketing authorisation holders of centrally authorised medicines (corresponding to shortages of 280

molecules), 35 molecules are included in the most recent version of the Union list of critical medicines (version 2) ([50]).

In addition, among the 63 notifications of critical shortages by national competent authorities to EMA via the SPOC working party, 29 molecules are included in the Union list of critical medicines (version 2) ([51]).

Root causes of medicine shortages

Causes for shortages are complex and multifactorial and can include challenges along the entire pharmaceutical value chain, such as quality and manufacturing problems, commercial decisions, and complex supply chains. Since 2019, root causes of shortages have been classified by the Medicine Shortages SPOC working Party (formerly known SPOC Network) under eight distinct categories to harmonise critical shortage detection, reporting and management across the EU medicines regulatory network. These have been further analysed in the context of the exploratory study in view of a Critical Medicines Act ([52]):

- Quality issues
- Manufacturing issues
- Regulatory issues
- Safety and efficacy issues
- Unpredicted major events or natural disasters
- Unexpected increased demand
- Distribution issues
- Commercial reasons

([50]) Union list of critical medicines - European Medicines Agency

([51]) These numbers should not be considered in isolation as there may be multiple shortage notifications for a given molecule/INN in cases where there are both NAPs and CAP authorisations or different presentations.

([52]) Exploratory study in view of a Critical Medicines Act by Ecorys (forthcoming study).

Figure 7 – SPOC Network (now Medicine Shortages SPOC Working Party classification of root causes of shortages

SPOC classification	Definition
Quality issues	Unforeseen disruptions within the manufacturing process leading to quality defects (API or finished product), including recalls.
Manufacturing issues	Unforeseen disruptions within the manufacturing process caused by GMP compliance problems (API or finished product). Manufacturing issues also include capacity issues.
Regulatory issues	When requirements or obligations relating to the grant of the authorisation have not been fulfilled after authorisation and 'placing on the market', e.g. Brexit. Failure to implement safety features, i.e. MAH failure to implement the unique identifier and the tamper evident features on the pack are also considered regulatory issues.
Safety and efficacy issues	If the medicinal product lacks therapeutic efficacy (or decrease efficacy), there are new safety risks identified requiring precautionary action, or the risk-benefit balance of the medicine is no longer favourable.
Unpredicted major events or natural disasters	May indirectly lead to shortages of medical products, e.g. the ongoing swine fever in China or the earthquake in Japan in 2011
Unexpected increased demand	Due to previous defects, due to market cessation/shortage of alternative products (e.g. generics), due to great awareness about a specific disease prevention or new treatment guidelines and/or recommendations of physicians'/veterinarians'/other healthcare professionals' organisations, change in reimbursement conditions, change in epidemiology
Distribution issues	Distribution channel structures, parallel trade or export to outside of the EU, quotas, supply chain policy (e.g. DTO), logistic issues
Commercial reasons	Company-driven decisions linked to business aspects such as pricing negotiations; discontinuation; change in reimbursement status; low sales (i.e. low number of patients); business strategies prioritising other markets.

Source: Future-proofing pharmaceutical legislation - study on medicine shortages, December 2021

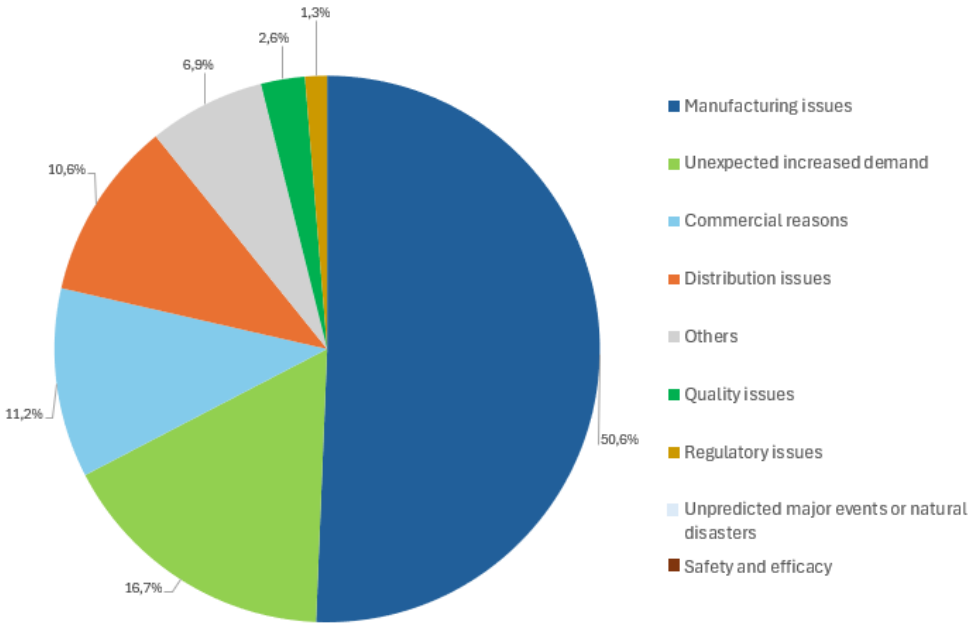
The 2021 study on medicines shortages ([53]) pointed to the fact that half of reported shortages can be traced back to issues with quality and manufacturing. In addition, commercial reasons, including market withdrawals, and unexpected increases in demand were also highlighted as other common causes of shortages. For example, the COVID-19 pandemic posed a major challenge to the continued availability of medicines used in the treatment of COVID-19 patients due to a surge in demand.

A recent survey conducted by the EU4Health programme-funded Joint Action of Member States on shortages (CHESSMEN) ([54]) confirmed these findings and identified that over 50% of reported shortages are caused by manufacturing issues, a category which includes shortages related to the availability of active substances.

([53]) Future-proofing pharmaceutical legislation - Study on medicine shortages, 2021

([54]) CHESSMEN analysis report on root-causes, 2024

Figure 8 – Root causes of medicines shortages in 2022 and 2023 in EU/EEA countries



Source: CHESSMEN joint action

The CHESSMEN joint action also looked at more granular reporting on root causes of shortages available in certain countries. In this context, manufacturing issues such as capacity constraints (representing 13,1% in 2022 and 14,7% in 2023), delay in manufacturing (7,4% in 2022 and 7,8% in 2023) or unavailability of API (2,4% in 2022 and 2,3% in 2023) were more frequently reported by marketing authorisation holders. Furthermore, market discontinuation appears to be the first cause of shortages due to commercial reasons, representing 4,9% in 2022 and 4,2% in 2023.

The analysis of shortage reporting provides a good understanding of the most acute causes of shortages reported by the marketing authorisation holders but a more detailed analysis of the underlying supply challenges leading to these shortages is required (see section 3.3 on problem drivers). It is therefore necessary to go beyond reported causes of shortages, to identify vulnerabilities in the supply chains, including dependency on third countries, lack of diversification and market concentration, that affect the resilience of supply chains as well as their ability to adapt and respond to unpredicted events, such as manufacturing and quality issues or unexpected increase in demand. Other external factors, such as procurement practices and pricing policies could also impact the decisions of pharmaceutical companies to invest or not in resilient supply chains.

3.2. Problem 2: Market failures affecting the availability of and accessibility to medicines of common interest

Medicines of common interest are medicines (other than critical medicines) for which, due to underlying market failures, availability or accessibility to patients in the quantities and presentations necessary to meet the needs of patients in certain Member States is not sufficiently ensured. After marketing authorisation, certain medicines are not launched in all Member States or are launched with major delays or in insufficient quantities or are

subsequently withdrawn. Companies have the choice where and when to launch centrally authorised medicines. Under the current legislation, they only risk to lose the market authorisation, if the product is not launched in at least one Member State within three years of its authorisation (the so-called 'sunset clause'). Some companies enter into pricing and reimbursement negotiations only a significant time after the marketing authorisation is granted or not at all. This creates an unpredictable situation for patients, healthcare systems and Member States. The decision for a company to launch and when depends on different commercial factors, for example the size of the patient population, or national pricing and reimbursement policies or the organisation of health systems. In some cases, these factors can result in a market failure – for example, when the patient population is very small, or when the characteristics of the medicine - such as novel antimicrobials intended for limited use, limit its potential uptake.

More specifically, these market failures are evident in the case of medicines for rare diseases, where availability or accessibility varies considerably between Member States. Germany, France or Italy for instance have a high market uptake, with more than 100 medicines for rare diseases available. On the contrary, countries like Lithuania, Bulgaria or Ireland had fewer than 50 orphan medicines available ([55]). Furthermore, compared with standard medicines, access conditions for patients are worse for orphan medicines. Out of the 190 orphan medicinal products developed and authorised in the 2000-2020 period, data were collected for 155 of them and it was found that only about half of them were accessible to patients in a majority of Member States ([56]).

3.3. What are the problem drivers?

Vulnerabilities in the pharmaceutical supply chain

The structured dialogue on security of medicines supply which involved supply chain actors, public authorities, representatives of patients and healthcare providers and the research community, looked at the functioning of global pharmaceutical supply chains and identified causes and drivers of different potential vulnerabilities threatening the supply of critical medicines, active pharmaceutical ingredients (APIs) and raw materials ([57]). Several potential sources of supply chain vulnerabilities were identified and described, including the increasing complexity and specialisation of pharmaceutical supply chains, challenges linked to certain production process and technologies as well as dependencies especially when combined with the lack of geographical and consolidation of the supply chain.

In 2024, the Commission conducted a technical assessment of supply chain vulnerabilities for critical medicines ([58]). The analysis focused on a selection of 11 critical medicines from the Union list. Six indicators were considered: a) EU industrial presence, b) diversification (number of manufacturing sites and countries), c) market concentration (concentration of

([55]) Evaluation of the medicines for rare diseases and children legislation (2020); Chapter 5.1.2. Effectiveness. Reference year 2016.

([56]) Ibid.

([57]) Structured dialogue on security of medicines supply, 2021

([58]) Commission assessment shows the need to reinforce resilience of critical medicines supply chains - European Commission, 2024

production volumes in few companies or countries), d) supply chain risks (self-assessment), e) unpredictable demand (lack of demand visibility and predictability) and f) economic viability. The issues identified by the pilot analysis included the significant dependences on non-EU active substances suppliers and risks stemming from market concentration. The pilot analysis pointed to the need to strengthen resilience, such as diversifying supply sources, increasing production capacity flexibility and developing robust risk management frameworks to handle economic and market variability effectively. Finally, the exploratory study in view of a CMA as well as the Critical Medicines Alliance also looked at the supply chain vulnerabilities. See more details under section 4.

EU dependencies on third countries for the production of API and critical medicines

The COVID-19 pandemic clearly exposed significant vulnerabilities in the EU's pharmaceutical, in particular the heavy dependence on foreign sources for active substances. This situation underscored the critical importance of economic security, as disruptions in global supply chains—whether due to pandemics, geopolitical tensions, or other factors—can have severe implications for national and regional security, economic resilience, and public health.

The production of active pharmaceutical ingredients (APIs) for generic medicines has been largely moved to Asian countries in the past years for economic reasons. The Structured Dialogue findings suggest a strong position of Asian producers in the API market for generic products ([59]). The analysis of the certification database of EDQM ([60]) covering chemical APIs confirms the heavy dependence of the Union on non-EU manufacturers with approximately 75% of API production sites located outside the EU, notably in India and China ([61]). For approximately 21% of the APIs analysed in the exploratory study in view of a CMA, there was no production within the EU at all. This clearly represents a significant vulnerability in the event of international supply chain disruptions. Moreover, this is likely an underestimation of vulnerabilities during the production process, as these data only cover API production and do not account for stages further upstream (i.e., raw materials and intermediates), for which data are more limited ([62]).

The shift to non-EU production could be explained by economic factors, as the cost of APIs sourced in Asia can be 20 to 40% lower than those produced in the EU. Also, significant economies of scale for Asian suppliers of APIs, precursors and

([59]) Commission Staff Working Document on vulnerabilities of the global supply chains of medicines, October 2022

([60]) The European Directorate for the Quality of Medicines & HealthCare (EDQM) maintains a Certification database which includes information on Certificates of Suitability (CEPs) granted by the EDQM. This database contains details about certified API manufacturers and their production sites. According to EDQM estimates, a significant proportion of manufacturers utilise the CEP procedure for substances with European Pharmacopoeia monographs. For older substances, such as paracetamol, this figure can exceed 95%.

([61]) Exploratory study in view of a Critical Medicines Act by Ecorys (forthcoming study).

([62]) Ibid.

intermediates can lead to lower production costs ([63]). The Structured Dialogue also emphasised that European manufacturers tend to focus on specific APIs (e.g. low production volumes, complex production processes) but technical know-how and capacities to increase European API production are still available. Nevertheless, some technologies used upstream in the manufacturing chain of medicines may no longer be available in Europe. This high dependency on non-EU countries for API production therefore exposes to disruptions resulting from external factors such as trade interruptions.

The vulnerability assessment pilot confirmed the significant dependences on non-EU API suppliers, with a high vulnerability of 4 out of 11 substances due to reliance on API manufacturing outside the EU.

Lack of diversification and market concentration

The exploratory study in view of a CMA identified five distinct manufacturers (or manufacturing facilities) for each API used for production of critical medicines on the Union list of critical medicines in average (median value). Nevertheless, a certain degree of concentration can be observed, with the number of manufacturers ranging from one to as many as thirty-five. Each API is produced in an average of three countries, again with significant variations (from one to nine different countries) ([64]).

Reliance on a sole or limited number of suppliers, especially when they are in one single geographical region can pose significant supply risks, especially if the capacity to manufacture the products in question is not readily available in the EU. In case of manufacturing or quality issues affecting a single source supplier, production cannot be quickly taken over by another supplier. Similarly, market cessation or withdrawal would result in a shortage in absence of alternative supplier.

According to the vulnerability assessment pilot analysis, the level of diversification varies significantly from one critical medicine to another. Nevertheless, the diversification of manufacturing sites is not sufficient to ensure the resilience of supply chains given that a significant proportion of the production might come from a limited number of producers. In this respect, the vulnerability assessment pilot analysis highlighted that for all the critical medicines investigated, over 30% of their supply was coming from a single country or manufacturer, underscoring a risk of vulnerability. This concentration of production also increases the risk of supply chain disruption due to geopolitical issues, trade restrictions, or production problems.

Increased complexity and specialisation of pharmaceutical supply chains

The increased complexity of pharmaceutical supply chains coupled with a trend of specialisation can also make them vulnerable ([65]). While the production of older chemical medicines often involves several manufacturers, the supply chain of innovative and biological medicines tends to be more integrated. Complex and novel innovative

([63]) Commission Staff Working Document on vulnerabilities of the global supply chains of medicines, October 2022

([64]) Exploratory study in view of a Critical Medicines Act by Ecorys (forthcoming study).

([65]) Commission Staff Working Document on vulnerabilities of the global supply chains of medicines, October 2022

manufacturing processes of innovative medicines pose specific challenges such as the difficulty of dual sourcing or to make manufacturing adjustments. As a result, restoring supply after temporary disruption or a manufacturing issue might take significant time. Ramping up production in response to increased demand would also be more difficult than for chemical medicines.

Fragmented procurement practices and pricing policies

Overall, generic competition and Member States procurement practices have a positive impact on the affordability and availability of medicines. In markets with multiple suppliers, competition may lead to diverse and more resilient supply chains.

While price competition for off-patent medicines improves affordability and availability of medicines for patients, pharmaceutical firms may adapt production technologies and supply chains to maximise profits by reducing production costs, for example, relocating production to non-EU countries. Some of the industry's measures to maximise profits may have effects on the resilience of supply chains.

For example, in the short-run, profit maximising firms may choose to produce products with the highest profits leading to undersupplied markets or not supplied markets at all. As a result in the short run, this can lead to less resilience due to less suppliers in certain markets, i.e. higher market concentration ([66]). Generally, in the long-run, entry of new suppliers can be expected to fill the gaps in the supply chain. However, in certain cases, investments to enter a market may not be profitable to sustain entry.

Another example shows, as suggested by the study on medicines shortages ([67]), that national procurement practices can have an impact on short-term supply shocks. For example, "winner-takes-all" tenders, whereby the winning bidder becomes the sole supplier to a market for a given period for a specific medicine, may reduce the number of firms in the market. Losing tenderers may decide to stop production (and potentially to withdraw from other markets or not renew the marketing authorisation) for that medicine altogether as their market share has become too small to be economically attractive or viable. In the short run, this again can have the effect of thinning out competition, leaving the market dependent on a single or only a few suppliers and leaving society vulnerable to supply shocks, for example, due to production problems.

Nevertheless, it is also important to distinguish between generic medicines and innovative medicines. Some of the market dynamics which are observable for generic medicines do not necessarily apply to innovative medicines.

Limited market size and other external factors

Issues with availability of certain medicines can be due to the size of the targeted population or limited intended use of the medicine. Limited attractiveness of the market is as a key barrier encountered in several countries ([68]), in particular for small countries. Due to their size, these markets are often considered as less attractive by the pharmaceutical

([66]) Exploratory study in view of a Critical Medicines Act by Ecorys (forthcoming study).

([67]) Future-proofing pharmaceutical legislation - Publications Office of the EU

([68]) Study on Best Practices in the Public Procurement of Medicines, September 2022

industry, leading to significant delays or even no access to potentially lifesaving treatments for patients. Moreover, these countries, frequently may have a more limited negotiating power, eventually resulting also in higher prices for innovative treatments.

More recently, the potential impact of certain national contingency stock requirements on the availability of medicines in other Member States has also been raised by certain stakeholders, including some Member States ([69]).

3.4. How likely is the problem to persist?

Based on the analysis of the problems and drivers (see sections 3.1 and 3.3), without action, it is highly likely that medicines shortages will continue to be a significant issue in the absence of additional preventive measures to reinforce the resilience of supply chains of critical medicines and reduce our dependencies on third countries. The number of reported shortages has been progressively increasing over the past decade. Shortages are attributed to various factors, including supply chain vulnerabilities and external factors, which require long-term structural changes to address effectively. In addition to monitoring measures included in EMA's extended mandate (Regulation (EU) 2022/123), the proposed extension of systems and processes to mitigate and manage critical shortages and improve the supply security of critical medicines is set out in the proposed revision of pharmaceutical legislation, with a focus on regulatory measures. These regulatory measures are expected to support the security of supply of critical medicines by requiring companies to hold shortage prevention plans, establishing the Union list of critical medicines, assessing the supply chain vulnerabilities, empowering the MSSG to provide targeted recommendations to the relevant stakeholders and empowering the Commission to take additional measures. Nevertheless, these measures should be complemented by an industrial policy toolbox combining measures to support increased investment in EU manufacturing capacity (push measures) and measures incentivising and rewarding supply chain resilience and diversification (demand side measures). These measures are required to address the identified supply chain vulnerabilities, reverse the current trend related to the decreasing number of suppliers of critical medicines and the overreliance on third country suppliers for the production of their active substances but also to ensure that procurement practices adequately take into account the security of supply of critical medicines.

Similarly for other medicines of common interest, the identified problem and related driver (see sections 3.2 and 3.3) are expected to persist without targeted measures to further support their accessibility and availability.

([69]) Employment, Social Policy, Health and Consumer Affairs Council (Health), 21 June 2024

4. CONSULTATION AND USE OF EXPERTISE

A rich evidence base and extensive stakeholder input concerning medicine shortages and critical medicines have been gathered and analysed in preparation for the revision of the pharmaceutical reform. The Critical Medicines Act proposal was preceded by comprehensive consultations with stakeholders through the Structured Dialogue on the security of medicines supply ([70]) and in the Critical Medicines Alliance ([71]). The *evaluation* of the EU pharmaceutical legislation ([72]) highlighted that medicine shortages are an increasing problem in the EU and that they have grown worse since the COVID-19 pandemic. Overall, there has been a marked increase in the number of reported shortages across the EU. These shortages are placing a significant burden on health systems and health professionals, putting patients at risk of sub-optimal care and health systems at risk of higher healthcare costs ([73]).

In February 2021, the Commission consulted stakeholders in a structured dialogue on security of medicines supply ([74]). Participants in this dialogue included: (i) actors in the supply chains of critical medicines; (ii) public authorities; (iii) patient and health non-governmental organisations; and (iv) the research community. This dialogue further deepened the understanding of the complexity of global pharmaceutical supply chains.

These consultations also explored the stakeholders' view on this topic ([75]). These consultations confirmed that stakeholders (in particular, civil society organisations and healthcare professionals) see medicine shortages as a crucial issue. In the targeted surveys, civil society, public authorities and health service stakeholders considered that the area that legislation was the least effective in addressing was issues related to security of supply and medicine shortages. They also gave their view on policy measures, such as shortage prevention plans, a shortage monitoring system at EU level or the shortage notification. Furthermore, a dedicated validation workshop was held on supply chains in April 2022. During this workshop, various stakeholders explained that diversification of the supply chain is challenging and not always feasible due to the difficulty of finding alternative suppliers upstream in the supply chain ([76]).

Furthermore, the preparatory work on the Critical Medicines Act proposal included the consultation of relevant stakeholders through the Critical Medicines Alliance, the publication of a call for evidence as well as a survey, targeted consultations and other outreach activities in the context of a supporting study. Stakeholders feedback on the Call for Evidence has been analysed and duly taken into account during the preparation of the proposal. The aim of the consultation strategy was to receive input from relevant

([70]) Structured dialogue on security of medicines supply - European Commission

([71]) Critical Medicines Alliance - European Commission

([72]) Reform of the EU pharmaceutical legislation - European Commission

([73]) Future-proofing pharmaceutical legislation - Study on medicine shortages, 2021

([74]) The list of organisations can be consulted here

([75]) Reform of the EU pharmaceutical legislation - European Commission

([76]) See Annex 2 synopsis report (stakeholder consultation) for the reform of the EU pharmaceutical legislation.

stakeholders throughout the pharmaceutical manufacturing and distribution chain, as well as citizens, patients, public administrations and healthcare providers.

4.1. Critical Medicines Alliance

More than 300 stakeholders of critical medicine supply chains, as members of the **Critical Medicines Alliance** that includes industry representatives, trade associations, patient organisations, medical profession organisations and Member States, have been consulted on key topics of interest for critical medicines' supply chain strengthening. After the launch of the Alliance in 2024, technical discussions took place at working group level throughout the rest of the year. Specifically, the Steering Board of the Alliance, the main governing body that includes representatives of the trio of current Council presidencies, representatives from five pharmaceutical associations and two civil society groups, created two Working Groups, one on incentives to strengthen manufacturing capacity in the EU while the second looked at diversification of supply chains through partnerships with like-minded non-EU countries. Each working group, further subdivided into subgroups and taskforces, met on a regular basis over 2024 to discuss, at expert technical level key challenges and considerations on topics and objectives of the working groups. Together, the subgroup/taskforces created specific recommendations for the consideration of the Steering Board. The results of these recommendations, endorsed and compiled by the Steering Board in its Strategic Report ([77]), provide for actions on vulnerability assessment, incentives for investments in manufacturing capacity, contingency stocks and procurement approaches, as well as leveraging partnerships with non-EU countries. In particular, the Alliance recommended: (i) establishing a European list of Critical Vulnerable Medicines; (ii) implementing a European Investment plan to strengthen production capacities for critical medicines in Europe by combining EU funding programmes and State aid; (iii) implementing a comprehensive harmonised and balanced framework on contingency stocks; (iv) promoting virtuous public procurement practices by means of applying specific 'MEAT' criteria ([78]) and making further use of joint procurement; and (v) promoting a level playing field for environmental and social standards, as well as fair competition between critical medicines manufactured in the EU and in the rest of the world. On partnerships with non-EU countries, the Alliance specifically recommended making use of the developed methodology to assess the prospects of countries for different types of partnerships.

Finally, the Alliance recommended that the MSSG (Executive Steering Group on Shortages and Safety of Medicinal Products) formalises the possibility for outreach to non-EU country jurisdictions, as part of the Voluntary Solidarity Mechanism ([79]).

([77]) Critical Medicines Alliance - European Commission

([78]) Most economically advantageous tender which allows for more prominence to be given to quality beyond price considerations alone.

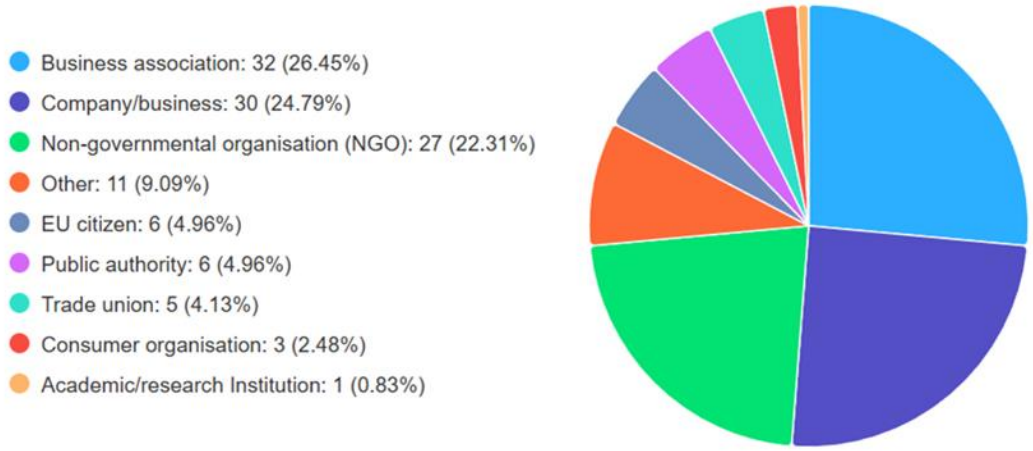
([79]) A summary of the Strategic Report's main recommendations can be found in Annex 1.

4.2. Call for Evidence

A general consultation on the proposed Regulation was launched in a **Call for Evidence** that was published on 30 January 2025 ([80]). The Call for Evidence took place from 30 January to 27 February 2025 ([81]). The document was published on the Better Regulation portal of the European Commission (also known as 'Have Your Say' Portal),) to give stakeholders an opportunity to comment on the need for action and the envisaged initiative; and to provide input on any further issues to be considered when developing this policy field.

The Commission received 121 valid contributions to the Call for Evidence request, submitted by business associations (26%), company/businesses (25%), non-governmental organisations (22%), EU citizen (5%), public authorities (5%), trade unions (4%), consumer organisations (2%), academic/research institutions (1%), and other (9%). The chart below shows the share of responses by the various stakeholders' groups.

Figure 9 – Categories of respondents



A majority of the responses received were submitted by business associations and companies, though NGOs and consumer organisations also accounted for a significant share of replies. The responses came from 22 countries (including 5 non-EU countries). Among these, Belgium was the most represented (32%) as most European business associations and civil society organisations are headquartered in the country, followed by Germany (15%), France (7%), Italy (6%) and Spain (5%).

A broad majority of the responses supported the Commission in tabling a Critical Medicines Act, seeing it as a crucial tool to prevent shortages of critical medicines. To highlight some key considerations, the various stakeholders' groups, companies and business associations noted the persistent dependencies on non-EU suppliers, particularly for active pharmaceutical ingredients (APIs), and the resulting increased risk of medicine shortages. They welcomed the European Commission's commitment to securing supply

([80]) Critical Medicines Act

chains, and call for a comprehensive legal framework, promoting EU-based production of APIs, coupled with improved access to funding mechanisms.

To ensure transparency, accountability and efficiency, many NGOs proposed regular risk assessments and vulnerability analysis of the pharmaceutical supply chains and a coordinated monitoring system taking into account existing national systems to avoid duplications.

Public authorities in particular supported the voluntary joint procurement of critical medicines. Responses from various stakeholder groups noted the need to address fragmentation stemming from national stockpiling requirements. There was also wide support on the importance of global partnerships to maintaining robust supply chains.

4.3. Targeted consultations

This evidence gathering process was complemented by targeted consultations through exploratory and targeted interviews and through targeted surveys ([82]) in the context of the supporting study.

Between August and September 2024, a total of 11 *exploratory interviews* were conducted with key stakeholders with experience and knowledge relevant to critical medicines shortages. The primary objective was to further expand the overall understanding of the context of the study.

These exploratory interviews were conducted with key stakeholders from the following groups: EU institutions and agencies; national authorities; producer and suppliers; NGOs; and international organisations.

Targeted interviews were subsequently conducted in two different rounds. In the first part, these interviews mainly served to enhance the knowledge gathered through desk research and to collect stakeholders' view in particular on the problem drivers. In the second part, the information gathered through the interviews was used to complement the information collected through a targeted survey by providing possible quantification of the anticipated economic impacts.

The targeted interviews comprised 17 interviews in the first round, primarily contributing to study objective 1 (establishing an up-to-date understanding of the main problem drivers for critical medicine shortages), and informing objective 2 (establishing a dynamic baseline by providing an overview of the status-quo at EU or MS level) and objective 3 (identifying policy options to reduce shortages of critical medicines in the EU). These interviews aimed to validate the problem tree, substantiate problem drivers and develop the baseline scenario, assess drivers by importance qualitatively, gauge policy measures to address drivers, and identify additional sources or contacts for analysis.

All targeted stakeholder interviews contained a combination of questions applicable to all interviewees and more in-depth questions that could be answered by specific stakeholder groups. During the second round of interviews two interview guides were used: one tailored to stakeholders from the pharmaceutical industry, and another tailored to public authorities.

([82]) Ibid.

The second round of interviews comprised 13 targeted interviews. This set of interviews was mainly used to support the quantification of the economic impacts and targeted primarily two sets of stakeholders: pharmaceutical companies and public authorities.

The *targeted surveys* targeted five stakeholder groups separately with a primary focus on the identification and assessment of the expected significant economic, social, and environmental impacts of the policy options. Additionally, the surveys were intended to contribute to further validating and substantiating the analysis of the main problem drivers. Similarly, they were intended to provide quantitative insights for the baseline and further contributed to the overall market analysis of critical medicines.

4.4. Other sources of evidence

Different other sources of evidence taken into account by the Commission, such as, for example, the Study on best practices in the Public Procurement of Medicines ([83]), are referred to in the specific context where they are relevant.

5. MAIN MEASURES OF THE LEGISLATIVE PROPOSAL

5.1. Objectives of the proposal

In light of the current geopolitical situation and the importance of a viable European based pharmaceutical industry for the EU's economic security, the proposed Regulation aims to complement the measures proposed in the revision of the EU pharmaceutical legislation in order to address the supply chain vulnerabilities of critical medicines and support the security of supply and availability of these medicines.

The scope of the proposed Regulation is primarily focused on critical medicines on the Union List of Critical Medicinal Products which is formally established in the proposed pharmaceutical Regulation.

The proposed Regulation also introduces non-regulatory actions to improve access to and availability of medicines of common interest, to ensure patients across the EU can benefit from these medicines when and where they need them. These medicines can include medicines for rare diseases (orphan medicinal products) ([84]) or novel antimicrobials.

The general objective of this Regulation is to strengthen the security of supply and the availability of critical medicines within the EU, thereby ensuring a high level of public health protection and supporting the security of the Union, and to improve the availability and accessibility of other specific medicines, where the functioning of the market does not otherwise sufficiently ensure their availability and accessibility to patients, whilst giving due consideration to the appropriateness to ensure the affordability of medicinal products.

The specific objectives of the initiative are:

- to facilitate investments in manufacturing capacities for critical medicines, their active substances and other key inputs in the EU;

([83]) Study on Best Practices in the Public Procurement of Medicines, September 2022

([84]) Orphan medicinal products - European Commission

- to lower the risk of supply disruptions and strengthen availability by incentivising supply chain diversification and resilience in the public procurement procedures for critical medicines and other medicinal products of common interest;
- to leverage the aggregated demand of participating Member States through collaborative procurement procedures; and,
- to support the diversification of supply chains also by facilitating the conclusion of strategic partnerships.

5.2. Choice of the legal instrument and legal basis

The proposal takes the form of a Regulation of the European Parliament and of the Council. The selection of a Regulation over a Directive is driven by the need for immediate and uniform application across the EU and supported by the assessment of proportionality of the EU intervention. This choice ensures legal certainty by minimising the risk of divergent interpretations and implementations by Member States. In addition, the cross-border implications of the legislation require a cohesive and consistent approach, achievable through a Regulation.

The proposal is based on Article 114 of the Treaty on the Functioning of the European Union (TFEU), as the measures it introduces aim to ensure smooth functioning of the internal market. The proposal also has important public health objectives and Article 114(3) TFEU integrates considerations related to ensuring a high level of health protection.

5.3. EU added value / necessity for EU action

The objectives of this proposal cannot be sufficiently achieved by Member States acting individually, as the challenges of medicine shortages and supply chain vulnerabilities extend beyond national borders. In addition, uncoordinated Member States efforts may undermine the smooth functioning of the internal market. EU-level action is needed to ensure a coordinated and effective response to these cross-border issues.

The proposal takes into account this principle in the design of the individual actions, particularly when procuring critical medicines and other medicinal products of common interest.

The proposal targets critical medicines for which there is a demonstrated need to intervene, and the selected intervention can lead to an effective reduction in the risk of shortages. Specific measures also apply to other medicines of common interest affected by market access issues in Member States.

5.4. Complementarity with other EU legislative initiatives on medicine shortages

To improve the security of supply and availability of medicines, including those of critical medicines, the EU has implemented several measures in the recent years. Regulation (EU) 2022/123 has strengthened the EMA's role in monitoring of events and coordinated prevention and mitigation of medicine shortages in preparation for and during crisis situations. The establishment of EMA's Medicines Shortages Steering Group (MSSG) and the Medicine Shortages Single Point of Contact working party (SPOC WP) aims to enhance crisis preparedness and response but also monitoring of supply and demand of medicines considered as critical in the context of a public health emergency or a major event. Launched in February 2025, the European Shortages Monitoring Platform (ESMP)

supports data collection and monitoring of medicines supply and demand under different MSSG-led preparedness and during crisis situations.

In addition, the proposed revision of the EU pharmaceutical legislation, currently under discussion by the co-legislators, includes new obligations to support prevention and mitigation of medicines shortages and strengthen the security of supply of critical medicines at all times. Proposed measures include:

- the reinforcement of obligations on marketing authorisation holders (MAHs) to share information with authorities, incl. early notification of shortages, temporary suspension as well as market cessation and permanent withdrawal;
- the obligation for MAHs to prepare shortage prevention plans (SPP) for all medicines;
- the definition of the roles and responsibilities of NCAs and EMA in relation to the monitoring of shortages and coordination of responses to manage critical shortages;
- the identification and management of critical medicines via the establishment of a Union list of critical medicines (based on a common EU methodology which includes the vulnerability assessment of supply chains ([85]));
- the extension of the scope of the ESMP, including to support the notification obligations and data exchange on stock, supply and demand data;
- the provision of MSSG recommendations to address critical shortages and ensure security of supply of critical medicines; and,
- the possibility for the EC to take additional measures to ensure the security of supply of critical medicines, including by imposing EU wide contingency stocks requirements.

The dedicated expert groups (MSSG and SPOC Working Party) formally established under the EMA mandate extension have already demonstrated an improved collaboration and communication between the relevant stakeholders. Their mandates are extended beyond public health emergencies and major events under the proposed pharmaceutical legislation. The extension of established systems and processes and introduction of new measures will support early identification, prevention and mitigation of potential medicines shortages, including of critical medicines, through improved monitoring and coordination. Furthermore, the proposed pharma package legally establishes the Union list of critical medicines and will contribute to a better understanding of supply chains of critical medicines, which is a precondition to reinforce supply chain resilience, by imposing an obligation on MAHs to provide relevant data. In this respect, Shortage Prevention Plans are an essential tool to support the assessment of supply chain vulnerabilities. These are complemented by additional obligations for MAHs and other actors to provide the necessary information to the authorities. Without this obligation, competent authorities rely of pharmaceutical companies to voluntarily provide the relevant data as emphasised in the vulnerability pilot performed on 11 molecules.

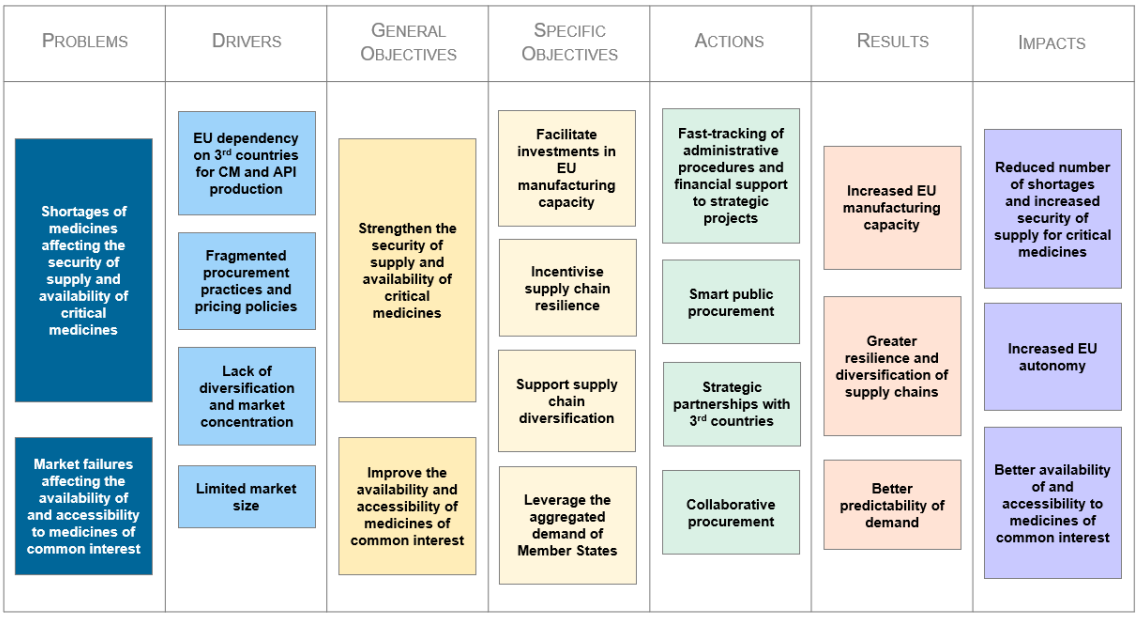
Nevertheless, while those measures provide much needed regulatory replies to mitigate and prevent shortages and reinforce the security of supply of critical medicines, they should

([85]) According to the proposed revision of the EU pharmaceutical legislation, the European Medicines Agency (EMA) will be tasked to develop this common EU methodology in collaboration with Member States. This work has already been initiated by EMA, in cooperation with MSSG members, and will take into consideration previous initiatives, including the vulnerability assessment pilot conducted by the Commission and the recommendations of the Critical Medicines Alliance.

be complemented by industrial policy tools to act on upstream vulnerabilities in the supply chains with the main goal to reduce the number of shortages and their impact. The purpose of the Critical Medicines Act is to establish these complementary tools.

5.5. Intervention logic of the proposal

Figure 10 – intervention logic diagram



5.6. Description of the proposed measures (preferred option)

The proposed Regulation puts forward an industrial policy toolbox to address supply chain vulnerabilities and reinforce the resilience of supply chains of critical medicines. In addition, it contains specific measures that are also relevant to improve access and availability of other medicines of common interest.

In order to avoid duplications and divergence during the negotiation process, the CMA proposal relies on certain concepts, definitions and processes already introduced in the proposed pharmaceutical package:

- In terms of scope, as regards the critical medicinal products, the proposed Act refers to the Union list of Critical Medicines envisaged under the proposal for the pharmaceutical legislation. The proposed pharmaceutical Regulation introduces the concept of the Union List of critical medicines, as well as the processes for adoption and review. This Union list should be prepared based on a common EU methodology which will incorporate the evaluation of supply chain vulnerabilities.

- Specific measures of the proposed Act require the completion of a vulnerability evaluation. This vulnerability evaluation builds on the one outlined in the new pharmaceutical legislation. The proposed pharmaceutical Regulation already outlines the data collection process, common EU methodology and implementation of the vulnerability evaluation. The CMA proposal will look at EU level

vulnerabilities. It also mandates the Critical Medicines Coordination group (CMG) to provide advice to the MSSG on the prioritisation, review or update of critical medicines for the vulnerability evaluation.

In addition, the CMA proposal complements the regulatory measures on access to medicines that are included in the proposed pharmaceutical legislation to further support access to and availability of other medicines of common interest.

The proposed Act also includes the possibility for the Commission or national authorities to request the information necessary for the application of the Regulation from marketing authorisation holders and other actors in the supply and distribution chain of the medicines in scope of the Regulation, whilst avoiding duplication. This may include certain information on supply chain vulnerabilities, if not available under the reform of the general pharmaceutical legislation, information needed for the application of different measures of the proposal or necessary for the purpose of its evaluation.

The CMA proposal is articulated around four pillars:

- Strategic projects to facilitate investments in manufacturing capacity in the EU
- Public procurement to incentivise supply chain resilience and diversification
- Collaborative procurement to leverage the aggregated demand of the Member States
- Strategic partnerships to support supply chain diversification

While the four pillars of the CMA proposal are applicable to critical medicines, only specific measures are considered as relevant to ensure increased access and availability other medicines of common interest, namely certain demand-side measures related to public procurement and collaborative procurement.

5.6.1. Enabling conditions for investment

To address EU dependencies on third countries for the production of critical medicines and their active substances identified as a problem driver under section 3.3, the necessary conditions to support investments in manufacturing capacities in the EU should be put in place.

Criteria and procedure for the recognition of strategic projects

The proposed Regulation includes the recognition of industrial projects that create, increase or modernise EU manufacturing capacity of critical medicines, their active substances and other key inputs as strategic projects.

To be considered as a strategic project, an industrial project needs to meet at least one the following criteria:

a) it creates or increases manufacturing capacity for one or more critical medicinal products or for collecting or manufacturing their active substances;

b) it modernises an existing manufacturing site for one or more critical medicinal products or their active substances to ensure greater sustainability or increased efficiency;

c) it creates or increases manufacturing capacity for key inputs necessary for the manufacturing of one or more critical medicinal products or their active substances; or,

d) it contributes to the roll-out of a technology that plays a key role in enabling the manufacturing of one or more critical medicinal products, their active substances or key inputs.

These criteria are broad, covering a wide spectrum of industrial projects that create or increase EU manufacturing capacity not only of critical medicines but also their active substances and other key inputs.

In terms of recognition procedure, the proposed Regulation relies on existing structures and processes to avoid unnecessary delays and the creation of additional administrative layers, such as a one-stop shop at national or EU level. A decentralised approach for the recognition of strategic projects at national level whereby a project promotor can go directly to the relevant authority to request a specific benefit was therefore retained. When receiving such request, the concerned authority will be required to verify compliance with one of the criteria defined in Article 5. If needed, this authority can request confirmation that the criteria are met to a designated authority. Member States are required to identify such designated authority and inform the Commission.

Facilitating administrative and permit-granting processes

National permit-granting processes can be unpredictable and, in certain cases, excessively lengthy, undermining the planning and investment security needed for an effective development of new manufacturing projects in the EU. The proposed Regulation introduces several enabling measures to ensure the timely implementation of strategic projects.

First of all, strategic projects are considered to be in the public interest, meaning that Member States shall ensure permit granting processes are carried out in the fastest way possible. This priority status will ensure the fast-tracking of permit-granting procedures at national level, in particular considering any form of accelerated procedures that exist in applicable Union and national law. This can include digital submission of required information. When provided for in national law, project promotors may also request the status of the highest national significance and the application of urgency procedure for dispute resolution.

Strategic projects may also receive, upon request, administrative, regulatory and scientific support from Member States, with particular attention for SMEs. The administrative support covers not only the permit-granting process but also compliance with applicable administrative and regulatory obligations. Regulatory support by Member State includes the prioritisation of GMP inspections for new, extended or modernised manufacturing sites. Finally, the proposed Regulation includes the possibility to request scientific advice by the European Medicines Agency on innovative manufacturing processes for active substances, critical medicinal products and key inputs that can increase manufacturing efficiency and reduce manufacturing costs through digitalisation and automation. This is an area where the EU could lead and have a competitive advantage compared to third countries. It is proposed to establish a mechanism whereby EMA can assist and advise project promoters of innovative technologies and manufacturing processes for critical medicines and their active substances.

One reason that can lead to unpredictable timelines of permit-granting procedures is that the procedure for performing the necessary environmental assessments is not consistently implemented, within and across Member States, especially regarding timing. The CMA proposal includes the possibility for coordinated or joint environmental assessments upon request by a project promotor under defined timelines, which typically are the procedures that can take the longest during permitting.

The CMA approach therefore rests on a large procedural margin for organising the environmental assessments granted inter alia in the Environmental Impact Assessment Directive, through the possibility of performing joint or coordinated assessments, when the obligation to perform such an assessment arises simultaneously. Given that this possibility already exists under the CMRA and NZIA, Member States will be able to rely on similar procedures to ensure accelerated environmental assessment of strategic projects. Furthermore, these strategic projects may be considered to have an overriding public interest with regards to environmental impacts in a series of environmental legislations.

Finally, authorities shall consider including provisions for development of strategic projects in planning (zoning, spatial plans, land use plans).

Financial incentives

The proposed Regulation covers funding opportunities at national and EU level.

At national level, Member States may prioritise strategic projects that address an identified vulnerability in the supply chain of a critical medicine. Undertakings that benefit from financial support shall prioritise supply to Member States and use their very best efforts to ensure that the critical medicine concerned remains available in the Member States where it is being marketed. The Member State that provides the financial support to a strategic project may submit a request, on its own behalf or on behalf of another Member State that encounters a threat of shortages of the critical medicine in question, to the undertaking to provide the necessary supplies of a critical medicine, active substance or key inputs, as applicable, to the Union market to avoid shortages in one or several Member States.

At EU level, the proposed Regulation focuses on funding opportunities under the current Multiannual Financial Framework (MFF) given it is not possible to pre-empt the results of the political negotiations on the future budget of the European Union. Under the 2021-2027 MFF, strategic projects may be supported by EU funding programmes, including EU4Health, Horizon Europe, Digital Europe Programme if the applicable requirements are met. The Legal Financial Digital Statement of the proposal provides for a total of EUR 80 million for the period 2026-2027 to finance manufacturing investments and manufacturing capacity through grants under the EU4Health programme.

In addition, the CMA proposal amends Regulation 2024/795 establishing the Strategic Technologiesfor Europe Platform (STEP) which aims to support the European industry and boost investment in critical technologies in Europe by raising and steering funding across 11 EU programmes to three target investment areas: a) digital technologies and deep-tech innovation; b) clean and resource-efficient technologies and c) biotechnologies, including critical medicines. This aims to allow facilitated financial support to strategic projects addressing a supply chain vulnerability.

These strategic projects addressing a supply chain vulnerability shall be deemed to fulfil the STEP objectives, which in turns facilitates the awarding of the STEP sovereignty seal through existing EU funding programmes such as the EU4Health programme. The

possession of the STEP sovereignty seal will facilitate strategic projects' access to shared management funds such as the Cohesion funds. Indeed, they may be fast-tracked (direct award possibility) under Cohesion policy funds (ERDF, ESF+) and must be considered as a priority for funding under national Recovery and Resilience Plans (RRF). In addition, strategic projects that obtained the STEP sovereignty seal can receive cumulative or combined funding from other Union programmes, including funds under shared management. In order to enhance visibility and help them attract public funding, these projects will also be listed on the STEP Portal. Under InvestEU, these projects are to be taken into account by the Commission in its 'policy check' and the project is to be examined by implementing partners. These different advantages aim to facilitate access to funding for projects that received the STEP sovereignty seal.

Finally, the coordination of financial support provided at national and EU level to strategic projects will be ensured within the Critical Medicines Coordination Group (CMG) to ensure synergies between the different initiatives and avoid duplications (see section 5.6.3). Given the limited financial resources, it is essential that Member States and the Commission coordinate their efforts. This is why the proposal introduces an obligation for Member States to inform the CMG about the intention to provide financial support to strategic projects sufficiently in advance, to allow the CMG to carry out its coordination task. Similarly, the Commission will have to inform the CMG of the strategic projects that benefited from financial support from the Union. In addition, the Commission may inform the CMG of the intention to propose the establishment of funding possibilities specifically designed to address vulnerabilities in the supply chains or any other programme that may benefit the availability of critical medicines. Nevertheless, this information possibility needs to comply with the specific rules and conditions of these Union funding programmes, that clarifies the involvement of Member States and stakeholders in these programmes. The CMA, while relying on these mechanisms for funding implementation, facilitates information sharing and national coordination.

5.6.2 Demand side measures

Public procurement requirements and related measures

The Commission study on public procurement of medicines ([86]) found that most medicines are still procured by lowest price with little use of additional quality requirements or criteria.

The study also found that procurement can be a powerful policy tool to encourage better resilience of supply chains and diversified suppliers. This can be done through the use of quality requirements and criteria, the use of multiple winner tenders and joint/collaborative procurement ([87]).

Therefore, the proposed Regulation includes a set of measures that lower the risk of supply disruptions and strengthen availability by incentivising supply chain resilience in the public procurement procedures of critical medicinal products and other medicinal products of common interest.

([86]) Study on Best Practices in the Public Procurement of Medicines, September 2022

([87]) Ibid.

First, when procuring critical medicines for the procurement procedures that fall under the scope of the Directive 2014/24/EU, contracting authorities will be obliged to use procurement requirements other than price-only award criteria that promote the resilience of supply in the Union. The proposal is not prescriptive as to the type of requirements that shall be used, (award criteria, selection criteria, tender specifications, contract clauses…), the exact criteria to be used, nor the weight that shall be given to these non-price criteria. This is intended to keep a level of flexibility depending on the type of medicine procured, the number of suppliers, national health setting etc. Possible approaches are the use of stockholding obligations, the number of diversified suppliers, contract performance clauses on timely delivery, monitoring of supply chains and their transparency to the contracting authorities. Exceptions are possible where justified by market analysis or considerations related to the financing of health services.

Second, specifically for critical medicines where a high dependency on a single or limited number of suppliers has been demonstrated through a supply chain vulnerability evaluation, contracting authorities will be obliged, where justified, to apply procurement requirements that favour suppliers that manufacture a significant proportion of these critical medicines in the EU. This will have to be applied in compliance with the EU international commitments and shall take into consideration existing international agreements in the field of public procurement.

Similarly, for other medicines of common interest, it will be possible (although not mandatory) to apply similar preference for EU production in public procurement, when justified by market analysis and public health considerations and again in compliance with the EU international commitments. In both cases, exceptions will also be possible.

In general, these measures do not exclude the use of additional qualitative requirements, including in relation to environmental sustainability and social rights.

To complement these measures, Member States will be required to develop national programmes that will cover public procurement practices to promote consistent use of requirements within a Member State. These will include measures to promote the use of multi-winner tenders and potentially also measures related to pricing and reimbursement, in order to cover medicines that are not acquired through public procurement. Indeed, not all critical medicines reaching patients are purchased via public procurement—for example, in many Member States, medicines dispensed in community pharmacies are not publicly procured but might only be assigned a price and reimbursement status by the authorities. To ensure these medicines are also addressed, national programmes may incorporate supply security requirements within pricing and reimbursement policies.

In addition, the Commission will issue guidelines on procurement practices, to support the implementation of these measures. The guidelines will build on best practices identified in the context of the cooperation of national competent authorities on pricing and reimbursement and public health care payers (NCAPR) and will detail procurement practices that support availability and security of supply.

Finally, Member States will have to notify their programmes to the Commission, who will distribute the programmes to the CMG. The Critical Medicines Group will facilitate a discussion aiming to ensure coordination of national programmes, incl. the application of criteria to favour EU manufacturing of critical medicines with high dependencies. The CMG may issue an opinion on the national programmes, which Member States will need to give due consideration and may take into account when revising their programmes.

Contingency stocks

The proposed regulation includes specific measures with regard to national contingency stock requirements and other security of supply measures. Contingency stock requirements refer to obligations imposed by Member States on supply chain actors to hold buffer stocks of certain medicines to mitigate the risk of supply chain disruptions. This should not be confused with the concept of 'stockpiling' whereby a (public) health institution owns/buys a certain stock to anticipate and manage specific crisis (e.g. stockpiles of medical countermeasures related to chemical, biological, radiological and nuclear (CBRN) threats).

The proposed Regulation introduces an obligation for the Member States to ensure that any such measures on security of supply, does not negatively impact supply to other Member States, in particular when proposing and defining the scope and timing of contingency stock requirements.

In addition, Member States must ensure that contingency stock requirements are proportionate and respect the principles of transparency and solidarity. To support Member States for the implementation of this measure, the Commission will issue guidelines. When preparing these guidelines, the Commission will consider the previous work and discussions that took place in the context of the Pharmaceutical Committee.

These measures complement the measures proposed in the Pharma Package, which provides the possibility to impose EU wide contingency stock requirements for critical medicines (active pharmaceutical ingredient or finished dosage forms) on marketing authorisation holders, wholesale distributors or other relevant entities via Commission implementing acts.

Collaborative procurements

Availability and access disparities exist for critical medicinal products and medicinal products of common interest throughout the Union, disproportionately affecting some Member States. As the experience of different cross-country collaborations and the COVID-19 vaccines show, collaborative procurement can be a powerful tool to increase economies of scale, bargaining power and equal access to medicines ([88]). The Critical Medicines Act therefore provides a framework for Member States to request Commission support in the use of different collaborative procurement tools for critical medicines and other medicines of common interest.

The relevant provisions build on already existing mechanisms, making available different tools to adapt to different context and needs for Commission's support. For 'cross-border procurement', Article 39 of Directive 2014/24/EU of the European Parliament and of the Council provides for the possibility of procurement involving contracting authorities from different Member States. For 'Commission procurement on behalf of or in the name of Member States', as well as the Commission and Member States engagement in 'Joint Procurement', the EU's recast Financial Regulation sets out the general procedural framework (Article 168(2) and 168(3)).

([88]) Study on Best Practices in the Public Procurement of Medicines, September 2022

The Act provides a sectoral basis for these collaborative procurement tools and limits them to defined cases, where it contributes to the achievement of the above-mentioned objectives and respecting the principles of subsidiarity and proportionality.

Cross-border procurement

The Baltic Procurement Initiative - jointly undertaken by at least two of the three member countries (Estonia, Latvia, and Lithuania) for vaccines included in their national immunisation schedules – and the Nordic Pharmaceutical Forum – comprising Denmark, Iceland, Norway, and Sweden, which focuses on joint purchases of well-established hospital medicines, have respectively concluded cross-border procurements of vaccines and off-patent medicines such as antibiotics. An example is Iceland, which benefitted from cross-country joint procurement with Denmark and Norway (joint Nordic tenders) to increase the number of medicines available to patients ([89]). These experiences have shown that this tool can be useful to improve access and availability of medicines, however its implementation is time- and resource-intensive, especially in the starting phase, and considered a barrier. Challenges encountered in cross-border joint procurement include, amongst others, the differences between national legal, policy and administrative systems and processes, the requirement for more resources compared to national procurement and the need to address language issues.

To further facilitate the deployment of such initiatives, Article 21 of the proposed Act provides for the possibility of three or more Member States to request the Commission to provide its assistance during the preliminary phase of setting up such a procurement initiative for medicinal products of common interest. Following such a request, the Commission informs all other Member States of this initiative and sets an appropriate deadline for them to declare interest, while assessing the request in light of the objectives of the Regulation, all of which should take no more than three weeks.

If the Commission accepts the request, it has to provide secretarial and logistic support, facilitate communication and cooperation between Member States, and provide advice on applicable Union public procurement rules and on regulatory matters related to medicinal products. Under Article 21, the Commission does not participate in the actual procurement procedure and therefore cannot be held responsible nor liable for any breaches of procurement law or the implementation of the procedure.

Commission procurement on behalf of or in the name of Member States

Nine or more Member States may request the Commission to procure on their behalf or in their name critical medicines with a vulnerability in their supply chains or for which the MSSG has recommended a common procurement initiative, as well as medicinal products of common interest, for which a Joint Clinical Assessment (JCA) report has been published or which have undergone a clinical assessment carried out under the voluntary cooperation among Member States according to the HTA Regulation. Since this type of procurement requires considerably more resources for the Commission, the higher threshold of Member states participating in the procedure and eligibility criteria as regards the medicinal products reflect the assessment of where the Commission intervention would be the most appropriate in the light of the objectives of the act. The requirement for a published JCA

([89]) Amgros. Second Joint Nordic Tendering Procedure for Medicines completed. 2022. Available from: https://amgros.dk/en/knowledge-and-analyses/articles/second-jointnordic-tendering-procedure-for-medicines-completed/

or a completed voluntary joint clinical assessment is intended to ensure that the procedure can be carried out effectively, supported by a shared understanding of the clinical evidence on the relative effects of the procured medicine on health outcomes.

Participation in this procurement procedure is open to all Member States, who are informed of the request by the Commission through the Critical Medicines Group. The Commission assesses the request and informs interested Member States of its decision within one month. This longer timeline is needed to assess the utility, necessity and proportionality of the request. In particular, taking into account that the procurement procedure that involves several Member States may have impact on the market including the impact on the access and availability of medicinal products for markets of the Member States that do not participate in the procedure, the Commission has to verify whether the procurement could constitute discrimination or restriction to trade or a distortion to competition.

If the Commission accepts the request, it conducts the procurement in line with the recast Financial Regulation Article 168(3), following an agreement with the Member States that determines the practical arrangements, liabilities to be assumed and the decision-making process. The agreement may include conditions to conduct the procurement as exclusive for the Member States or to agree to minimum binding quantities, upon acceptance of these conditions by the Member States. The Member States also provide resources necessary for the successful conclusion of the procedure, in particular through involvement of staff with expertise and knowledge.

Joint procurement

The threshold of interested Member States and products eligible for joint procurement under Article 23 is the same as for Commission procurement on behalf of or in the name of the Member States. Additionally, the Joint Procurement procedure may also be initiated at the Commission's initiative, in particular when the Commission identifies the need to procure for the purpose of donating or for its own needs.

Participation to the procurement procedure, the Commission assessment of the request and the agreement also follow the same process as for Commission procurement on behalf of or in the name of Member States.

The procurement procedure is conducted in line with the recast Financial Regulation Article 168(2).

To note that the relevant provisions are without prejudice to and do not prevent the use of other collaborative procurement tools established under sectoral legislation, such as joint procurement of medical countermeasures under Regulation (EU) 2022/2371 of the European Parliament. Where there is an overlap between the medicines in scope of this Act and medical countermeasures under the Serious Cross-Border Threats to Health Regulation, the objective of the joint procurement initiative should determine the applicable framework.

Figure 11 – Summary table of the different collaborative procurement tools introduced in the CMA proposal

Collaborative procurement type	Cross-border procurement	Procurement on behalf or in the name of MS	Joint Procurement
Legal basis	Article 39 Directive 2014/24/EU (Public Procurement Directive)	Article 168 (3) Regulation 2024/2509 (Recast Financial Regulation)	Article 168 (2) Regulation 2024/2509 (Recast Financial Regulation)
Scope	Other medicinal products of common interest (OMPCI)	- Critical Medicines with vulnerability or MSSG recommendation - OMPCI with JCA	
MS threshold	3 or more	9 or more	
Other conditions	N.A.	Demonstrated improvement access/availability/security of supply	
Procedure	- MS: reasoned request - EC: informs other MS, assesses and decides	- MS request - EC: informs and invites other MS, assesses and decides	- MS request OR at EC initiative - idem
EC role	- Facilitating communication and cooperation - Secretariat and logistics - Advice on EU procurement rules and regulatory matters	- Carries out procurement procedure - Upon acceptance of participating MS, can be conditioned to exclusivity / minimum binding quantities	

5.6.3. Critical Medicines Coordination Group

The proposed Act establishes the Critical Medicines Coordination Group ("Critical Medicines Group" or CMG), composed of the Member States and the Commission. Each Member State shall appoint up to two high-level permanent representatives with relevant expertise for implementing the Regulation.

As the tasks of the CMG cover multiple policy areas, requiring a broad set of expertise covering industrial policy, public health, regulatory aspects and public procurement, Member States may appoint different representatives depending on the tasks of the group. Nevertheless, the representatives are responsible for ensuring national coordination.

The European Medicines Agency holds observer status. Although the remit of the CMG and the MSSG are of distinct nature, the Critical Medicines Group is to work closely with the MSSG, the Agency, and national authorities responsible for medicinal products, and may hold joint meetings with the MSSG when regulatory input is needed. The Commission will organise and coordinate the Group's work through a Secretariat and will chair its meetings. The Group may set up working groups and shall aim to reach consensus where possible, while allowing members to have their differing positions formally recorded.

The proposed Act outlines the tasks of the Critical Medicines Group, which include facilitating coordination in the implementation of the Regulation and advising the Commission, so as to maximise the impact and avoid unintended effects on the internal market.

Specific tasks include the facilitation of coordination on strategic orientation of financial support for strategic projects, sharing information on manufacturing capacity for a given critical medicinal product, and discussing Union-wide capacity needs. The Group will also facilitate exchanges on the need for a collaborative procurement initiative and on the national programmes. It will enable cooperation on and coordination of Member States public procurement policies for critical medicines. As critical medicines' supply chains

may evolve, the group will be able to advise the MSSG on prioritisation of critical medicines for vulnerability evaluations and may suggest the MSSG to review or update the existing evaluations. Additionally, it shall periodically discuss strategic partnerships and prioritisation of third countries, as well as consistency and synergies between national and EU international actions or cooperation. The Group may also provide opinions upon the Commission's request on matters related to applying the Regulation.

5.6.4. International cooperation

The CMA proposal also introduces measures to further support the diversification of supply chains, to complement other measures that increase diversification (such as the measures on non-price criteria in procurement). International trade agreements or other forms of international cooperation can enhance the availability and security of supply of critical medicinal products by providing access to alternative sources of supply in third countries. These objectives can be pursued by building partnerships relying on the network of existing trade agreements and by additionally pursuing strategic partnerships with third countries to further deepen bilateral cooperation, including with EU candidate countries, and potential candidate countries.

Recognising the important role of the Council regarding the EU's international commitments, the Commission may support these objectives by identifying existing commitments and assessing whether they effectively contribute to the objectives as mentioned above or whether they could be improved or upgraded. The Commission may also identify what types of potential partnerships could be concluded with the most relevant third countries.

To this end, the Commission will explore the possibilities to establish strategic partnerships with likeminded regions/countries, to aim at diversification of supply chains. In addition, the Commission will also build on already existing cooperation forms.

The 'strategic partnerships' as defined in the Critical Medicines Act are non-binding agreements. They are defined as a commitment between the EU and a third country, group of third countries or international organisations to increase cooperation related to one or more critical medicinal products that is established through a non-binding instrument and which facilitates beneficial outcomes for both the EU and the relevant third country, group of third countries or international organisation.

The CMG will support these measures by discussing a) the potential contribution of such partnerships to the CMA objectives, b) the prioritisation of third countries and c) consistency and synergies between national and EU actions.

5.7. Options considered and measures discarded

In the context of the preparatory work on the Critical Medicines Act proposal, several policy measures were considered and discarded early in the process while others were discarded later in the process looking at their potential impacts (see also section 6 on the analysis of the main impacts). The exploratory study in view of a Critical Medicines Act also looked at different policy options and assessed their impacts ([90]).

([90]) Exploratory study in view of a Critical Medicines Act by Ecorys (forthcoming study)

Scope of the CMA proposal

Given that the pharmaceutical package already establishes the Union List of Critical Medicines, which includes a vulnerability evaluation of the supply chains, the option of including specific provisions on the Union list of critical medicines and the vulnerability evaluation was discarded, to avoid confusion and duplication of concepts as well as to prevent potential risk of divergence during the co-decision process.

Instead, the proposed Act builds on the Union list of Critical Medicines and vulnerability evaluation as envisaged under the new pharmaceutical proposed legislation, as explained in section 5.5.

Benchmarks for EU production of APIs and finished critical medicines

Both the Critical Raw Materials Act and the Net Zero Industry Act have defined specific benchmarks for the EU production of specific materials and technologies by a certain deadline. This approach could have been considered in the Critical Medicines Act where benchmarks for EU production of APIs and EU finished critical medicines would be defined with clear values, such as '*at least XX% of EU production of critical medicines and their active substances by 2035 with the objective to decrease shortages by XX%*'. This policy measure was discarded given that benchmarks alone do not address the root causes of supply chain vulnerabilities or shortages of medicines. Even more importantly, given the specificities of the different categories of critical medicines and the very different challenges they face in terms of supply chain resilience, it is not possible to define a single benchmark that would be applicable across the range of critical medicines. In addition, the concern had been raised that implementation of benchmarks would require extensive reporting by all concerned stakeholders.

EU production capacity reservation

The possibility to reserve production capacity following the limited experience of the framework contract for the reservation of capacities for the manufacturing of vaccines (EU FAB) was considered at an early stage for strategic projects but discarded for the following reasons. While the EU FAB model has its value in a crisis preparedness context, particularly for rapid response to public health emergencies, it is considered less suited to addressing the broader challenge of structurally securing supply chains and preventing shortages of critical medicines as a long-term solution. With over 270 molecules currently on the Union list of critical medicines, reserving production capacity for an appreciable number of these medicines was considered logistically difficult and cost ineffective. Unlike pandemic scenarios, which typically involve a limited number of vaccines and can benefit from platform technologies, the wide variety of critical medicines, spanning different therapeutic areas and requiring distinct manufacturing technologies, makes a one-size-fits-all capacity reservation model impractical. Instead of relying on reactive mechanisms that activate only once a shortage arises, the proposed Act focuses on long-term measures to strengthen supply continuity outside crisis times. This includes supporting resilient and active EU-based manufacturing sites that can respond flexibly to supply pressures. The objective to foster a robust manufacturing and operating ecosystem in the EU through strategic investments. EU level financial support for critical medicines' strategic projects would be complemented by financial support by Member States, covering the broadest number of critical medicines and their APIs possible, with coordination ensured through the CMG. In addition, stronger supply chains would be incentivised through demand-side measures, creating the conditions for sustainable EU-

based production. Through these means, the Act aims to reduce dependencies and address vulnerabilities in supply chains to prevent shortages from occurring in the first place.

EU-wide stockpiles of critical medicines

'Stockpiling' refers to stockpiles established by a (public) institution in order to anticipate and manage a specific crisis, in contrast with the notion of "contingency stocks" which refers to an obligation imposed by Member States on supply chain actors to hold a certain amount of buffer stocks of certain medicines to mitigate the risk of supply disruptions.

The option of establishing an EU-wide stockpile of critical medicines to mitigate the risk of shortages was carefully considered but ultimately not included in the proposed Act, for several reasons. Most importantly, the proposed reform of the pharmaceutical legislation already proposes a legal framework to impose EU-wide contingency stocks, either of finished products or APIs, on supply chain actors for certain critical medicines. This mechanism enables the creation of distributed, rotational stock ([91]) within the supply chain itself, which is considered a more sustainable, cost-effective, and targeted solution than public sector buying and storing critical medicines for use in normal times, i.e. outside crisis scenario. Unlike a centralised stockpile, these contingency stocks are integrated into the normal flow of production and distribution, reducing the cost of stock management and risk of waste and ensuring products are closer to the point of need.

Moreover, establishing and maintaining a centralised EU-wide stockpile for the wide range of critical medicines - currently over 270 molecules - would present significant logistical, operational, and financial challenges. It would require complex infrastructure to store medicines with varying shelf lives, storage conditions (e.g., cold chain requirements), and turnover rates. Central stockpiles also risk becoming static, leading to inefficiencies, expiration of unused stock, and high management costs without necessarily improving timely access during shortages. In contrast, decentralised, rotational EU-wide contingency stock requirements ensure that medicines remain usable, up to date, and readily accessible across the Member States. Finally, central stockpiling does not address the root causes of shortages. The proposed Act takes a forward-looking approach, to reduce the need for emergency stockpiling altogether by making supply chains more resilient and less prone to disruption.

New EU platform/database to monitor stock levels

The establishment of an IT system that monitors in real time the stock levels of critical medicines across the entire supply chain ([92]) in all Member States, and level of demand for each critical medicine in each Member State (or aggregated at EU level) was considered but discarded as it would be very difficult, if not impossible, to implement. In addition, such real-time monitoring would not help addressing the root causes of shortages such as those related to manufacturing or quality issues. The measures proposed under the reform of the pharmaceutical legislation allow for structured data collection on demand and supply through the European Shortages Monitoring Platform (ESMP), both in the context of a critical shortage requiring EU-coordinated action, and for critical medicines also outside

([91]) It means that stocks are regularly used and replaced as part of the normal the supply chain. Rotating stocks through normal use allows to replenish stocks, avoid expiration and make sure that supplies are ready for deployment when needed.

([92]) Upstream and downstream – from the sourcing of raw materials and APIs until the delivery of the critical medicine to the patient.

the context of a shortage. The reform explicitly includes an expanded scope for the ESMP for this purpose, thereby facilitating data collection on stocks, supply, and demand. Going further to establish real-time, continuous monitoring of stock levels at the level of the suppliers, wholesale distributors and pharmacies was not considered cost-effective, particularly in light of the high implementation and maintenance costs such system would entail, coupled with the limited added value compared to the functionalities already included in the ESMP.

New EU funding programme

The Commission cannot pre-empt the outcome of the MFF negotiations. Therefore, it was not possible to provide for any specific financing mechanism or fund beyond 2027 in a proposal for sectorial legislation.

Specific State aid rules for critical medicines

When Member States decide to finance strategic projects or otherwise support critical medicines or API production in Europe, compliance with State aid rules should be ensured. To assist national authorities, the Commission has provided a guidance document on how such support could be designed while minimising the potentially negative effects on the market ([93]).

Based on the information available at this stage, including the description of the typical project by the Critical Medicines Alliance, a new, dedicated State aid framework introducing new specific rules for critical medicines was discarded. The current State aid rules were considered sufficient to address the needs of the sector. In particular, the State aid rules regarding Services of General Economic Interest are already an appropriate instrument to address the security of supply issues in the field of critical medicines since:

- they enable Member States to coordinate to tackle supply chain vulnerabilities of critical medicines by entrusting operators to reserve capacity, produce, or stockpile critical medicines or key ingredients needed for the production of these critical medicines.

- they are very flexible as (i) they can address market failures at national or EU level, (ii) they allow the financing of Strategic Projects but also of the operating deficit (if any) of producing critical Medicines and (iii) they do not require a notification below EUR 15 million/year which should cover most of the projects envisaged by the sector ([94]).

Supply chain resilience score

The possibility of introducing a scoring system to assess and publicly disclose the reliability and robustness of the supply chain for individual medicines was carefully considered but ultimately discarded. While such a system could support contracting authorities in applying and assessing non-price criteria in their public procurement

([93]) For more information see: Guidance on the application of State aid rules in the context of the Critical Medicines Act

([94]) The strategic report of the Critical Medicines Alliance states that a typical project support would be between EUR 5 to 20 million depending on the complexity of the product.

procedures, it raises significant legal and practical concerns, notably in terms of liability but also due to the rapidly evolving supply chains.

Level playing field in application of standards

Several stakeholders called for measures to ensure a level playing field between EU and non-EU producers of critical medicines and their APIs. These proposals were carefully considered but ultimately not included in the legislative proposal, either because the proposals depend on enforcement of other existing legal instruments, or due to concerns about their potential unintended consequences on availability and affordability of medicines and lack of strong evidence that this would contribute to attain the objectives of the proposed Act. Nevertheless, the proposal preserves the flexibility for contracting authorities to include social and environmental criteria as part of their public procurement processes, in line with existing EU rules. This approach supports voluntary uptake of sustainability-based incentives without creating disproportionate burdens or trade barriers.

International voluntary solidarity mechanism

Following the Communication on addressing medicines shortages in the EU, the Voluntary Solidarity Mechanism (VSM) was launched in October 2023. The mechanism is intended as a last-resort solution allowing Member States to request support from other Member States in obtaining stocks of medicines for which they experience a critical shortage. The VSM has been launched several times since its establishment and for each case a solution could be found within the EU.

The establishment of an international VSM that would extend this mechanism to third countries was considered but discarded for the following reasons. While the Critical Medicines Act proposes proactive measures to prevent the risk of shortages for critical medicines, it does not introduce reactive measures to mitigate ongoing shortages. The Commission has already proposed a comprehensive set of measures to mitigate ongoing or potential or actual shortages as part of the reform of the general pharmaceutical legislation. This includes earlier notification of shortages to be able to mitigate the risks before shortages occur, including through EU coordinated action.

Already today, the European Medicines Agency and the national competent authorities work closely together to mitigate critical shortages. When critical shortages cannot be resolved at national level, Member States can use the (European) Voluntary Solidarity Mechanism. The cases addressed so far have been successfully resolved within the EU, indicating that there is no structural need to extend this mechanism to third countries. In very specific cases and when absolutely necessary, supply can already today be sourced from outside the EU to solve a critical shortage under the existing pharmaceutical legislation (Article 5 and 126a of Directive 2001/83). Nevertheless, this possibility should be reserved to very specific situations and is not intended to be systematically used to mitigate shortages. To safeguard safety, quality, and efficacy of medicines for EU patients, it was deemed inappropriate to introduce a structural framework for import of stocks from third countries of medicines that are not authorised within the EU.

Skills

The need for specialised skills in the pharmaceutical manufacturing is recognised but EU initiatives in this field do not require new measures under the CMA proposal. In this respect, the Commission already announced a number of ongoing initiatives in the 2023 Communication on addressing medicine shortages in the EU, including the EU Skills

Agenda to address the widespread issue of skills gaps across the EU and the 'Pact for Skills' to tackle the most pressing industry skills gaps with active involvement of industry and key actors in education and training.

6. ANALYSIS OF THE MAIN IMPACTS FOR THE PROPOSED MEASURES

The presented analysis takes predominantly the form of a reasoned qualitative assessment, drawing on previous studies, a wide range of responses to consultations and other sources, including the recent exploratory study in view of a Critical Medicines Act ([95]).

While the above-mentioned studies and consultations may provide certain specific scenarios that show some potential quantitative impacts of various policy options, the inherent variability in the scope and implementation of the proposed measures, coupled with the heterogeneous nature of their attributable impacts across different contexts and stakeholders, precluded any meaningful direct and aggregated quantitative assessment. This complexity arises from factors such as differing national healthcare systems, varying market dynamics, the diversity of the medicines in scope and the multi-faceted nature of some interventions. For instance, the impact of public procurement measures on prices will notably depend on, and vary between, (i) the type of critical medicine and (ii) the specific market situation, but also (iii) the specific procurement measure and overall approach chosen in the given Member State or region within a Member State, including the specific non-price criteria or requirements that will be applied by the contracting authorities and weight given to these non-price criteria. For the reasons, any aggregated quantitative projection or modelling, as for instance attempted in the exploratory study in view of a Critical Medicines Act, can only be based on a high number of (often very strong and uncertain) assumptions, greatly limiting the robustness, reliability and informative value of such attempts of aggregated quantification. Against this background, the choice in this SWD of a predominantly *qualitative* assessment, complemented by, where possible, disaggregated quantitative evidence and illustrations, is clearly a more reliable and informative approach.

6.1. Baseline

The pharmaceutical industry's supply chain for many critical medicines is highly complex, global and fragmented. External factors such as procurement practices and pricing policies led to further market consolidation and supply chain vulnerabilities as described in section 3.3. Such supply chain vulnerabilities increase the risk and impact of medicine shortages, which have detrimental consequences for patients and healthcare systems in the EU.

The burden of medicine shortages is significant not only for individual patients (patient health impact), but also for the society (price increases, administrative costs and use of healthcare resources).

Patients face increasing difficulty to get the medicines they need, affecting their quality of life and leading to a potential deterioration of their health status due to delays in treatment and suboptimal care. Consumer surveys show that between January 2023 and January 2024, nearly 40% of households experienced a medicine shortage, with 16% facing recurring shortages. Amongst those affected, 53% reported experiencing health problems, and 40% noted a worsening of symptoms, 13% had to take temporary sick leave, and 12%

([95]) Exploratory study in view of a Critical Medicines Act by Ecorys (forthcoming study).

experienced side effects from alternative or substitute medications ([96]). In 2023, hospital pharmacists identified delays in care or therapy (59%), suboptimal treatment (43%) and cancellation of care (35%) as the main consequences of medicines shortages in the hospitals where they practice ([97]).

The potential impact of shortages on the overall health of patients is significant with an aggravated effect for critical medicines treating severe conditions for which a limited number of alternative treatments are available, and insufficient supply may result in serious harm or risk of serious harm to patients.

In case of shortages affecting a critical medicine, it may not be possible to treat patients with the most appropriate treatment in line with the current standard clinical guidelines. This can lead to treatment delays and suboptimal care, as well as medication errors and adverse events. As an example, shortages of certain antibiotics, especially in absence of equivalent alternative treatment, can be detrimental given the risk of antimicrobial resistance. In shortage situations, public authorities (national competent authorities in the Member States, in coordination with the European Medicines Agency, as necessary) may have to take measures to mitigate and manage the shortage until normal supply is resumed. For instance, shortages of several live-saving medicines, including immunoglobulins or thrombolytics, has led public authorities to take measures to prioritise treatment of patients based on limited available supply of the medicine. Similarly, in cases of critical shortages of older cancer treatments, public authorities may also need to take mitigation measures such as recommending not to initiate such treatment for new patients in case of the limited availability.

However, in the absence of such mitigation measures, the impact of shortages on patients would likely be even more significant.

In addition, the management of medicines shortages leads to substantial costs for both public authorities and healthcare providers and lead to severe inequalities among patients in the EU. The Office of Health Economics (OHE) ([98]) has looked at the cost of medicines shortages ([99]) and identified price increases as a key feature, notably due to the cost of switching to higher-cost alternatives. It also emphasises the cost of using additional healthcare resource for the management of medicine shortages, including time and labour costs, particularly for pharmacists, to identify alternatives and substitution protocols, adjust inventories and modify purchasing practices as well as to coordinate with other healthcare providers and relevant stakeholders. The European organisation representing community pharmacists (PGEU) highlighted in their annual report on medicine shortages that community pharmacists spent an average of 10.6 hours a week dealing with shortages in 2024 – three times more than a decade ago ([100]).

([96]) BEUC Drug shortages survey report The survey has been conducted in 2024 with 4,017 consumers aged between 25 and 74 years from Belgium, Italy, Spain and Portugal.

([97]) EAHP 2023 Shortages Survey report

([98]) The Office of Health Economics (OHE) is an independent health economics research organisation.

([99]) OHE publication on the cost of drug shortages, September 2024.

([100]) PGEU Medicine Shortages Report 2024

The draft conclusions of the exploratory study on the Critical Medicines Act ([101]) provided broad estimations of certain costs attributable to shortages, acknowledging that much of the available evidence focuses on medicine shortages in general. The costs are broken down into the following categories:

- **additional costs of treatment**: shortages can lead to increased healthcare expenditure. Examples include an estimated potential EUR 51-135 million to a statin shortage in the EU and potential EUR 5.2-172 million cost attributable to a trastuzumab shortage ([102]). Furthermore, consumer surveys also report that 27% of respondents incurred additional costs due to the supply issues. On average, consumers spent an additional EUR 19 to obtain replacement medicines, with country-level averages ranging from EUR 7 to EUR 36. In rare cases, individual costs reached as high as EUR 400 ([103]).
- **workload of healthcare providers, with a focus on pharmacists**: managing medicine shortages significantly increases the workload of pharmacists. Based on the estimated time spent by community pharmacists to mitigate medicine shortages of critical medicines annually, it has been estimated that the EU-wide costs for community pharmacists reach EUR 399–793 million annually ([104]). Another 2024 study by the Royal Dutch Society for the Advancement of Pharmacy found management of all medicine shortages (critical and non-critical) in the Netherlands required 2,000 full-time employees, translating to an annual cost of €220 million in the Netherlands ([105]). Health care providers other than pharmacists are also affected to a certain extent.
- **administrative costs**: these include the burden on EU administrations, national competent authorities and businesses. For example, EMA's annual costs for shortage management alone are estimated to be around EUR 5–15 million.([106]) While the regulatory measures proposed in the revision of the EU pharmaceutical

([101]) Exploratory study in view of a Critical Medicines Act by Ecorys (forthcoming study)

([102]) Estimates are provided by the OHE publication on the cost of drug shortages, September 2024. Both are based on research modelling on the potential cost impact of hypothetical medicine shortages in the EU, taking into account patient health impact (delayed or no access to treatment, leading to poorer health outcomes), additional healthcare resources use (time and costs associated with shortage management) and medicine acquisition costs (costs associated with switching to higher cost alternatives). The potential estimated costs of the shortage scenarios vary widely depending on model assumptions, including QALY (metric that combines the quantity (length of life) and quality (health status) of life into a single measure to evaluate the cost-effectiveness of health interventions) losses per patient, the value assigned to QALYs lost, the proportion of products in shortage and the share of patients able to switch to alternative products.

([103]) BEUC Drug shortages survey report

([104]) Estimation provided by the exploratory study in view of a Critical Medicines Act (Ecorys, forthcoming study) based on the findings of PGEU Medicine Shortages Report 2024. This estimation extrapolates at EU level the average time spent per pharmacy to mitigate shortages of critical medicines, applying the average hourly cost for pharmacists. It is assumed that 15-30% of the shortage instances concern critical medicines.

([105]) 10 jaar geneesmiddelentekorten: enorme impact | KNMP

([106]) These estimates are drawn from the exploratory study for the Critical Medicines Act (Ecorys, forthcoming study). The calculations are based on the assumptions that approximately 1–3% of the annual EMA budget is spent on addressing shortages – a figure inferred from the EMA annual activity report 2024, given an annual EMA budget of EUR 492 million in 2024, this would equate to EUR 5–15 million.

legislation are expected to ensure a coordinated approach for the management of critical shortages at EU level and to support the security of supply of critical medicines, complementary measures of industrial nature are needed to address the underlining supply chain vulnerabilities with the ultimate goal to reduce the risk of occurrence and impact of shortages of critical medicines (see section 3.4).

6.2. Economic and social impacts of the proposal

6.2.1 Economic impacts

The proposed Critical Medicines Act is expected to have a positive impact on supply chain resilience and security by enhancing domestic production capabilities and reducing external dependencies, as well as by supporting supply chain diversification through public procurement and strategic partnerships. Some measures may encourage investments in EU manufacturing, innovative processes and new production technologies, thereby contributing to the competitiveness of the EU's pharmaceutical sector. In addition, the proposed Regulation intends to reduce the fragmentation of the internal market by ensuring exchange of information and coordination between national authorities on financial support to strategic projects and public procurement strategies and by reducing the need for additional national measures to ensure security of supply. Finally, the proposed Regulation aims to improve the availability and accessibility of other medicinal products, where the functioning of the market does not otherwise sufficiently ensure the availability and accessibility of those medicinal products to patients, whilst giving due consideration to the appropriateness to ensure the affordability of medicinal products.

Security of supply and resilience

By incentivising and supporting **Strategic Projects**, the CMA proposal is expected to increase the production of critical medicines, their active substances and key inputs in the EU, and reduce dependencies on third countries. The proposed policy actions are expected to mitigate the risks of supply chain disruptions due to overreliance on a limited number of suppliers located outside the EU.

The draft conclusions of the exploratory study on the Critical Medicines Act ([107]) demonstrate the large consensus among key stakeholder groups supporting Strategic Projects, aiming to increase EU manufacturing capacity. The designation of Strategic Projects received overwhelming support (95% support among survey respondents) with national authorities stressing that these projects could significantly strengthen manufacturing capacity, provided that issues like administrative complexity and coordination are well managed. Fast-tracked administrative procedures were highly supported, with 86% expecting favourable impacts. The provision of dedicated financial support based on existing EU funding instruments gathered strong approval (82% support) while 86% of respondents considered the clarification of State aid rules essential for stimulating investments that secure priority supply to the EU during shortages.

([107]) Exploratory study in view of a Critical Medicines Act by Ecorys (forthcoming study)

The proposed measures on **public procurement,** as well as pricing and reimbursement policies, are expected to incentivise greater investment in resilient supply chains. According to the study on best practices in the Public Procurement of Medicines (PPM) ([108]) published in 2022, the objective of supply security can be supported / reinforced using relevant award criteria, awarding multiple winners and collaborative procurement. Nevertheless, the impact of PPM on medicines shortages has not been quantitatively assessed in the literature, given the challenges with consistently measuring and comparing medicines shortages across countries. In the context of the exploratory study in view of a CMA ([109]), financial estimates for the burden of administrative and procurement-related adjustments were provided by a single stakeholder. They are consistent with known benchmarks in EU public administration. For example, the estimated EUR 350,000 per Member State to prepare national strategies aligns with average costs for public sector strategy initiatives under Interreg Europe ([110]). The EUR 200,000 – EUR 400,000 per Member State range to adopt MEAT criteria mirrors findings from co-financing schemes in Slovak regional authorities, where adoption of such models involved considerable administrative effort ([111]). These figures give a certain indication, but significant particularities are likely to exist for procurement in the pharma sector, and between Member States – not only due to their very different size but also due to major organisational differences between the national health systems.

Furthermore, **collaborative procurement** initiatives could also support supply security by pooling demand at EU level and reducing transactional costs for pharmaceutical companies and making the EU a more attractive place to conduct business. According to the PPM study ([112]), mitigating supply issues for older medicines is seen as an important purpose of collaborative procurement initiatives, including for the joint procurement of vaccines by the Baltic countries and the joint Nordic tenders. Potential benefits of collaborative procurement in addressing medicines shortages are not limited to small countries. France has also considered international collaborations, including joint procurement, as strategic pillar to address medicines shortages in an OECD report on shortages ([113]). In this respect, the draft conclusions of the exploratory study in view of a CMA ([114]) highlighted that more systematic cross-border procurement among Member States on voluntary basis (72% of respondents anticipating positive outcomes) would complement Strategic Projects by consolidating demand and reinforcing investment incentives.

Finally, by promoting supply chain diversification through the establishment of **strategic partnerships** with selected third countries, the CMA proposal is also expected to make supply chains more resilient to disruptions and shocks. While the CMA proposal aims to reinforce manufacturing capacity in the EU, it would not be realistic to reshore the

([108]) Study on best practices in the public procurement of medicines, October 2022

([109]) Exploratory study in view of a Critical Medicines Act by Ecorys (forthcoming study)

([110]) https://www.interregeurope.eu/help-centre/apply-for-funding/project-budget

([111]) https://www.nature.com/articles/s41599-024-04129-4

([112]) Ibid

([113]) Chapman S, Dedet G, Lopert R. Shortages of medicines in OECD countries. OECD Health Working Paper No. 137. Paris: OECD, 2022.

([114]) Exploratory study in view of a Critical Medicines Act by Ecorys (forthcoming study)

production of all critical medicines and their APIs within the EU. It may rather be sufficient to reshore only a proportion of this production to ensure increased resilience and supply security. Therefore, it is equally important to be able to rely on manufacturing capacity in like-minded countries, especially EU candidate countries and potential candidate countries, to increase the number of suppliers and diversify their location.

Based on the pharmaceutical industry study in prospective EU members ([115]), specifically in the Western Balkans and Ukraine, a key preliminary finding is that out of the 276 products listed in the updated Union List of Critical Medicines (ULCM), over 100 — more than one third — are already produced in the seven assessed markets, with many production capacities currently underutilised. Despite existing regulatory challenges, this suggests there is still significant potential to leverage existing manufacturing capacity in EU candidate and potential candidates.

International trade and dependencies

The CMA proposal is expected to deliver an impact on reducing global supply chain dependencies by more actively supporting reshoring and investment in EU-based production capacity.

The designation of **Strategic Projects**, coupled with administrative fast-tracking, financial incentives, and clearer State aid rules, supports significant expansion in EU pharmaceutical manufacturing. These proactive measures aim to decrease reliance on third-country suppliers, especially for critical medicines and APIs, thereby mitigating vulnerability to international trade disruptions. Clear State aid rules and financial incentives are expected to improve investment predictability, enabling more reshoring efforts without severely restricting global trade. On the other hand, creation of manufacturing capacities in the EU for critical medicines and their active ingredients, with highly consolidated supply chains, would benefit the EU trading partners and increase the global supply chain resilience. Overall, the CMA proposal would enhance EU self-reliance and negotiating power, moderately influencing international pharmaceutical trade dynamics while remaining within established global regulatory frameworks.

The proposed measures on **public procurement**, in particular the requirements favouring suppliers of critical medicines produced in the EU, are also expected to support efforts to reduce our dependencies on third country suppliers for specific critical medicines while limiting the impact on international trade. This measure targets only specific critical medicines where a high dependency on a single or limited number of third countries has been identified based on the outcomes of the vulnerability evaluation, reducing the impact of the proposed measure on global trade. In addition, the CMA proposal clarifies that these requirements are to be applied in compliance with the EU's international commitments.

Competitiveness and capacity to innovate

The CMA proposal is expected to have a positive impact on the competitiveness of pharmaceutical companies operating in the EU by encouraging investment in resilient and

([115]) Ongoing pharmaceutical industry study in prospective EU member countries conducted by NTU International Consortium. The study is specifically looking at the Western Balkans, i.e. Albania, Bosnia and Herzegovina (BiH), Montenegro, North Macedonia and Serbia (EU candidate countries) and Kosovo (a potential EU candidate), and Ukraine (EU candidate country).

modern supply chains and scaling up production facilities in the EU. Moreover, the proposed measures in the CMA are expected to build, expand and keep the relevant expertise to produce medicines in the EU.

Public investments to maintain and extend production facilities for critical medicines in the EU will leverage and complement private investments and make more investments in EU production facilities profitable. It is expected that the investments will flow into building new facilities or upgrading existing production lines. As a result, the investment will lead to more modern, state-of-the-art, potentially more environmentally sustainable, and cost-efficient production facilities in the EU.

The proposed measures to support **Strategic Projects**, such as fast-tracked permit-granting procedures, dedicated administrative and regulatory support to projects promoters and facilitated financial support, are expected to incentivise companies to invest in the creation, extension and modernisation of manufacturing sites of critical medicines and their APIs and key inputs in the EU. The strategic report of the Critical Medicines Alliance highlighted that infrastructure and capital expenditure (CAPEX) **investment support** has been identified by its members when consulted on investment strategies and objectives as the top priority, particularly investing in modernisation and greener production technologies, and enhancing process efficiency, notably in the manufacture of APIs. In this context, members of the Alliance (representing industry, civil society and the Member States) have agreed that a typical project support would be between EUR 5 to 20 million depending on the complexity of the product ([116]).

The proposed measures in the CMA proposal, in particular financial incentives as well as regulatory and scientific support to Strategic Projects, are expected to primarily support innovation in new manufacturing processes with the objective to increase efficiency and support sustainable production. The draft conclusions of the exploratory study in view of a CMA indicate that simplified processes and transparent state aid rules could encourage investment in greener and more resilient manufacturing.

Through the measures proposed in the CMA, public and private investment will also flow into the innovation of production technologies and facilities, creating incentives for innovation. The potentially newly developed technologies would make the pharmaceutical industry in Europe more competitive.

The CMA proposal provides measures to support building better integrated supply chains, also locally in the EU, will create a more stable and predictable business environment if supply chains become less vulnerable to disruptions. The increase in stability and predictability reduces the uncertainty of investments in the EU pharma sector and could trigger even more investments in EU medicines production.

If the proposed measures in the CMA will lead to an increase in production capacity in the EU, the increase in scale can lead to economies of scale, potentially leading to lower production costs in the EU. Making production in Europe more productive through more innovative production technologies and benefitting from potential economies of scale would lead to a more competitive pharmaceutical sector in the EU.

([116]) Strategic Report of the Critical Medicines Alliance, February 2025

Functioning of the Single Market

The impacts of the CMA proposal on the functioning of the single market are expected to be positive. Taking the form of a Regulation, the CMA proposal aims to provide a sufficient level of harmonisation and to reduce the EU's market fragmentation by establishing clear criteria for the identification and recognition of strategic projects, conditions for administrative and financial support of such strategic projects as well as by mandating the use of non-price requirements by public procurers and measures to avoid any negative impact of contingency stock requirements imposed at national level.

The CMA proposal will help strengthening the resilience of critical medicines supply chains within the Single Market, with an important role for the **Critical Medicines Coordination Group** (CMG) to assist and facilitate exchange of information between public authorities. This coordination group will have a central role for the coordination of financial support provided by national authorities and the Commission to project promotors. It is expected to reduce the risks of distortion of competition, subsidy race and single market fragmentation due to State aid interventions.

For **Strategic projects** receiving financial support, the obligation to prioritise supply to the Union market and ensure that the concerned critical medicine remains available in the concerned Member States is also expected to support the functioning of the Single Market. In this context, the relevant Member State may request the necessary supplies of the critical medicine, active substance or key input to the Union market to avoid shortages in one or several Member States.

The proposed measures on **public procurement**, especially the requirements to use other criteria than price-only for critical medicines and to favour EU production when a high dependency on a single or limited number of third countries has been identified, will increase harmonisation between public procurement practices while leaving sufficient room for manoeuvre at national level to adapt these practices depending on the type of critical medicines and the specificities of national healthcare systems.

To avoid negative impacts on the Single Market, the CMA proposal requires Member States to ensure that **national contingency stock requirements** are proportionate and respect principles of transparency and solidarity. This obligation is expected to have a beneficial impact on marketing authorisation holders and wholesalers that are confronted with an increasing number of national requirements imposing to hold additional safety stocks for the different markets. Ensuring proportionality of these national requirements, when it comes to the medicines in scope, the size of stocks and the timeline to build them, as well as solidarity between Member States to facilitate the sharing of these contingency stocks in case of shortages in another country will improve the functioning of the single market.

Moreover, **collaborative procurement** will contribute to improving the Single Market for medicines by supporting the availability and accessibility of medicines authorised in the EU. In this context, it should be noted that the Commission will further support these collaborative procurement initiatives while avoiding negative impact on the Single Market. More specifically, in the context of EU joint procurement, the Commission will verify whether the procurement could constitute discrimination or restriction to trade or a distortion to competition. This measure is expected to limit negative impact of joint procurement initiatives on the single market.

Overall, the CMA proposal aims to strengthen the security of supply of critical medicines in the Union, to reduce the occurrence and impact of shortages of critical medicines, reducing the need for national authorities to take additional measures to mitigate the impact of such shortages. It is therefore expected that, in the long term, the number of national measures on export restrictions due to supply disruptions will be reduced, having a positive impact on the single market.

Affordability of medicines

The suggested policy actions in the CMA proposal may impact pharmaceutical prices and, thus, on the affordability of medicines. Given the wide variety of proposed measures and the flexibility in the implementation of certain policies, positive or negative price effects are difficult to quantify. The following paragraphs shed light on a possible direction of exemplary price effects due to changes in criteria in public procurement or due to collaborative procurement.

Given that the proposed measures on public procurement include (additional) procurement requirements other than price-only, the submitted offers may take into account the higher costs of the additional procurement requirements and eventually lead to price increases for critical medicines. According to a stakeholder survey carried out in the context of the exploratory study in view of the Critical Medicines Act, 59% of respondents expected price increases from resilience-based procurement, and 75% expected increases due to broader MEAT criteria. Views on cross-border/joint procurement were mixed: 37–42% expected price reductions, whilst 31–33% expected rather increases. Currently, globally integrated supply chains can be highly vulnerable but are also efficient. Production of medicines in Europe or sourcing of API from Europe tends to be more expensive than sourcing from other parts of the world ([117]). If public procurement requirements favour sourcing of medicines or API from Europe, or require or incentivise the use of multiple suppliers, the establishment of buffer stocks or other requirements, the submitted tenders are expected to reflect the associated rising costs.

However, the quantification of production costs and the expected impacts of public procurement measures on prices will notably depend on the following aspects: type of critical medicine (e.g. off-patent/on-patent), market situation (e.g. number of different suppliers that may compete for a tender), the specific non-price criteria or requirements selected by the contracting authorities (stockholding obligation which can range from few weeks to several months depending on various factors, number of diversified suppliers, supply chain monitoring, contact performance causes on timely delivery or transparency requirements), the use of award criteria compared to minimum requirements or inclusion of requirements in the tender specifications, weight given to the non-price criteria, the potential use of the exemptions when justified by market analysis or considerations related to the financing of health services and whether the companies would pass on the costs to the customers. While certain non-price criteria/requirements are not expected to entail significant price increases, other might have more substantial impacts. Other factors may limit the price increase, such as lower transport costs, less compliance with trade regulation, or economies of scale if more API or pharmaceuticals are sourced from the EU. Yet other factors may limit the budgetary impact on health systems, such as higher supply

([117])For example, compare to the Decision "State Aid SA.62915 (2022/N) – Austria – Aid for maintaining Sandoz penicillin production in Kundl (Tyrol)"

security/sustainability and less costs due to shortages. Consequently, it is difficult to estimate with accuracy a potential price increase that may apply to critical medicines.

Moreover, some studies indicate that the proposed measures on **collaborative procurement** could support the affordability of the concerned **critical medicines** and **medicines of common interest**. Nevertheless, it will depend on various factors such as the type of medicine subject to the collaborative procurement, the volumes and the market size. According to the PPM study, collaborative procurement, including within country and cross-country, can help achieve lower prices and make small markets attractive for suppliers, thereby achieving better availability of medicines and mitigating the risk of shortages. Collaborative procurement also provides other benefits, such as information sharing and capacity building. However, the stakeholder consultation in the context of the PPM study did not clarify whether collaborative procurement is expected to lead to lower prices. The draft conclusions of the exploratory study in view of a CMA ([118]) also revealed divergences of opinion regarding the impact of collaborative procurement on prices, with around 40% of stakeholders expecting price decreases (particularly for high-cost, low-volume products) and a third expecting increases.

While characteristics of the procurement system can have an impact on pharmaceutical price, the characteristics of procurements are different across Member States and a precise quantification at EU-level is probably impossible to conduct. For example, in the PPM study ([119]), the analysis of quantitative data showed that lower unit prices were observed in countries with more advanced PPM (i.e. more centralised procurement, use of different PPM procedures and techniques, MEAT award criteria, and application of supporting policies and tools). This is consistent with previous studies which have generally found that collaborative procurement (e.g. through the use of a Central Purchasing Body – CPB) results in lower prices. Nevertheless, the relationship between affordability and specific procurement characteristics is not straightforward as for certain individual countries a different trend can be observed. The PPM study found that stakeholders from the public sector generally consider PPM to positively impact affordability. More advanced procurement practices, such as the use of framework agreements, Dynamic Purchasing Systems (DPS), and application of MEAT criteria were assessed as contributing to improved affordability in an online survey.

SMEs

In addition to fast-tracked permit-granting procedures and financial incentives to strategic projects, the proposed Regulation includes specific measures to provide administrative, regulatory and scientific support to pharmaceutical companies, with a specific focus on Small and Medium-sizes Enterprises (SMEs). SME's may for instance benefit from dedicated advice from EMA when developing projects relying on innovative manufacturing processes. Where appropriate, Member States will have to establish a dedicated channel for communication with SMEs to provide guidance and respond to queries related to the implementation of the Act. Finally, SME's already benefit from less demanding conditions in order to be granted State aid, which may facilitate access to financing of strategic projects.

([118]) Exploratory study in view of a Critical Medicines Act by Ecorys (forthcoming study)

([119]) Study on best practices in the public procurement of medicines, October 2022

The draft conclusions of the exploratory study in view of a Critical Medicines Act ([120]) found that the proposed measures could positively impact SMEs by reducing entry barriers and lowering initial investment risks. While the increased availability of financial and administrative support may positively impact SMEs by reducing entry barriers and lowering initial investment risks, the complexity of administrative processes and resource requirements might still favour larger firms, for example in applying for and leveraging strategic project designations. Improvements to the investment environment, such as dedicated financial support and clarified State aid rules could particularly benefit SMEs by providing clearer investment frameworks and reducing compliance uncertainties, thus somewhat enhancing SMEs' competitive positioning by comparison with other policy options.

Employment

The proposal is anticipated to have positive employment impacts. The designation of Strategic Projects, coupled with fast-tracked administrative support and targeted financial incentives is expected to incentivise substantial investment in EU-based manufacturing. This would likely lead to job creation in the EU in API production, formulation, and supporting supply chain functions, especially in regions with available infrastructure or prior pharmaceutical industrial activity.

([120]) Exploratory study in view of a Critical Medicines Act by Ecorys (forthcoming study)

6.2.2. Social impacts

Health impacts

Reduction in shortages of critical medicines

Overall, the CMA proposal is designed to complement the proposed revision of the pharmaceutical legislation to reduce the occurrence and impact of shortages of critical medicines by fostering supply chain resilience, reinforcing domestic manufacturing capacities and promoting supply chain diversification. The expected impacts of the proposed measures on health are expected to materialise in the medium or long-term. Patients are expected to be less affected by critical medicine shortages. Reducing medicine shortages would not only alleviate the current burden related to the management of shortages (see the section 6.1 on the baseline) but also improve patients' health, by limiting the risk of deterioration of their health status due to sub-optimal care or delayed treatment.

The draft conclusions of the exploratory study in view of a Critical Medicines Act ([121]) found that the proposed measures create a coherent framework of enabling conditions which, is likely to overcome key barriers to expanding EU-based manufacturing with concomitant results in terms of reducing the risk of shortages and thereby negative effects on patient health. Moreover, a reduction in shortages of critical medicines would in turn lead to healthcare professionals benefitting from fewer treatment disruptions, reducing thus the time spent on searching for therapeutics substitutions and associated administrative tasks. Several stakeholders highlighted the opportunity to redirect saved time and resources toward patient care.

Improved availability and accessibility of medicines of common interest

Effects of the proposed measures related to collaborative procurement on access and availability of medicines of common interest are expected to materialise in the short or medium term. More specifically, EU-led collaborative procurement should support the availability of medicines of common interest, particularly for smaller and lower-income Member States, where it can overcome a market failure due to limited patient population. Broader, improved availability of these medicines is anticipated to yield strong health benefits.

The draft conclusions of the exploratory study on the Critical Medicines Act ([122]) showed that cross-border procurement for medicines of common interest was consistently supported (68% positive), as seen to reduce inequalities in access. Nevertheless, concerns persisted around packaging differences, legal constraints, and labelling requirements that could hinder harmonisation and patient safety. On joint procurement for medicines of common interest, stakeholders noted that this could help reduce disparities in access, but only if linked to meaningful transparency and coordinated demand planning. Some flagged the risk of unintended consequences for generics markets, including reduced competition and supplier withdrawal.

([121]) Exploratory study in view of a Critical Medicines Act by Ecorys (forthcoming study)

([122]) Ibid.

6.2.3. Environmental impacts

The legislative proposal's environmental impacts are in line with the climate objectives. The measures' support for EU-based manufacturing through Strategic Projects relocate production capacity to the EU where carbon emission fall under the EU Emission Trading System (EU-ETS) and the environment is strongly protected against pollution by chemical production processes, all are possible positive environmental impacts. More specifically, one of the designation criteria for Strategic Project consists of the modernisation of existing manufacturing site in view of ensuring greater sustainability or increased efficiency. Furthermore, the CMA measures could reduce long-haul freight emissions and associated carbon intensity by shortening supply routes. However, increased production of critical medicines and their APIs in the EU may increase energy consumption and emissions, particularly in energy-intensive API synthesis.

6.3. Other impacts

Digital readiness

While the CMA proposal does not include a new database or IT platform to support the implementation of the proposed measures, it will rely on existing IT platforms, such as the European Shortages Monitoring Platform (ESMP) (see section 5.4). The ESMP is notably expected to support the vulnerability evaluation of critical medicines supply chains, requested for the implementation of certain measures of the CMA proposal.

The Act follows the 'only-once' principle by not duplicating data collection for identification of critical medicines and evaluation of vulnerabilities in their supply chains, by re-using data collected and processed established under the proposed pharmaceutical legislation.

In order to guarantee the interoperability of data regarding critical medicines and other medicines of common interest and facilitate seamless, automated electronic exchanges, the Commission and the EMA are expected to maintain these data in appropriate and interoperable formats. This includes utilising commonly used, machine-readable formats such as application programming interfaces (APIs), and employing controlled vocabularies where available, to facilitate data reuse. The digital implementation is executed by EMA, relying on existing tools, procedures and artefacts.

In addition, according to Article 6 of the CMA proposal, Member States will be requested to designate an authority ('designated authority') that shall confirm, upon request, whether a specific project constitutes a strategic project. Member States shall inform the Commission of their designated authority. This notification will be done electronically. The list of Member States' authorities designated for assessing and confirming Strategic Projects will be published on the ec.europa.eu website, relying on its standards for being findable and accessible.

Member States will also be required to notify their national programmes to the Commission in its role of the secretariat of the Critical Medicines Group, according to Article 16. The Commission will then ensure the distribution to all members of the coordination group. This notification and distribution will be done electronically.

Furthermore, the Commission will display details of Strategic Projects that address a vulnerability in the supply chains of critical medicines on the STEP Sovereignty Portal, a

publicly available website providing information about funding opportunities for projects linked to the STEP objectives and enhancing the visibility of those projects.

Fundamental rights

The proposal helps achieve a high level of human health protection and is therefore consistent with Article 35 of the Charter of Fundamental Rights of the European Union ('the Charter'). Article 16 of the Charter provides for the freedom to conduct a business. The measures under this proposal support creation or expansion of manufacturing capacity and foster demand for critical medicines and other medicines of common interest with resilient supply chains, which can reinforce the freedom to conduct a business in accordance with Union law and national laws and practices.

6.4. Costs and benefits of the proposal

In terms of overall benefits, these are expected to be significant. Increasing supply chain resilience and diversification of critical medicines and pooling demand for medicines of common interest is expected to improve the availability of these medicines, leading to positive health impacts for patients. Reducing the risk of supply disruptions will decrease unintended effects on patients related to sub-optimal care and delays in treatment, while giving the possibility to healthcare providers to reallocate resources towards patient care. The proposal's benefits will materialise over an extended period, while the impact on patient outcomes, healthcare systems and the economy may evolve and change.

In terms of administrative costs, the proposal does not entail significant additional regulatory burden for businesses. For undertakings developing a strategic project, it will facilitate the creation or expansion of manufacturing capacities of critical medicines, their active substances and key inputs in the EU by fast-tracking permit-granting procedures, streamlining environmental assessments and providing targeted support when needed.

The proposed measures, especially the designation and support to strategic projects as well as the changes required in public procurement practices, are expected to trigger certain compliance costs for national authorities. In addition, certain reporting obligations are included in relation to financial support provided to strategic projects, national programmes to ensure sustainability and resilience in public procurement and collaborative procurement initiatives. These reporting obligations are expected to support effective coordination between Member States and ensure coordinated approach not only on financial support to strategic projects but also on public procurement approaches to maximise impact on the market and efficiency gains. Consequently, the proposed Regulation will generate further synergies and ensure efficient coordination and collaboration between Member States to reach the Union's strategic objective to strengthen the security of supply and availability of critical medicines.

Finally, while the proposed measures may have an impact on the prices of critical medicines (see section 6.2 on economic and social impacts), these effects are expected to be compensated by the anticipated savings resulting from a reduction of shortages costs (see section 6.1 on the current burden of medicine shortages).

A mapping of the expected costs and benefits of the legislative proposal features is presented in Annex 2. The Commission will continue to gather and analyse relevant information and data which will be taken into account in the implementation of the Act.

GOVERNANCE, MONITORING AND EVALUATION

The proposal for the Critical Medicines Act emphasises the importance of accurate monitoring and governance as key mechanisms to minimise the costs of implementation. Accurate monitoring and governance help reduce unnecessary expenditure and contribute to maximising the economic benefits of the Act.

The proposal establishes the Critical Medicines Coordination Group to facilitate coordination in the implementation of the proposed Regulation and, where appropriate, advise the Commission, to maximise the impact of the measures envisaged and to avoid any unintended effects on the internal market. Members will consist of Member States, with a maximum of two representatives per Member State, and the Commission. The coordination group will be chaired by the Commission, who will also provide its secretariat. EMA will have an observer status.

The main tasks of this coordination group will be to:

- Facilitate coordination on strategic orientation for financial support of Strategic Projects
- Enable exchanges, cooperation and coordination on public procurement policies
- Facilitate discussion on collaborative procurement needs
- Advise MSSG to prioritise, review and update vulnerability evaluations
- Discuss periodically on international cooperation

This proposal introduces a requirement for Member States to inform the Critical Medicines Coordination Group about their intention to provide national financial support to strategic projects, as well as for the Commission to periodically inform the Critical Medicines Group of the Strategic Projects that benefited from financial support from the Union and of setting up any new funding possibilities. The data gathered is necessary to monitor and evaluate the success of this Regulation over time.

The Commission will evaluate the impact of this proposed Regulation and whether its objectives have been achieved by five years after the date of application and every five years thereafter. The main findings of the evaluation will be presented in a report to the European Parliament and the Council, which will be made public.

The following indicators have been identified to evaluate impact of the proposed measures on each of the objectives:

- Number of medicines on the Union List of critical medicines

- Number of critical shortages escalated to the SPOC WP for critical medicines on the Union list

- Proportion of critical shortages escalated to the SPOC WP that correspond to a critical medicine on the Union list

- Number of strategic projects identified as addressing an existing vulnerability in the supply chains of critical medicines

- Number of strategic projects for critical medicines that benefit from national financial support

- Number of strategic projects for critical medicines that benefit from financial support from the Union

- Number of dedicated advice provided by EMA to project promoters of Strategic Projects with innovative manufacturing processes

- Number of national programmes issued

- Number of cross-border procurement, procurement on behalf or joint procurements for critical medicines and other medicines of common interest

- Number of countries benefiting from cross-border procurement, procurement on behalf or joint procurements for critical medicines and other medicines of common interest

The monitoring will strongly rely on the work of the European Medicines Agency and the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), including representatives of EU Member States, the European Commission and EMA via the European Shortages Monitoring Platform. Data with regards to critical shortages escalated to SPOC WP that correspond to critical medicines is collected on a continuous basis by the EMA ([123]). In addition, the recently redesigned Tenders Electronic Daily portal ('TED') serves as an efficient tool for sharing and monitoring procurement procedures, including to monitor the uptake of non-price criteria in the public procurement of critical medicines.

([123]) Public information on medicine shortages – European Medicines Agency

ANNEX 1 - CRITICAL MEDICINES ALLIANCE RECOMMENDATIONS

On 28 February 2025, the Critical Medicines Alliance published its first Strategic Report. The report outlines key findings and recommendations to enhance the security and resilience of the EU's Critical Medicines supply chains.

It highlights the critical vulnerabilities within Europe's pharmaceutical supply chains, and proposes substantial investment in strategic projects, addresses procurement policies, while advocating for a harmonised and balanced framework of stockpiling requirements to ensure the security of supply. Recognising the interconnected nature of pharmaceutical supply chains, the Alliance also recommends strengthening partnerships with third countries to bolster supply resilience.

Key Sections and Recommendations

1. Assessing Vulnerabilities in Supply Chains

In April 2024, the Commission conducted a pilot exercise to assess the structural and non-structural vulnerabilities of selected medicines' industrial supply chains. Results of this pilot exercise and lessons learned (including data limitations, notably in the absence of the proposed pharmaceutical legislation) led the Alliance to identifying the need to further improve the methodology assessing the vulnerability of products on the list in order to prioritise efforts on those products most in need and to give patients the most benefit. The Alliance considers that an analysis of industrial vulnerabilities of medicines belonging to the Union list of Critical Medicines should result in a sub-set list of Critical Vulnerable Medicines. This assessment should be evidence-based in order for the EU to prioritise its policy instruments and financial efforts on manufacturing supply chains for which structural vulnerabilities have been identified.

- The Alliance recommends the establishment of a European list of Critical Vulnerable Medicines based on an assessment of structural vulnerabilities within their industrial supply chains (preliminary draft list by mid-2025) (the "Vulnerability Assessment").
- Specifically, the Alliance recommends the EU to implement the proposed revised methodology to perform a Vulnerability Assessment of medicines. The aim being to achieve an actionable list at the earliest time and to conduct periodic updates of the List of Critical Vulnerable Medicines.
- Specially, the Alliance recommends the EU to maintain involvement of the relevant Alliance stakeholders in the development of the list of Critical Vulnerable Medicines.

2. Strengthening European Manufacturing

The structural low profitability of 'mature drugs', mainly off-patent generic medicines, caused by intense downward price pressure, along with a growing competitiveness gap with Asian producers of raw materials, intermediaries, and APIs, has led to offshoring and concentration of strategic commodities' production primarily in China and India. Lower production costs and less stringent regulatory standards, in concomitance with consistent

and well-defined investment strategies in India and China have driven the transfer of API production to these countries. To assess the relevance of existing EU funding instruments to strengthen manufacturing capacities in the EU, the Alliance conducted an analysis of the existing financial incentives tools in the EU in addressing the identified needs. The Alliance developed a dedicated matrix of relevant EU programmes and State aid tools matched against areas most vulnerable to global supply chain disruptions.

- The Alliance emphasizes the need for an ambitious European investment plan to strengthen production capacities for Critical Medicines in Europe, and for ensuring an EU-level coordinated approach to implement it
- The Alliance recommends the creation of a Critical Medicines production-specific one-stop-shop, under an EU funding program dedicated to production of APIs and essential medicines.
- The Alliance recommends that public financing tools should be strategically coordinated with the EIB, multilateral banks and private sector banks, to improve access to private finance for high-risk projects.
- Specifically, the Alliance recommends the consideration of a new State aid regulation, restricted to Critical Medicines, allowing differentiated funding of large groups and SMEs within the EU for production capacity investment projects, the launch of a dedicated IPCEI, in specific cases, when documented evidence suggest a substantial competitivity gain potential from beyond state-of-the-art innovation and the launch of a Critical Medicines SGEI coordinated at EU level to limit the risk of critical shortages, through a compensated public service obligation, in specific cases of products with low market viability.
- The Alliance further recommends Member States to earmark parts of the shared management European funds to contribute to the objectives of the CMA.
- The Alliance should support a coordinated approach to skills development to address immediate workforce shortages and ensure long-term sustainability and competitiveness within the sector.

3. Security of Supply

On contingency stocks

To mitigate the risk of shortages, several Member States have implemented contingency stock obligations, which mainly require suppliers to maintain national reserves of Critical Medicines. These mandated supplier stocks are regulated by authorities but remain under the ownership of suppliers. However, these stocks are typically reserved for a single country, hindering the equitable distribution of essential medicinal products according to patient needs.

Current level of coordination among Member States regarding contingency stock shall improve. Unilateral national stocks fragment the market and negatively impact the patients´ access to medicinal products, as some countries might hoard supplies, worsening

shortages elsewhere and increasing health inequalities and tensions between Member States. While committees such as the EMA's Medicines Shortages Single Point of Contact Working Party and the MSSG provide essential technical oversight, there is a pressing need for enhanced strategic coordination at the EU level.

- The Alliance recommends the industry, Member States and/or the EU to implement a comprehensive harmonised and balanced framework on contingency stocks to be defined in the Critical Medicines Act.

The Alliance further put forward specific recommendations towards targeted parties, namely applying to mandated supplier contingency stock, when there is a requirement imposed by an authority (such as a government or regulatory body), but the responsibility for maintaining and owning the stock remains with the supplier, and contingency stock done, managed and controlled by the Member States or EU related to supply chain disruptions and the prevention of shortages of medicinal products (strategic reserves of Member States or EU intended for use during emergencies, such as health threats, natural disasters, economic crises, are excluded),

- Specifically, the Alliance recommends targeted parties to evaluate relevant data connected to manufacturing and storage capacities and use forecasting, when implementing contingency stock obligations to ensure proportionality.
- Specifically, the Alliance recommends targeted parties to implement stock management strategies to ensure prevention of waste.
- Specifically, the Alliance recommends targeted parties to transparently share data regarding stock requirements and related measures, and to develop a dedicated database.
- Specifically, the Alliance recommends for the targeted parties to assess the financial impact of contingency stocks obligations.
- Specifically, the Alliance recommends the prioritisation of EU contingency stocks for medicinal products with low consumption (such as orphans or innovative antibiotics) or with limited national contingency stocks obligations based on the agreement of the Member States.
- Specifically, the Alliance recommends the targeted parties to consider contingency stocks of unfinished medicinal products and relevant applicable obligations.

On public procurement

Procurement of medicines is a national competence, whether in the realm of pricing and reimbursement or the definition per se of procurement criteria. EU procurement legislation gives the Member States a large margin of manoeuvre in setting up the criteria for their tenders for the supply of Critical Medicines. Current procurement practices by Member States – with a particular focus on price as the most important, or even the only meaningful procurement criterion – have been a significant driver of the current market dynamics for mature medicines. These market dynamics have led to consolidation of suppliers and outsourcing to other jurisdictions outside the EU, of all or part of the manufacturing supply chains.

- The Alliance therefore recommends the EU to promote virtuous public procurement practices within the scope of the Critical Medicines through the systematic integration of essential procurement criteria like supply security, resilience, and environmental impact.
- Specifically, the Alliance recommends the systematic application of essential criteria in Critical Medicines public procurement in the EU, to be covered by the Critical Medicines Act.
- Specifically, the Alliance recommends for the Critical Medicines Act to promote public procurement practices that reward the security of supply granted notably by EU production and contributing to sustainable markets; an appropriate legislative instrument that ensures legal certainty and uniform application of the criteria in the EU should be identified by the Commission; in addition, an implementing act should be adopted providing guidelines on the application of each criterion.
- Specifically, the Alliance recommends the EU to implement a mechanism prescribing specific selection criteria and weighting ranges in tender evaluations.

On joint procurement

Joint Procurement between Member States (at EU level or regional level in a decentralised manner) on a voluntary basis can contribute to improve availability, affordability and security of supply of Critical Medicines, by strengthening the negotiating position of Member States, but also allowing for a stronger reliance on MEAT criteria to ensure overall positive effects on the supply chain. Joint Procurement can also improve demand signalling to incentivise production capacities. Joint procurement should ensure that there is no disruption to pre-existing (national or regional) contracts and participating Member States should not tender nationally/locally for the same medicines for the duration of the European or regional joint tender. Competing joint and national procurement would generate shortages as manufacturers would need to produce for both tenders without knowing which one takes precedence. In order for this joint procurement to be cost-effective from a public health perspective we need to ensure that: (i) there are objective criteria in place for establishing its scope, also relying on transparent and detailed information about current stocks within the EU, (ii) that it does not distort the internal market and (iii) that price-setting is based on a methodology jointly established with the member states participating.

- The Alliance recommends making use of Joint Procurement as a way to address the fragmentation of the market and to update the Joint Procurement Agreement's scope to tackle shortages of medicine.

4. Level-Playing Field

Ensuring a fair level-playing field between the EU and the rest of the world, where relevant could create new incentives for the production of Critical Medicines. The Alliance has

identified various factors related to manufacturing that can impact the competitiveness of EU-based production of Critical Medicines and their APIs within the EU.

In parallel, within the EU, due to diverse national laws and practices (e.g., priority status for strategic projects in permitting procedures, assistance on access to financing, and public procurement criteria), EU member states have significant flexibility to incentivize production and investment. However, varying levels of implementation could create uncertainty for investors and the industry, leading to an uneven playing field within the EU

- The Alliance recommends for the EU to promote a level playing field, concerning environmental and social standards but also fair competition between Critical Medicines manufactured in the EU and in the rest of the world.
- The EU to promote environmentally virtuous products manufactured in the EU, through the introduction of environmental criteria in public tenders. More globally, the EU should work to create a fair and equitable environment for the development and production of Critical Medicines by identifying, promoting and rewarding best practices. To address the level-playing field, the EU should introduce measures and tools that will support best manufacturing practices, including EU-based manufacturing of Critical Medicines, while ensuring their affordability.
- The Commission is recommended to promptly launch a study to:
    - To identify the sources of competitive disadvantage for EU manufacturers.
    - To provide a comparison of regulatory standards between EU and non-EU and quantify their impact on competitiveness, environmental risk and public health risk
- The EU to stand firm against unfair trade practices through active monitoring and addressing of unfair trade practices, by making more effective use of Trade Defence Instruments (TDIs) in line with WTO rules, where relevant in the pharmaceutical sector.

5. International Cooperation

While the Alliance focuses on strengthening the global competitiveness of the European pharmaceutical sector by stimulating local production in order to safeguard EU's supply security, the EU cannot independently produce all Critical Medicines.

As such, international cooperation and integration of the global pharmaceutical industry is a key determinant in securing Critical Medicines supply. Consequently, strengthening the resilience of the global pharmaceutical supply chain is fundamental. Given the complexity and interconnected nature of today's global supply networks, a collaborative approach emphasising flexibility, adaptability and diversification is essential. In this context, the Alliance explored ways of strengthening strategic international partnerships as a means to diversify international supply chains and enhance security of supply for Critical Medicines and reduce supply disruption risks

- The Alliance recommends the EU to leverage existing partnerships with third countries and to build new cooperation.
- The Alliance recommends the Commission to pursue partnerships with established trade partner countries, large producer and spare capacity countries, neighbouring and strategically positioned countries, and capacity-development countries.
- The methodological framework it has developed should serve as a basis to assess the prospects of non-EU countries for different partnerships. Notably it should consider indicators for production capacity, ease of trade, third-country policy and geographical/geopolitical factors.

6. International solidarity

Following the Commission Communication "Addressing shortages of medicines in the EU", the Voluntary Solidarity Mechanism (VSM) was launched in October 2023 at the level of the Executive Steering Group of the European Medicines Agency on Shortages and Safety of Medicinal Products (MSSG) to support Member States experiencing critical shortages. It enables EU and European Economic Area (EEA) Member States, where all other possibilities are exhausted, to request assistance from the MSSG in obtaining stocks of a medicine during critical shortages. However, in a situation where Member States' capacities would not be sufficient to address each other's needs, support from international partners may be sought (and vice versa).

- The Alliance welcomes the efforts of the MSSG in the developments of a voluntary solidarity mechanism and recommends the MSSG to formalise the possibility for outreach to third-country jurisdictions, as part of the Voluntary Solidarity Mechanism.
- The Alliance specifically recommends the MSSG to explore the possibilities for increase of supply to Europe on a temporary basis, including in view of seasonal demand peaks. The Alliance recommends the MSSG to create a dedicated, structured, transparent, and secure repository for information exchange on Member States' experience as regards their respective bilateral relations with international partners when dealing with national shortages.

ANNEX 2 – MAPPING OF EXPECTED COSTS AND BENEFITS OF THE LEGISLATIVE PROPOSAL

The mapping of the expected costs and benefits of the legislative proposal features is set out in the table below.

Measure	**Costs**	**Benefits**
Strategic projects		
Identification and recognition of strategic projects	Limited additional adjustment costs are expected for **public authorities and businesses** given that the recognition of strategic projects relies on existing structures and processes without creating an additional administrative layer. **Public authorities** are requested to designate an existing (specialised) authority to verify, upon request, if a specific project meets one of the defined criteria.	The status of strategic projects provides a range of potential benefits to project promoters, including fast-tracked permit-granting procedures, administrative/ regulatory/scientific support as well as financial incentives both at national and EU level. **The industry** will benefit from regulatory clarity on strategic projects and enhanced visibility, possibly triggering additional private investment to match and complement potential public support for strategic projects. **Patients and health systems** are expected to benefit, via the identification and recognition of strategic projects, from targeted efforts and investments in areas of greatest need, ensuring prioritisation of critical medicines and their ingredients. This is expected to enhance manufacturing capacity and improve supply security in the medium to long term.
Fast-tracked permit-granting procedures	The implementation of these measures will be mainly for **public authorities** that are requested to prioritise the handling of permit requests by strategic projects and expedite permit-granting procedures, incl. procedures relating to dispute resolution.	**Industry** will benefit from accelerated procedures, reducing administrative burden, regulatory clarity and predictability, allowing implementation of strategic projects in a faster way. **Patients and health systems** are expected to benefit from faster implementation and expanded

		manufacturing capacity of critical medicines, leading to increased security of supply of critical medicines in the medium to long term.
Environmental assessments and authorisation	**Public authorities** will be requested to coordinate or perform joint environmental assessment within a strict timeline, upon request and to consider applying environmental flexibilities offered by EU legislation in specific cases. These measures rely on existing procedures that were introduced in other similar sectorial legislation, thereby limiting the adjustment costs for authorities to implement these measures.	**The industry** will benefit from accelerated procedures, harmonized and reduced administrative burden, regulatory clarity and predictability and faster implementation of strategic projects. Public support can possibly be faster if matched and complemented by private investments. **Patients and health systems** are expected to benefit from faster implementation and expanded manufacturing capacity of critical medicines, leading to increased security of supply of critical medicines in the medium to long term, without lowering the level of environmental protection.
Administrative, regulatory and scientific support	**Public authorities** will be requested to provide administrative, regulatory and scientific support upon request by a project promotor.	**Industry** will benefit from targeted support, reducing administrative burden and allowing timely implementation of strategic projects. An increase in predictability by scientific support will potentially trigger additional private investments by the industry, complementing public support. **Patients and health systems** are expected to benefit from faster implementation and expanded manufacturing capacity of critical medicines, including innovative manufacturing methods, leading to increased security of supply of critical medicines in the medium to long term.

Financial support by Member States	This requirement is expected to lead to a very limited increase in administrative costs for **public authorities** related to the obligation to inform the CMG about the intention to provide financial support to Strategic projects.	**Public authorities** will be able to prioritise financial support to strategic projects addressing a supply chain vulnerability. The allocation of funding available at national level will remain at the discretion of each Member State. Public authorities will be able to share their efforts and coordinate their approach in the CMG by supporting different strategic projects in a complementary way, leading to more cost-efficiency and avoiding redundancies. Member States will also be able to rely on additional guarantees to ensure the critical medicinal products remain available in the Member States where they are marketed. The publication of the Commission guidance on the application of State aid rules in the context of the Critical Medicines Act further creates clarity and legal certainty on the possible ways Member States may support strategic projects, benefiting both national authorities and **industry**. **Patients and health systems** are expected to benefit from increased manufacturing capacity of critical medicines and their ingredients, improving the security of supply, of critical medicines in the medium to long term. Where financial support has been granted, patients and health systems will benefit from additional guarantees to ensure the availability in the Member States where the critical medicine is marketed.
Financial support from the Union	The **Commission** may support strategic projects under the current MFF,	**Industry** may benefit from new funding opportunities under the current MFF, especially under the

	including via existing EU programmes such as EU4Health, Horizon Europe and Digital Europe Programme. The proposal appropriates around EUR 40 million in 2026 and 2027, to finance manufacturing investments and manufacturing capacity. These costs will be redeployed within the existing financial envelope of the EU4Health programme, without change in the total envelope. Financial support at EU level after 2027 will depend on the outcome of the political discussions on the next MFF.	EU4Health programme and facilitated access to other EU funding opportunities, including cohesion funds, when receiving the STEP Seal for Strategic projects addressing a supply chain vulnerability, untapping the full potential of the existing funding opportunities at EU level. The increase in public funding and the visibility offered through the STEP Seal are expected to trigger complementary private investments. **Patients and health systems** are expected to significantly benefit from more investments in strategic projects and, thereby, increased security of supply of critical medicines in the medium to long term.
Public procurement and related measures		
Obligation to apply procurement requirements other than price-only, promoting the resilience of supply in the Union	Requires **public authorities and procurers** to adapt their procurement practices. The **industry** will also need to adapt internal processes to meet this new requirement. The requirement may have an impact on pharmaceutical prices which will depend on a large number of factors, incl. the type of critical medicine, market situation, specific non-price criteria or requirements used by the procurer, their weight, etc... (see section 6.2, affordability of medicines)	Change in public procurement practices is expected to bring significant benefit to **patients and health systems**, by ensuring better security of supply and availability of critical medicines. A more resilient supply chain means less supply disruptions, hence lower costs of dealing with shortages and a more efficient use of resources. Patients will benefit from less interruptions of treatments, including less side effects and adverse effects. **Industry** will benefit from clearer criteria of procurements and incentives to promote resilience and may trigger investment decisions in EU supply chains.

Obligation to apply procurement requirements favouring suppliers producing a significant proportion of critical medicines in the EU in case of high dependency on a single or limited number of third countries	Specific public procurement procedures will have to be implemented for certain critical medicines for which a high dependency on third countries has been identified through a vulnerability evaluation. This will imply adjustment costs for both **public authorities**/ **procurers and the industry**. The requirement may have an impact on pharmaceutical prices which will depend on a large number of factors, incl. the type of critical medicine, market situation, the existing capacity in the EU, etc... (see section 6.2, affordability of medicines)	Change in public procurement practices is expected to bring significant benefit to **patients and health systems**, by ensuring better security of supply and availability of critical medicines. By reducing dependencies on third countries, health systems and patients are expected to be less prone to the risk of shortages, leading to lower costs of dealing with shortages and a more efficient use of resources. Patients will benefit from less interruptions of treatments, including less side effects and adverse effects. **Industry** will benefit from clearer criteria of procurements and incentives to promote resilience and may trigger investment decisions in EU supply chains.
Requirement to establish national programmes supporting security of supply of critical medicines	**Public authorities** will be requested to prepare national programmes supporting the security of supply of critical medicines in the context of public procurement. These national programmes might also cover pricing and reimbursement policies. This task will represent administrative effort for **public authorities** that will need to coordinate this work at national level, especially for the initial development of these programs. Administrative costs for the **industry** are expected only for the monitoring of policy developments at national level.	This measure will increase predictability for **the industry and procurers** given that national programmes will define the public procurement framework applicable at national level. The industry will benefit from clearer criteria of procurements to promote resilience and may trigger investment decisions in EU supply chains. Change in public procurement practices, incl. encouraging the use of multiple winner tenders and potentially introducing considerations on security of supply in pricing and reimbursement policies is expected to bring significant benefit to **patients and health systems**, by ensuring better security of supply and availability of critical medicines. A more resilient supply chain means less supply disruptions, hence lower costs of dealing with shortages

		and a more efficient use of resources. Patients will benefit from less interruptions of treatments, including less side effects and adverse effects.
Safeguards related to national contingency stock requirements and other security of supply measures	**Public authorities** are requested to avoid negative impact of national measures on security of supply, in particular contingency stock requirements, on other Member States. As a result, **public authorities** will have to consider and mitigate the impacts of their national measures on other EU countries.	This measure is expected to bring benefits to **industry** that are confronted with an increasing number of national requirements for contingency stocks. It should support proportionality in relation to the medicines concerned, size of requested stocks and timeline to build them. The industry should also benefit from additional predictability (principle of transparency) and flexibility in the reallocation of stocks between countries in cases of shortages (principle of solidarity). This measure is expected to bring significant benefit to **patients and health systems** as it will ensure that national measures do not create shortages in other countries, and it will reduce barriers to reallocate stocks if needed to address a critical shortage.
Collaborative procurement		
Commission facilitated Member States' cross-border procurement	The **Commission** support will require the necessary human resources.	**Public authorities** in the Member States will benefit from additional support by the Commission when they consider a cross-border procurement initiative, including administrative and legal support, decreasing administrative costs on them. **Patients and health systems**, especially those from small countries, are expected to benefit from increased access to and availability of medicines of

		common interest in the short to medium term. The requirement may support the affordability of the concerned medicines, depending on various factors such as the type of medicine subject to the collaborative procurement, the volumes and the market size. (see section 6.2 on affordability of medicines) The **industry** may benefit from lower transaction costs by dealing with fewer fragmented authorities, also products may be brought earlier to market.
Commission procurement on behalf of or in the name of Member States	The **Commission** support will require the necessary human resources.	**Public authorities** will be able to ask the Commission to perform procurement on behalf of or in the name of Member States, leveraging the aggregated demand and reducing substantially administrative costs on them. It should lead to economies of scale by replacing national procurement mechanism at national level. **Patients and health systems**, especially those from small countries, are expected to benefit from increased access to and availability of critical medicines and other medicines of common interest in the short to medium term. The requirement may support the affordability of the concerned medicines, depending on various factors such as the type of medicine subject to the collaborative procurement, the volumes and the market size. (see section 6.2 on affordability of medicines) **Industry** may benefit from lower transaction costs by dealing with

		fewer fragmented authorities, also products may be brought earlier to market.
Joint procurement	The **Commission** support will require the necessary human resources.	**Public authorities** will be able to ask the Commission to perform joint procurement, leveraging the aggregated demand and reducing substantially administrative costs on them. It will lead to economy of scale by replacing national procurement mechanism at national level. **Patients and healthcare systems,** especially of small countries, are expected to benefit from increased access to and availability of critical medicines and other medicines of common interest in the short to medium term. The requirement may support the affordability of the concerned medicines, depending on various factors such as the type of medicine subject to the collaborative procurement, the volumes and the market size. (see section 6.2 on affordability of medicines) **Industry** may benefit from lower transaction costs by dealing with fewer fragmented authorities, also products may be brought earlier to market.
International cooperation		
Requirement to explore possibilities of concluding strategic partnerships	The **Commission** will explore potential strategic partnerships with like-minded countries.	Diversification of supply through exploring strategic partnerships is expected to bring significant benefit to **patients and health systems**, by ensuring better security of supply and availability of critical medicines.

ANNEX 3 - COMPETITIVENESS CHECK

1. OVERVIEW OF IMPACTS ON COMPETITIVENESS

Dimensions of Competitiveness	Impact of the initiative (++ / + / 0 / - / -- / n.a.)	References to sub-sections of the main report or annexes
Cost and price competitiveness	+/++	Sections 6.2 and 6.4 of the SWD
International competitiveness	+/++	Section 6.2 of the SWD
Capacity to innovate	0/+	Section 6.2 of the SWD
SME competitiveness	0/+	Section 6.2 of the SWD

2. SYNTHETIC ASSESSMENT

The proposed Critical Medicines Act is expected to improve EU competitiveness by supporting the functioning of the Single Market, enhancing domestic production capabilities and reducing external dependencies, as well as by supporting innovation in new manufacturing processes.

Cost and price competitiveness

The CMA proposal is expected to have a positive impact on the competitiveness of pharmaceutical companies operating in the EU by encouraging investment in resilient and modern supply chains and scaling up production facilities in the EU. For undertakings developing a strategic project, it will facilitate the creation or expansion of manufacturing capacities of critical medicines, their active substances and key inputs in the EU by fast-tracking permit-granting procedures, streamlining environmental assessments and providing targeted support when needed, without leading to significant additional regulatory burden for businesses.

International competitiveness

The CMA proposal aims at strengthening supply chain resilience and reducing global dependencies by more actively supporting reshoring and investment in EU-based production capacity. The proposed measures, including financial support to strategic projects and public procurement requirements, are expected to support European manufacturers' ability to compete with suppliers located elsewhere.

Capacity to innovate

The proposed measures, in particular financial incentives as well as regulatory and scientific support to strategic projects, are expected to support innovation in new manufacturing processes with the objective to increase efficiency and support sustainable production.

SME competitiveness

Similar effects are expected for SMEs as compared to large companies for the different competitiveness dimensions. Nevertheless, specific measures of the proposed Regulation regarding administrative, regulatory and scientific support to pharmaceutical companies have a specific focus on Small and Medium-sizes Enterprises (SMEs).

3. COMPETITIVE POSITION OF THE MOST AFFECTED SECTORS

Producers of critical medicines, their active substances and key inputs as well as other actors of the pharmaceutical supply chain are expected to be the most concerned by the proposed measures which aim at increasing manufacturing capacity in the EU and fostering supply chain resilience and diversification.

In addition, the CMA proposal is expected to have a positive impact on the healthcare sector, including on healthcare providers such as pharmacists, by reducing the likelihood and impact of shortages and therefore the resulting costs.