SPECIAL REPORT 19/2025

EN

Critical shortages of medicines

EU measures were of added value, but structural problems remain

EUROPEAN COURT OF AUDITORS

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Main messages

Why this area is important

01 Medicine availability is vital for effective health systems and shortages have been a recurrent long-standing issue throughout the EU. Record levels of shortages were reported in 2023 and 2024. Shortages may become critical when no appropriate alternatives are available at national level and coordinated action at EU level is deemed necessary to manage the critical shortage. This situation has an obvious impact on patients and represents a significant economic cost to national health systems.

02 Member states are responsible for organising their national health systems and providing healthcare. Nevertheless, the EU's role is to support member states in this area and is responsible for ensuring that the single market for medicines functions well. Therefore, during recent years, the Commission and the European Medicines Agency (EMA) have taken action to support member states in ensuring medicine availability and addressing critical shortages.

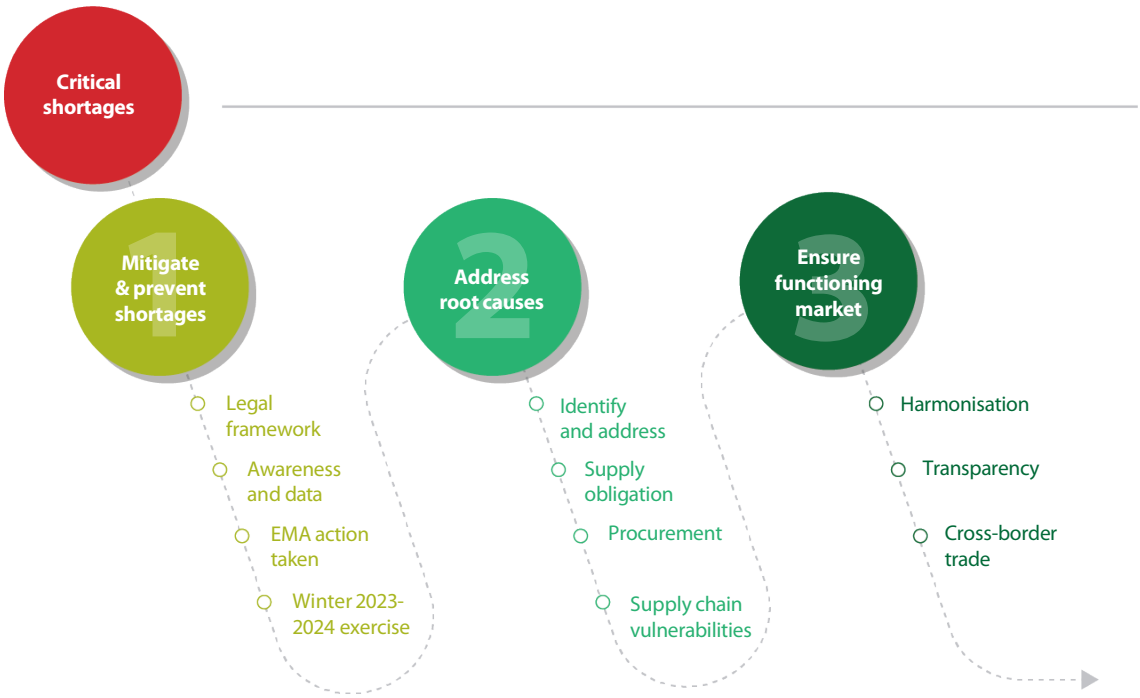
03 The objective of our audit was to assess whether EU measures to ensure medicine availability were effective. We examined (see ***Figure 1***) whether the Commission and EMA had:

(1) established and implemented an effective framework to prevent and mitigate critical shortages;

(2) identified and addressed the root causes of shortages;

(3) addressed market barriers to ensure a functioning single market for medicines.

Figure 1 | Main EU measures on critical shortages assessed in this report



Source: ECA.

04 We conducted this audit in light of the public health challenges caused by critical shortages of medicines and the on-going legislative work to address them. We anticipate that our findings and recommendations will provide useful input to improve the EU framework aimed at ensuring medicine availability and better address and prevent critical shortages.

05 We examined the work of the Commission and EMA until October 2024. We consulted many stakeholders, including organisations representing patients, doctors, pharmacists and the industry, as well as international organisations, and authorities in three member states and the US. Further information and details of the audit scope and approach are presented in ***Annex I***, which clarifies the distinction between "availability", "access" and "affordability". This report focuses mainly on "availability".

What we found and recommend

06 We conclude that there is not yet an effective framework for critical shortages of medicines. While EMA has provided valuable support to member states, and the Commission has taken initial steps by proposing legislative changes, efforts to tackle the underlying causes of these shortages remain at an early stage. In addition, fragmentation within the single market continues to hinder the availability of medicines across the EU.

The framework to deal with critical shortages

07 Monitoring medicine supplies in the EU is primarily a national competence, with EMA providing coordination. We found that EMA voluntarily supported member states dealing with critical shortages of medicines. Although co-legislators had been calling for a stronger EMA mandate for all medicine shortages since 2017, EMA only received a mandate in 2022 to support member states in preparing for and dealing with shortages during a health crisis. It was not until 2023 that the Commission proposed a mandate for EMA in respect of all critical shortages in the EU (see paragraphs ***24***-***28***).

08 EMA's awareness of shortages of medicines was hindered by incomplete, incomparable, and late notifications from industry. Other data that would be needed to support member states, such as on possible alternatives and availability, is not readily available to EMA other than in a health crisis. This limits EMA's ability to support member states in preventing and mitigating critical shortages. A European Shortages Monitoring Platform was set up in 2024 to improve the situation, but many functions still need to be added so that its potential can be fully utilised (see paragraphs ***29***-***41***).

09 Between 2022 and October 2024, 136 critical shortages were reported to EMA by EU National Competent Authorities (NCAs). We found that, overall, EMA's support for member states in mitigating critical shortages was of significant added value for them. However, its contribution to preventing shortages was focused on issuing guidance and its communication with the public lacked important information, leaving pharmacists, doctors, and patients with insufficient advice on alternative medicines in the event of shortages (see paragraphs ***42***-***48***).

10 The Commission's 2023 legislative proposals have the potential to significantly improve the framework for dealing with critical shortages. However, the proposals might not address all issues. For instance, they do not include a mechanism to ensure respect of the obligation to report shortages in good time or do not address the lack of legally binding tools for EMA and the Medicine Shortages Steering Group to influence industry action during a critical shortage (see paragraphs ***49***-***50***).

11 In autumn 2022, industry reported critical shortages of antibiotics across the EU. These shortages were not classified as a health crisis, but EMA and NCAs continued to deal with them. In addition, the Commission and EMA launched a joint exercise. We found that it succeeded in creating awareness at EU level about the need to ensure the availability of antibiotics. However, some of the measures subsequently proposed by the Commission were not implemented and neither the Commission nor EMA could demonstrate the effects of the measures taken. Despite increased awareness and the number of EEA

countries reporting critical shortages for 2 important antibiotics being about 50 % lower than during the previous winter, shortages persisted (see paragraphs *51*-*57*).

12 We conclude that while EMA's support for member states was of significant added value, the EU system to address critical shortages of medicines still lacks an adequate legal framework and relevant and timely information.

Recommendation 1

Further improve the system to address critical shortages

(a) The Commission should take action to ensure:

- timely reporting of shortages of centrally authorised medicines to EMA, and
- there are appropriate measures to resume continuous supply of medicines in the event of a critical shortage.

(b) The European Medicines Agency should operate a single medicines database and a single reporting platform, consolidating and ensuring interoperability of relevant existing and planned databases. These should include:

- all medicines authorised in the EU and their marketing status, per member state;
- information on the availability of medicines, including shortages;
- information on the classification of medicines as critical for the EU or certain member states, existing alternative medicines in the EU by therapeutic class, and identified supply chain vulnerabilities.

(c) The European Medicines Agency, together with member states, should improve its communication with the public by providing information on possible alternative medicines.

Target implementation date: (a) end of 2027, (b) and (c) end of 2028

Addressing root causes of shortages

13 We found that the Commission analysed and identified many root causes of shortages. However, this analysis did not examine in detail the critical issues identified, which reduced its usefulness for targeting effective mitigating measures (see paragraphs *60*-*62*).

14 The Commission launched measures to address root causes in three areas:

- industry obligation to ensure continuous supply;
- enhancing procurement;
- addressing supply chain vulnerabilities.

15 We found that industry's legal obligation to ensure continuous medicine supply did not work well in practice. This has been known since 2017 but the Commission's actions have not led to consistent application and enforcement of this obligation. Against this background and faced with shortages, member states started to impose unilateral national stockpiling requirements for industry, not coordinated with other member states. While stockpiles in a given member state can help minimise shortages and provide authorities with time to act, such stock may have spill-over effects and exacerbate shortages in other member states. Not all member states notified the Commission of these stockpiling measures and thus it could not limit spillovers (see paragraphs ***64***-***69***).

16 National medicine procurement is primarily price focused and does not reward resilient supply which could result from local manufacturing or diversification. Since local production was less competitive, the focus on price favoured production outsourcing to low-cost countries (e.g. in Asia) and concentration of manufacturers worldwide, leading to dependencies and vulnerabilities for medicines supply. The Commission coordinated useful meetings of National Competent Authorities on Pricing and Reimbursement and Public Healthcare Payers but has not yet issued its planned procurement guidance or organised voluntary joint procurement for critical medicines (see paragraphs ***70***-***73***).

17 Based on the Council's request in 2020, the Commission analysed supply chain vulnerabilities, but it was not until April 2023 that it proposed first measures to address them. The first EU-wide critical medicines list is an important step. But work so far has not yet ensured their availability as some medicines on the list were in critical shortage throughout the EU during this audit. Since 2021, in the absence of an EU industrial policy, some member states began "reshoring" production of critical medicines by implementing their own national measures. These efforts remained uncoordinated and might result in duplication of effort as well as a significant cost for taxpayers. In March 2025, the Commission proposed an industrial policy for medicines through a Critical Medicines Act aiming to improve the production and supply of critical medicines within the EU. Concrete EU measures to address existing supply chain vulnerabilities will depend on the adoption and implementation of the proposed legislation (see paragraphs ***74***-***81***).

18 We conclude that the Commission has recently started to address root causes. The unsatisfactory functioning of the legal obligation for industry to provide continuous supply has resulted in fragmented national action on stockpiling. As for the Commission's work on supply chain vulnerabilities and sustainable procurement processes, this is only just beginning.

Recommendation 2

Launch comprehensive coordinated action to address root causes of medicine shortages

The Commission should:

(a) take action to enhance consistent application and enforcement by member states of the industry obligation to provide continuous supply; and

(b) assess the need and feasibility of coordinating national stockpiling requirements.

Target implementation date: end of 2027

The single market for medicines

19 A well-functioning single market for medicines is a prerequisite for medicine availability. This requires a harmonised regulatory environment (on regulatory procedures, standards, and packages), a transparent market, and no internal barriers to trade (see paragraphs ***82-83***).

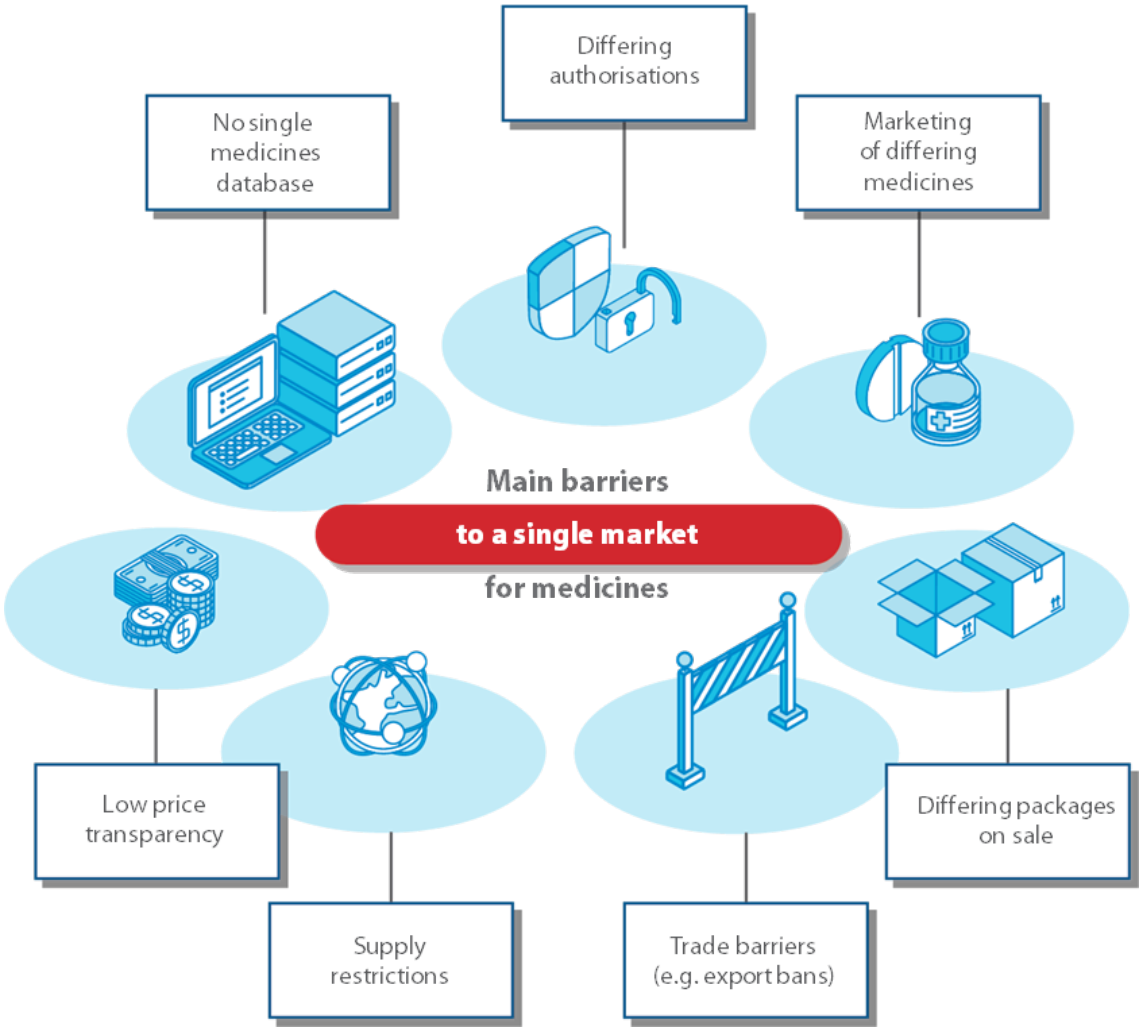
20 The main achievement in harmonising regulatory procedures was the creation of an EU path for medicines, which allows some medicines to be centrally authorised. However, most medicines are still authorised at national level and those authorised for the entire EU are not actually marketed in all member states, which contributes to unequal access to medicines and difficulties in trading them. Furthermore, while medicine safety and quality standards have been harmonised, inspections have not been used at EU level to prevent and address shortages. The Commission's proposal to extend EMA's role in inspections could significantly strengthen the framework. Lastly, medicine packages differ significantly across the EU, making the trading of medicines in the EU more costly and complex. The Commission has proposed some further harmonisation, but differing package sizes and national labelling requirements may persist (see paragraphs ***84-94***).

21 The 1988 Transparency Directive requires member states to ensure a certain level of transparency in relation to medicine prices and reimbursement decisions, as differing measures can hinder trade within the EU. The Commission found that the law is not applied appropriately by member states. Medicines prices differ significantly between member states and transparency is low, as prices are often confidential. A revision of the Transparency Directive was planned as far back as 1992, but a 2012 Commission proposal was not adopted. The Commission currently has no plans to revise the Directive citing insufficient support by member states (see paragraphs ***95***-***98***).

22 Member states have tried to limit shortages caused by parallel trade and supply quotas by erecting various barriers to trade. However, these measures can in turn create shortages in importing countries. Member states did not always notify the Commission of unilateral measures that might restrict trade, which reduced awareness of such measures at EU level. We found that the Commission has not sufficiently addressed shortages resulting from parallel trade, supply quotas, and erected trade barriers (see paragraphs ***99***-***102***).

23 We conclude that the Commission has partly harmonised regulatory procedures, but there are many shortcomings in the single market for medicines, notably the market fragmentation, including different packages, insufficient price transparency, and cross-border barriers to trade (see ***Figure 2***). In this context, EU citizens were faced with reduced availability of certain medicines, and it was difficult to mitigate shortages.

Figure 2 | Main barriers to a single market for medicines



Source: ECA.

Recommendation 3

Improve the functioning of the single market for medicines by addressing barriers

The Commission should:

(a) based on its stock-taking exercise, take action to ensure better application of the Transparency Directive by member states, e.g. through centralising information on pricing and reimbursement status and procedures, until proposing a revision of it;

(b) take action to enhance consistency of medicine packages within the EU, such as in relation to names, pack sizes and labelling requirements;

(c) assess the impact of supply quotas and parallel trade on shortages, and propose appropriate solutions;

(d) better identify barriers to trade erected by member states and seek to remove them.

Target implementation date: end of 2028

02

A closer look at our observations

There is not yet an effective framework for critical shortages

24 A shortage of medicines can become critical if there are no appropriate alternatives (see ***Annex I***, ***Figure 4***). As many critical shortages cannot be sufficiently mitigated by individual member states, cross-border mechanisms are needed to deal with them. The Commission, EMA and national competent authorities (NCAs) have recognised the important role of EU coordination to address critical shortages of medicines when they occur. In 2017, the European Parliament called on the Commission to enhance EMA's mandate in coordinating pan-European action on medicine shortages[1]. This was supported by the Council.

25 We assessed whether the Commission and EMA had:

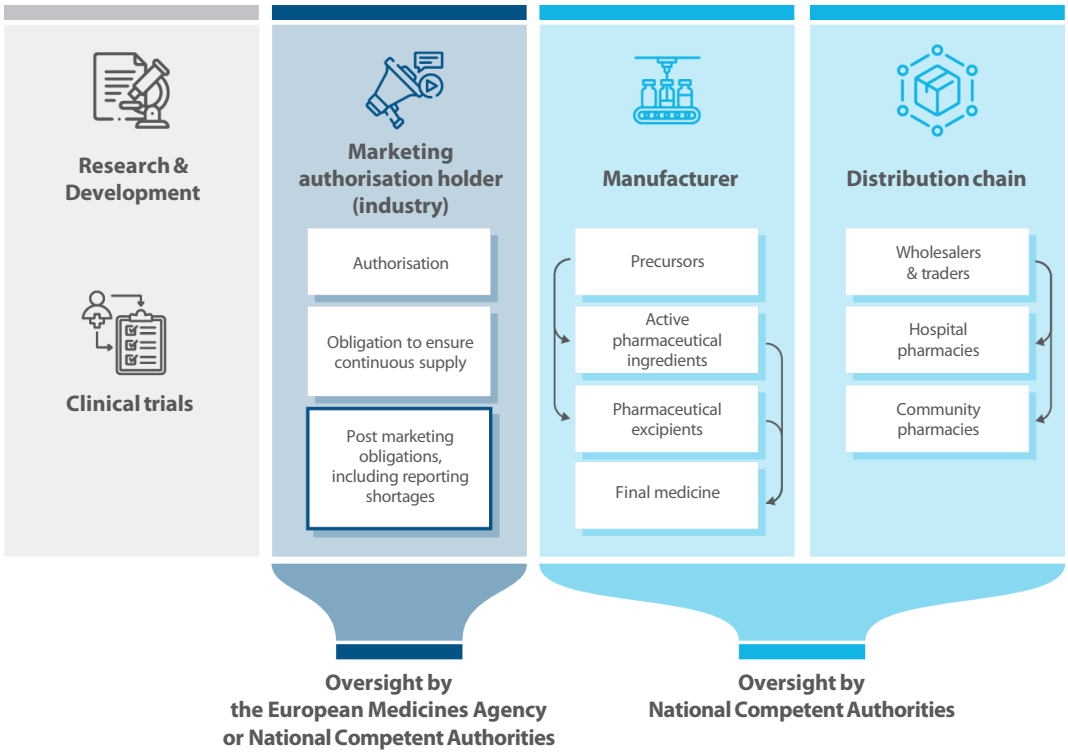
- created an effective system to prevent and mitigate critical shortages;
- sufficient information to prevent and mitigate critical shortages;
- supported member states in preventing and mitigating critical shortages;
- avoided critical shortages of antibiotics during winter 2023-2024.

[1] European Parliament resolution of 2 March 2017 on EU options for improving access to medicines (2016/2057(INI), paragraph 103.

The EU system to prevent and mitigate critical shortages of medicines still lacks an adequate legal framework

26 We reviewed the existing system for preventing and mitigating shortages in the EU. Within the overall system from development of medicines until their distribution (see ***Figure 3***), industry is supposed to report shortages at least 2 months in advance to regulators, i.e. EMA and NCAs. NCAs report shortages to EMA when they consider that they are critical and EU-level support is needed.

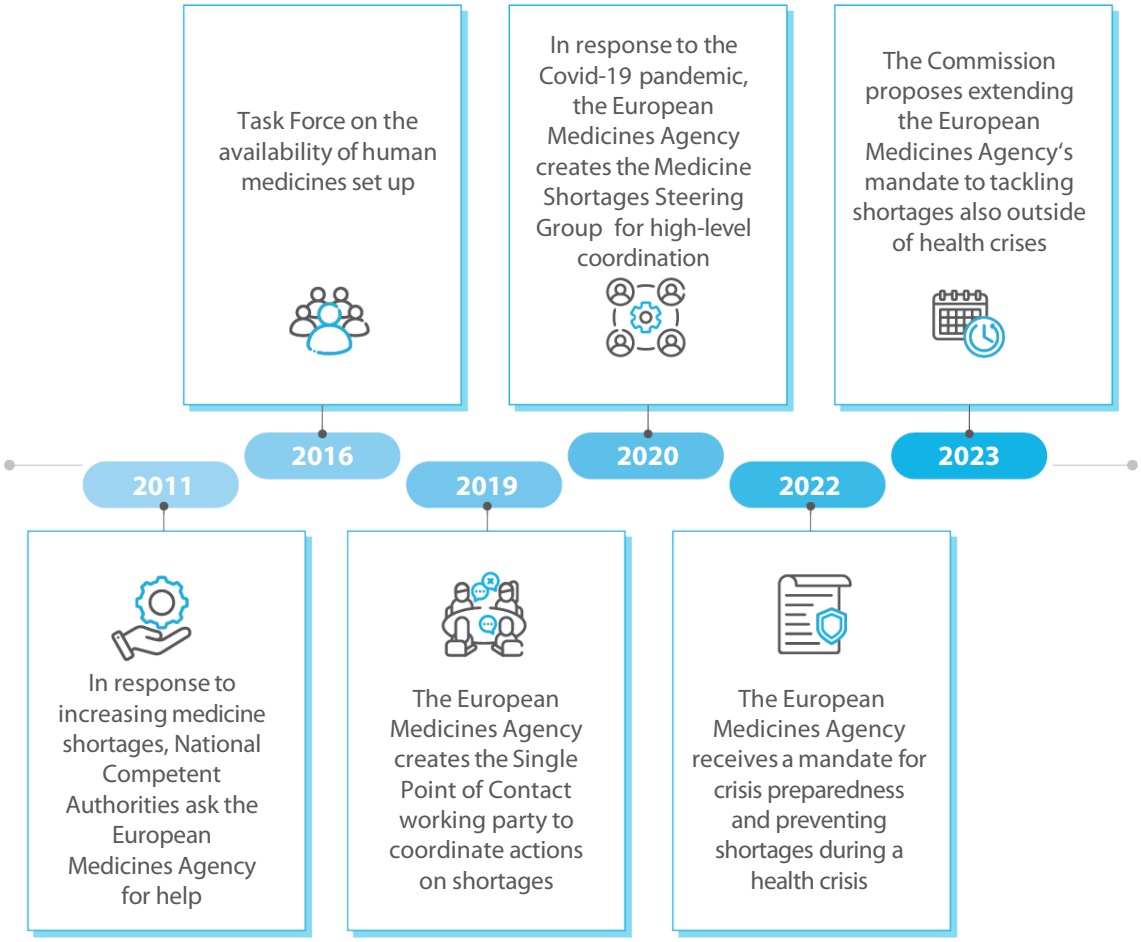
Figure 3 | Oversight system for medicines in the EU



Source: ECA.

27 Responding to member states' needs, EMA has supported them in dealing with critical shortages since 2011. EMA's role has increased significantly during recent years (see ***Figure 4***).

Figure 4 | Development of an EU oversight system for critical shortages



Source: ECA.

28 In 2022, EMA obtained a formal mandate to support member states in preparing for and dealing with shortages only during a health crisis defined in the legislation as a "major event" or "public health emergency"[2]. However, EMA does not have a mandate to support member states in dealing with critical shortages, unless focused on a potential health crisis. We found that the lack of an adequate legal framework created several challenges, as outlined in the following sections.

EMA lacks sufficient awareness of shortages and appropriate data

29 EMA needs timely, complete, and comparable information to be able to prevent critical shortages from occurring or support member states if they do happen at member state

[2] Articles 2(a) and (b) of Regulation (EU) 2022/123.

level. We assessed the information EMA received and compared it with what we considered would be needed to carry out such action.

Weaknesses in shortage notifications from industry limit EMA's awareness of the issue

30 EMA needs access to data on all shortages at member state level to support them in preventing critical shortages from occurring in the first place. Under Directive 2001/83/EC, the Commission expects industry to notify shortages at least 2 months in advance[3] to regulators, i.e. EMA for the 1 458[4] centrally authorised medicines and NCAs for all medicines. This reporting mechanism does not allow EMA to be aware of all shortages at member state level, as most medicines available in the EU are not centrally authorised. Furthermore, we found that the existing mechanism did not work well in practice.

31 First, some member states disagree with the Commission's interpretation of Directive 2001/83/EC that shortages need to be reported by industry. They consider the legal basis not to refer specifically to shortages. Consequently, 21 out of 31 NCAs reported in a 2022 survey that there was a national legal requirement to report shortages, aside from the requirement arising from the Directive.

32 Second, almost all member states, instead of using the EU definition of shortages (see ***Annex I***) for their notifications, apply national definitions, differing in particular on duration, as shown in ***Figure 5***. The EU definition is not specific about duration or location, such as whether the shortage is at wholesalers or pharmacies. The problem of diverging definitions has been recognised by the World Health Organisation (WHO)[5], industry[6] and NCAs[7] since 2016.

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[3] Paper on the obligation of continuous supply, European Commission, 2018.

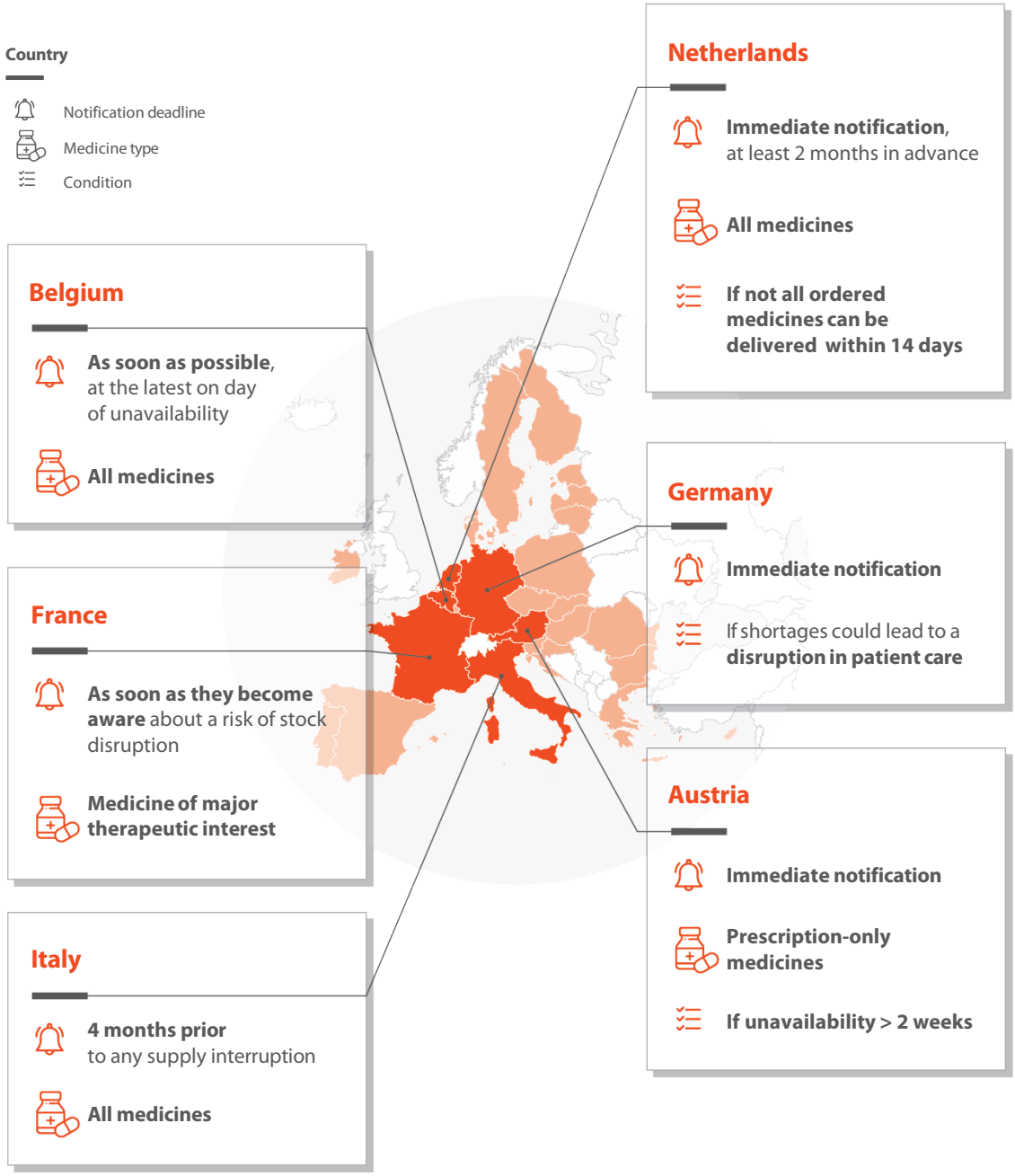
[4] Union Register of medicinal products, as of April 2025.

[5] World Health Assembly Resolution WHA69.25 on Addressing the global shortage of medicines and vaccines, 2016, p. 3, and Meeting Report: Technical Definitions of Shortages and Stockouts of Medicines and Vaccines, WHO, 2016.

[6] European Federation of Pharmaceutical Industries and Associations (EFPIA), *Medicine shortages: EFPIA proposals for action*, 2022, pp. 4-5, Pharmaceutical Group of the European Union (PGEU), *Position paper on medicine shortages*, 2024, p. 7, European Social Insurance Platform (ESIP), *Position Paper on Preventing and Managing Medicine Shortages*, 2020, p. 7.

[7] Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA), HMA/EMA, 2019, p. 1.

Figure 5 | Examples of industry obligations to notify shortages in different member states



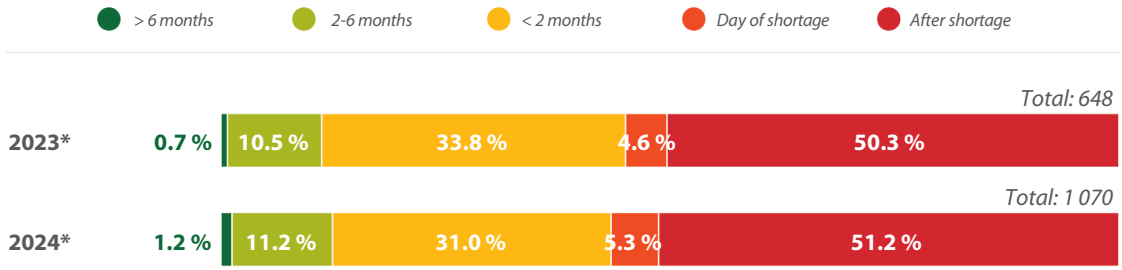
Source: ECA, based on CHESSMEN.

33 Third, based on national rules, industry has to report different information to each NCA concerned and use differing templates, as the Commission has noted[8].

[8] Future-proofing pharmaceutical legislation – Study on medicine shortages, European Commission: Directorate-General for Health and Food Safety, Ecorys BV, Milieu Law and Policy Consulting, Technopolis Group, Jongh, T. d. et al., 2021, p. 4.

34 Fourth, most shortages were not notified 2 months before they occurred, but only on or after the start date. For notifications to EMA, this was the case for 55.9 % of shortage notifications (see ***Figure 6***). Furthermore, according to EMA, there were shortages which were not notified at all.

Figure 6 | Timeliness of shortage notifications to EMA in 2023 and 2024



Source: ECA based on rounded EMA data for centrally authorised medicines, from May 2023 until end of October 2024.

35 Lastly, there are no mechanisms (e.g. sanctions system) with which the Commission or EMA could promote or ensure industry compliance with reporting requirements. As for industry's reporting to their NCAs, member states could, in their national rules, provide for sanctions for failure to notify. However not all member states used this option (18 out of 30 European Economic Area (EEA) countries did so) and only 8 applied them. This was confirmed by a broader study in 2024[9].

36 As a result, EMA does not receive timely, complete, and comparable information about shortages. This hinders its awareness of shortages and its ability to support member states in preventing critical shortages in good time.

EMA struggles to obtain the data needed to mitigate critical shortages

37 EU law requires industry and NCAs to provide EMA with data on possible alternative medicines and availability (stock, demand, supply, or manufacturing capacities data) during a declared health crisis. [10] We found that EMA faced challenges obtaining this data (see ***Box 1***).

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[9] Sabine Vogler, *Tackling medicine shortages during and after the COVID-19 pandemic: Compilation of governmental policy measures and developments in 38 countries*, Health Policy Volume 143, 2024.

[10] Article 10(6) of Regulation (EU) 2022/123.

Box 1

Challenges in obtaining data during a health crisis

After EMA's extended mandate had entered into force during the COVID-19 pandemic, industry was obliged to provide EMA with information on critical medicines authorised centrally and nationally to prevent and treat COVID-19. While industry had provided information for most centrally authorised products by March 2023, half of the industry for nationally authorised dexamethasone medicines (36 out of 74 companies) did not provide data. Furthermore, many companies provided incomplete information.

Source: ECA based on EMA Update on Medicine Shortages Activities to the Industry Standing Group meeting, 21 March 2023.

38 We note that such data would help EMA support member states facing a critical shortage also outside a health crisis. However, EMA does not have a mandate to request this information and it is not readily available. EMA tried to collect as much data as possible from NCAs and industry on a voluntary basis using many surveys for each critical shortage but faced challenges in obtaining all the necessary data in this way. EMA started to build a central database for medicines which is supposed to include all authorised medicines and their marketing status, but not information on alternatives or availability.

39 Against this backdrop, we note that:

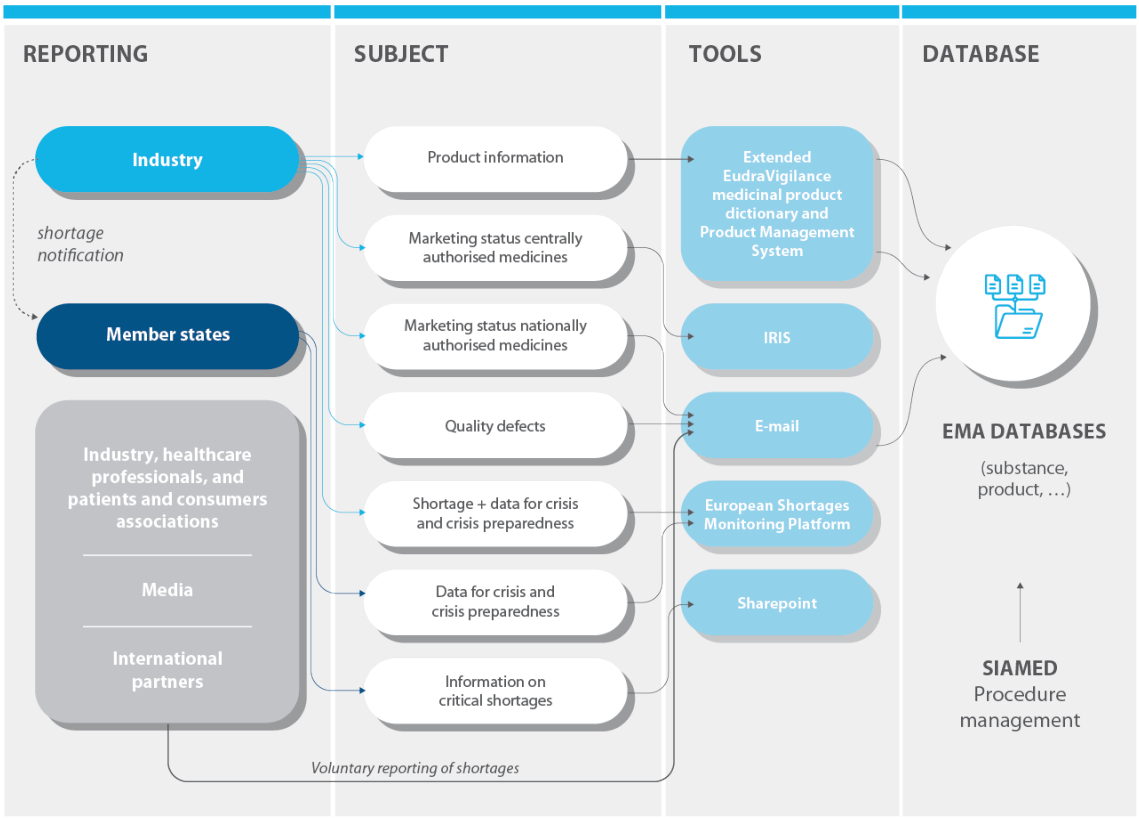
— without data on potential alternatives, EMA could not always effectively support member states experiencing critical shortages;

— without data on stock, supply and demand, and manufacturing capacity, EMA had insufficient information about availability. Thus, it could not always estimate the shortfall in supply nor target mitigating action, such as supporting the redistribution of alternatives from other member states.

New European Shortages Monitoring Platform

40 Since November 2024, EMA has been hosting the European Shortages Monitoring Platform. The platform is based on EMA's extended mandate from 2022 (see paragraph ***28***) and is meant to act as a harmonised reporting portal for shortages in preparation for and during a health crisis (see ***Figure 7***).

Figure 7 | EMA IT systems and information flow with the European Shortages Monitoring Platform



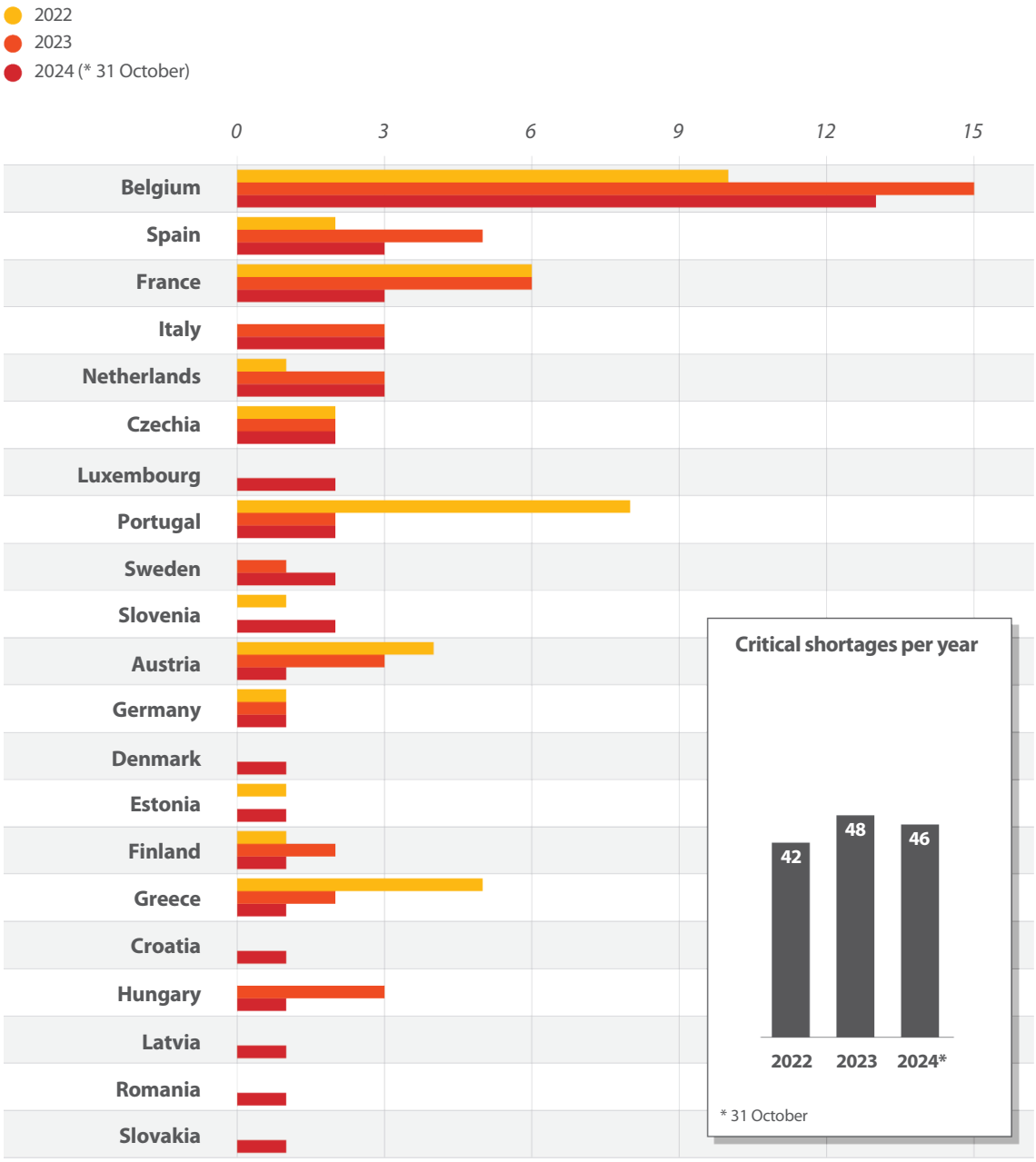
Source: ECA mapping of EMA IT tools.

41 We assessed the design of the platform and note that it has the capacity to significantly facilitate reporting and data analysis. As of early 2025, the platform is functional, but many functions, such as machine-to-machine communication, still need to be added so that its potential can be fully utilised.

EMA's support for member states was of significant added value for them but faced challenges

42 Between 2022 and October 2024, EU NCAs reported 136 critical shortages to EMA (see ***Figure 8***). We assessed EMA's work in supporting members states to prevent and mitigate critical shortages. Most of this work was done through the Medicine Shortages Steering Group (MSSG) and the Single Point of Contact (SPOC) working party, which are (co-)chaired by EMA and include NCAs as well as the Commission.

Figure 8 | Critical shortages reported by EU NCAs, 2022-2024



Note: Data for 2024 is up to 31 October 2024, excluding critical shortages reported by non-EU member states or identified by EMA. Member states not mentioned did not report critical shortages.

Source: ECA based on EMA data.

43 EMA supported member states in preventing critical shortages. However, this work was focused on issuing guidance, for instance recommending the use of shortage prevention plans, and crisis preparedness.

44 EMA also supported member states in mitigating critical shortages through exchanging information, coordinating action and communication. First, EMA facilitated the exchange of information on critical shortages. One of the main ways for NCAs to mitigate critical shortages was to identify available stock or existing alternative medicines in other member states or outside the EEA and then import those medicines. As there is no central database including all medicines at EU level (see paragraph ***38***), NCAs relied on information-sharing through surveys in the SPOC. However, this was voluntary and not all NCAs replied to SPOC surveys. Despite these limitations and the significant workload involved, NCAs considered EMA's work very useful (see ***Annex III***).

45 Second, EMA coordinated action to address critical shortages. For instance, it interacted with industry to increase manufacturing and support necessary regulatory procedures during a critical shortage of thrombolytics. EMA also intervened to ensure equal treatment of member states, for example, during a critical shortage of verteporfin. We note that EMA and the MSSG did not have the tools to impose or influence industry action to address supply chain vulnerabilities (see ***Box 2***).

Box 2

Examples of critical shortages, EMA's action and challenges faced

Critical shortage of thrombolytics (early 2022 until mid-2024)

Thrombolytics are very important for treating patients at risk of a heart attack or stroke, or after such an event. EMA intervened to increase supply. However, production was concentrated at a single manufacturing site. Thus, only the subsequent setting up of an additional manufacturing site eased the supply shortages, which took time.

Critical shortage of verteporfin (see ***Annex I***, ***Box 1***)

Industry did not supply Denmark, as it had been supplied indirectly by parallel traders. EMA intervened and brought the problem to the Medicine Shortages Steering Group. EMA organised a joint hearing of the industry but despite a commitment to provide some supply to Denmark, this was not always fulfilled in good time.

Source: ECA based on EMA information for alteplase, tenecteplase and verteporfin.

46 Third, EMA published information on critical shortages for healthcare professionals (e.g. doctors, pharmacists) and patients via its online shortage catalogue and in direct healthcare professional communications (e.g. information letters). The aim was to enable healthcare professionals to take mitigation measures (e.g. prescribe an alternative treatment) and reduce costs and frustration[11].

47 EMA's shortage catalogue is limited to the most critical shortages. Important information on existing shortages is spread over various national databases of differing quality. Not all member states have such a database. In addition, EMA's catalogue and its communications for healthcare professionals do not contain essential information on alternative medicines and their availability (see paragraph ***39***). Pharmacists and doctors thus have to use significant resources tracking stock, identifying alternatives and making decisions about rationing scarce supplies[12].

48 Overall, EMA's support for member states in mitigating critical shortages was of significant added value for them. However, its contribution to preventing shortages was focused on guidance and its communication with the public lacked important information.

The proposed legal changes could significantly improve the framework but might not address all issues

49 In April 2023, the Commission proposed changes to EMA's legal framework. Among other things, these proposals included:

(1) a legal mandate for EMA to prevent and mitigate critical shortages in cooperation with member states;

(2) extending the European Shortages Monitoring Platform beyond health crises (see paragraph ***40***) and detailed EU-wide reporting requirements for shortages;

(3) mandatory shortage prevention plans to be drawn up by industry, which may help EMA with prevention work.

50 We note that, if the legislation is adopted as proposed by the Commission, EMA may still lack information about all shortages at member state level. The proposals do not include a mechanism to ensure respect of the obligation for industry to report shortages related to

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[11] Standing Committee of European Doctors (CPME), *CPME Policy on Medicine Shortages*, 2020, p. 6.

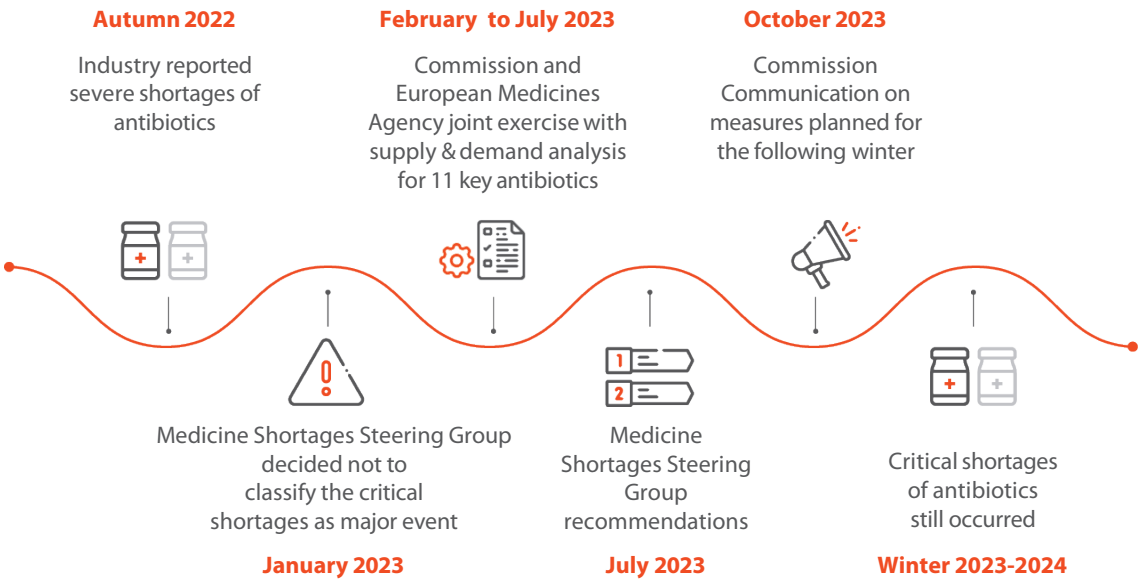
[12] PGEU, *PGEU Medicine Shortages Report 2023*, 2024, pp. 2 and 14.

centrally authorised medicines to EMA in good time, meaning that there is still a risk of late or non-reporting. We also note that the proposals do not address the lack of legally binding tools for EMA and the MSSG to influence industry action during a critical shortage.

Some measures to avoid critical shortages of antibiotics during winter 2023-2024 were not implemented and their success could not be demonstrated

51 In autumn 2022, around 50 industry participants reported shortages of the important antibiotic amoxicillin to NCAs. EMA therefore started monitoring shortages of antibiotics via the SPOC. This revealed that 28 EEA countries were experiencing shortages of antibiotics and 14 of them considered the shortages critical. These were due to many factors, including increased demand, manufacturing delays, production capacity issues and rising energy costs. ***Figure 9*** shows the timeline of events that followed. Using documentation from the Commission's and EMA we examined how they dealt with this situation.

Figure 9 | Key events related to winter 2023-2024



Source: ECA.

52 Due to the systemic nature of critical shortages of some antibiotics throughout the EU, some stakeholders asked EMA and the MSSG in January 2023 to declare a "health crisis". This would have allowed EMA to use the tools under its extended mandate[13]. The MSSG decided not to recommend to the Commission to declare a health crisis[14].

53 EMA and NCAs thus continued to manage on-going shortages with their "usual" tools (see paragraphs ***42*** to ***48***). In addition, the Commission and EMA decided, in February 2023, to work jointly on analysing the availability of 11 antibiotics that were in shortage in recent years, to identify shortfalls and target measures that would ensure sufficient supply.

54 EMA could not draw reliable conclusions about expected availability for three out of the eleven antibiotics. As there was no "health crisis" (see paragraph ***52***), there was no legal basis for collecting supply and demand data from industry and member states and EMA and the Commission faced challenges in obtaining this data on a voluntary basis. However, the joint exercise created awareness about the need to ensure the availability of antibiotics and allowed industry to increase production where possible. Most member states thought that the exercise helped to some or a limited extent to minimise shortages of antibiotics (see ***Annex III***).

55 In October 2023, to target possible shortfalls, the Commission published a Communication on addressing medicine shortages in the EU outlining, amongst other things, planned EU measures to avoid critical shortages of key antibiotics during winter 2023-2024, including the actions already recommended by the MSSG in July 2023. We assessed the measures planned and found that those implemented did raise awareness. However, some of the proposed measures were either not implemented by the Commission at all, or not until after winter 2023-2024 (see ***Table 1***).

[13] Article 2(b) of Regulation (EU) 2022/123.

[14] Minutes – MSSG meeting of 26 January 2023, p. 2.

Table 1 | EU measures planned for winter 2023-2024

Measure	Implemented	by	Our assessment
Continuous monitoring of supply and demand forecasts	Yes	EMA	Continuous reporting and monitoring by NCAs, industry and stakeholders in place until spring 2024. This raised awareness at all levels.
Interaction with industry to prevent shortages and increase manufacturing	Yes	Commission EMA	Using outcomes of their joint exercise, EMA and the Commission contacted industry in summer 2023 to discuss potential measures, such as how to increase production capacity of antibiotics at risk of shortage. Additional work in autumn 2023 resulted in identification of (limited) additional amounts of certain antibiotics for the EU, which were delivered to member states in critical need based on bilateral agreements.
Voluntary solidarity mechanism	Yes	EMA	A voluntary solidarity mechanism was set up in October 2023 but was not deployed for antibiotics during winter 2023-2024, as no member state asked EMA to launch the mechanism. It was used for the first time in March 2024 for another medicine.
Intensified exchange of information with international regulators	No	Commission EMA	While international exchange of information took place, we did not find an increase in activity compared to the previous winter. The information exchange showed that due to the global nature of these shortages, additional antibiotics could not be sourced from abroad.
Targeted joint procurement	No	Commission	The Commission planned joint procurement but was not ready for winter 2023-2024. The result of its first such procurement of RSV-vaccines may be available for winter 2025-2026.
Exchanging antibiotics with countries in the Southern Hemisphere	No	Commission	While meetings with some countries (e.g. Australia) took place, no antibiotics were exchanged.
Information to the public	Yes	Commission EMA	Further to the Commission Communication from October 2023, EMA launched a social media campaign on preventing antibiotic shortages in November 2023, and this raised awareness of the issue.

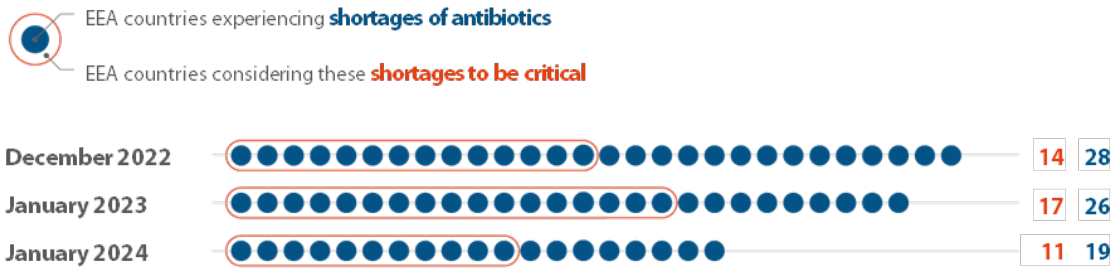
Measure	Implemented	by	Our assessment
Deploying the available rescEU stockpile of antibiotics	Yes	Commission	No member state triggered the EU Civil Protection Mechanism to request antibiotics from the rescEU stockpile, which has been funded by the EU and is still being built up. In any case, the amounts of medicines in these stockpiles were very limited, as the stockpiles were mainly intended for natural disasters or pandemics and would therefore not be sufficient to address a critical shortage of medicines.

Source: ECA assessment based on Commission and EMA data.

56 Furthermore, neither the Commission nor EMA assessed the effects of the measures taken. They could therefore not demonstrate the link between the reduction of critical shortages and the specific EU measures that were implemented.

57 The objective of avoiding critical shortages of antibiotics in winter 2023-2024 was not achieved as shortages persisted. EMA asked EEA countries to report on critical shortages at three points in time, albeit with differing focus. In 2022, 14 EEA countries reported critical shortages when asked about all antibiotics. In 2023, 17 EEA countries reported critical shortages when asked about 2 specific antibiotics. In 2024, 11 EEA countries reported critical shortages when asked about 11 antibiotics (see ***Figure 10***). For 2 antibiotics (amoxicillin and amoxicillin with clavulanic acid), which were covered by all three surveys, the number of EEA countries reporting critical shortages was about 50 % lower in 2024 compared to the previous winter.

Figure 10 | Winter antibiotic shortages reported in the EEA, 2022-2024



Source: ECA, based on data from EMA.

The Commission analysed root causes of shortages but its work to address them faces many challenges

58 Addressing the root causes is key to reducing the frequency of shortages[15]. In 2017, the European Parliament had called upon the Commission to take this action.

59 Therefore, we expected the Commission to:

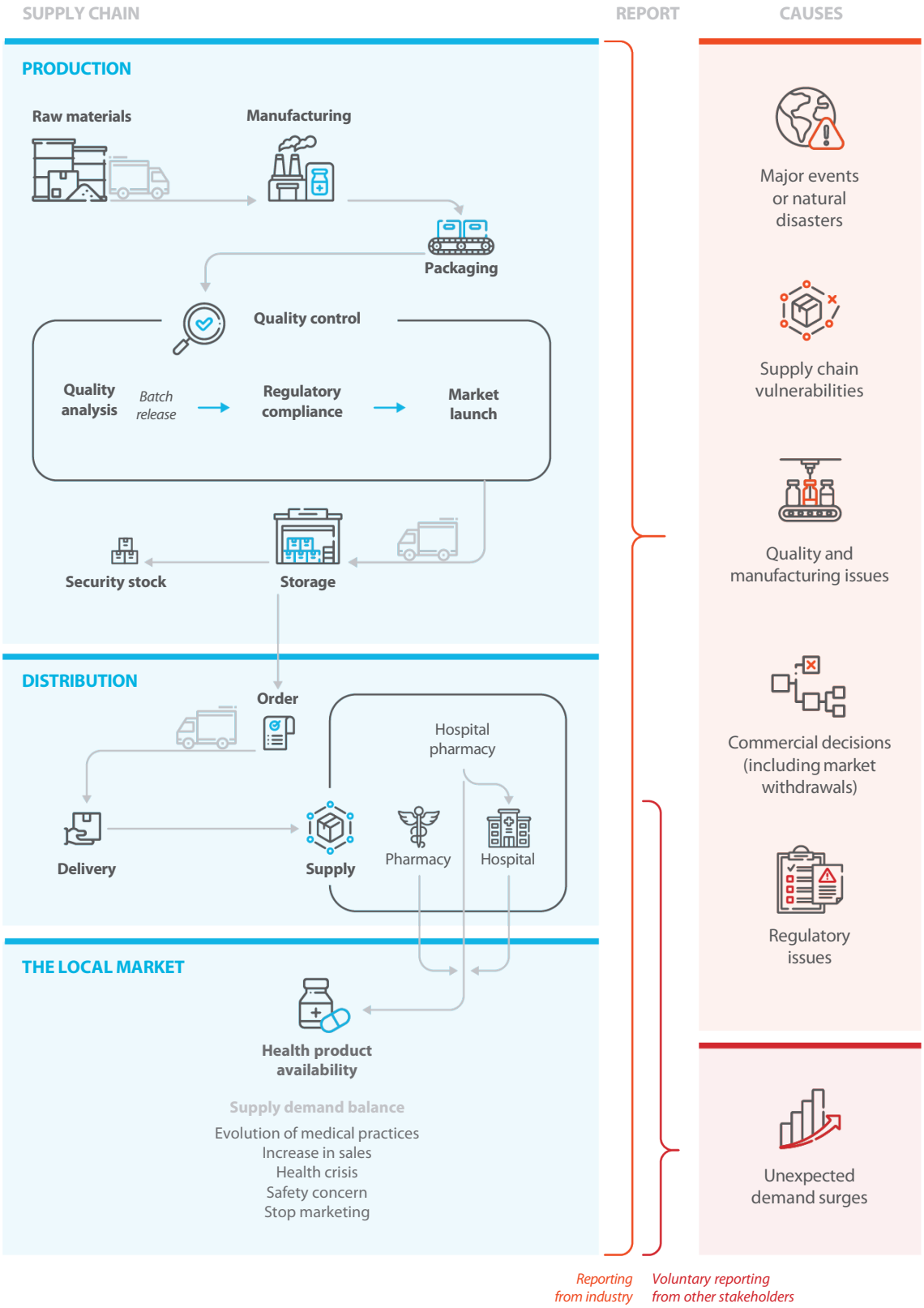
- identify the root causes of medicine shortages;
- address key root causes effectively.

The Commission identified many root causes

60 We assessed the Commission's analysis of shortages and their root causes across the EU. We found that the Commission conducted or requested a lot of assessments and identified many root causes (see ***Figure 11***).

[15] OECD, *Securing Medical Supply Chains in a Post-Pandemic World*, 2024, p. 58.

Figure 11 | Root causes for shortages identified by the Commission



Source: ECA based on Commission and EMA studies.

61 The Commission's analysis focused primarily on external dependencies, geopolitical risks, and fragmented supply chains[16]. It emphasised the EU's strategic vulnerabilities. EMA[17] and industry[18] emphasised operational shortcomings such as insufficient inventory management, lack of early warning systems, and weak stakeholder collaboration, as well as economic factors, such as pricing and reimbursement of medicines, parallel trade and supply quotas. EMA also considered higher but fluctuating demand in recent years – due to global economic and population growth (including aging) – as one of the root causes of shortages that is expected to continue. NCAs analysed 83 266 shortage notifications and found that manufacturing issues represented half of all root causes (see ***Annex II***).

62 The Commission's analysis was constrained by the fact that available data on root causes was aggregated and lacked detail. The analysis also did not examine in detail the critical issues identified, such as supply chain vulnerabilities and production constraints. This reduced the analysis usefulness for targeting effective mitigating measures. In 2024, the Commission started additional analysis, which was discussed in a new forum, the Critical Medicines Alliance.

The work to address root causes is only starting and faces many challenges

63 We assessed the Commission's main measures to address root causes of medicine shortages, which it implemented through various forums (see ***Figure 12***). We grouped these measures into three areas, as per the Commission's 2020 Pharmaceutical Strategy:

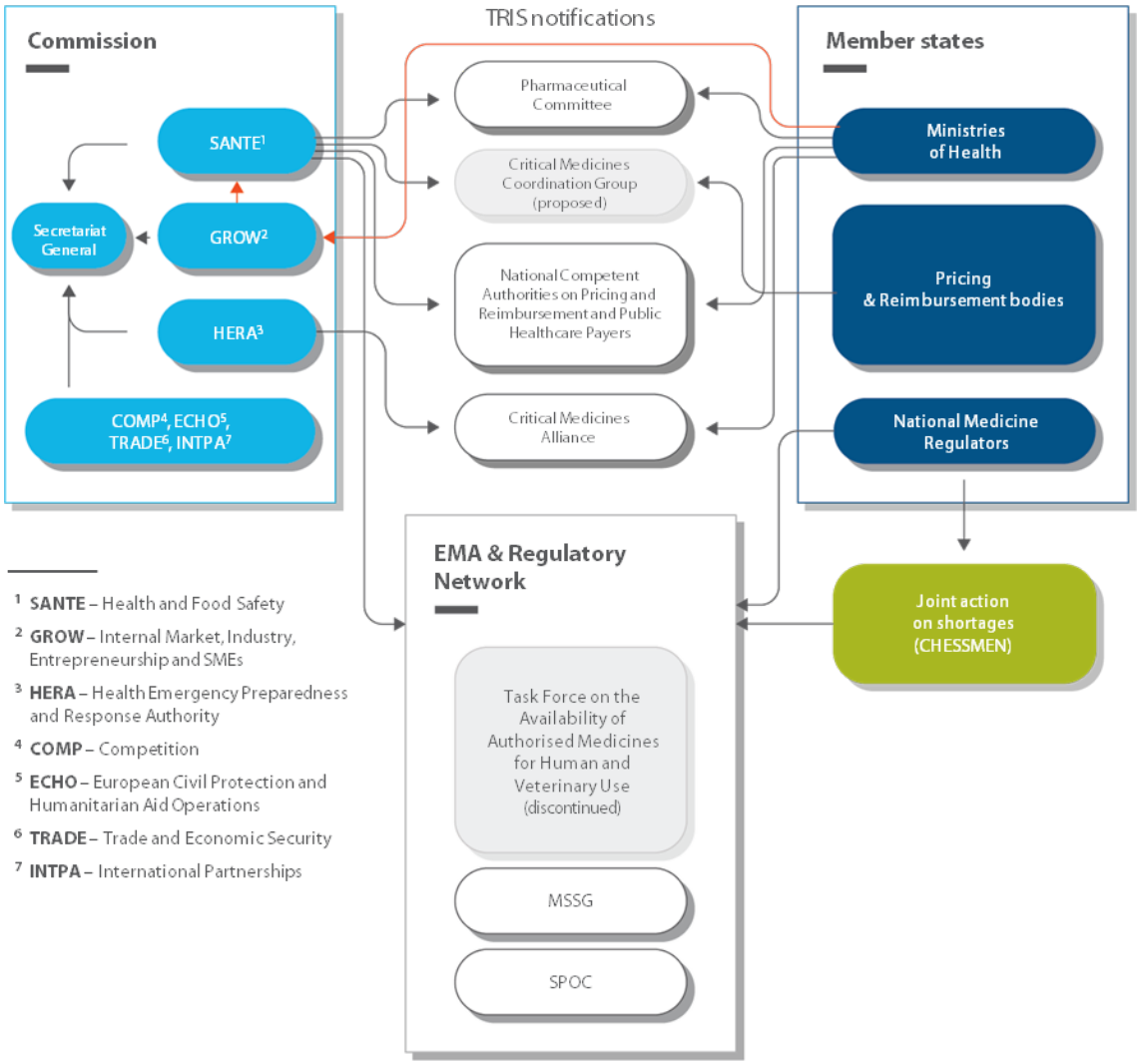
- using industry obligations to provide continuous supply;
- enhancing procurement to achieve security of supply;
- analysing and addressing vulnerabilities in the supply chain of critical medicines.

[16] SWD(2023) 192, p. 23.

[17] Developing a proactive approach to the prevention of medicines shortages due to manufacturing and quality problems, EMA, 2015, and Good practice guidance for patient and healthcare professional organisations on the prevention of shortages of medicines for human use, HMA/EMA, 2022.

[18] Supply chain Stakeholders' views on root causes and solutions, 2019.

Figure 12 | Forums used by the Commission to address root causes



Source: ECA.

The legal supply obligation for medicines does not work well in practice, so member states began introducing stockpiling measures

64 Industry has a legal obligation to "ensure appropriate and continued supplies" of medicines to meet patient needs[19]. The European Parliament had already noted in 2017 that this obligation was not always applied and called on the Commission to monitor compliance[20]. In 2018, the Commission published a paper on the supply obligation

[19] Article 81 of Directive 2001/83/EC.

[20] European Parliament resolution of 2 March 2017 on EU options for improving access to medicines (2016/2057(INI)).

outlining expectations but noted in 2020 that it was necessary "to significantly reinforce the obligation"[21].

65 We note that the supply obligation for industry still does not work well in practice. It is implemented inconsistently across member states, requiring differing measures from industry, and enforcement is rare. In our survey, 23 NCAs reported that this obligation did not work well in practice (see ***Annex III***).

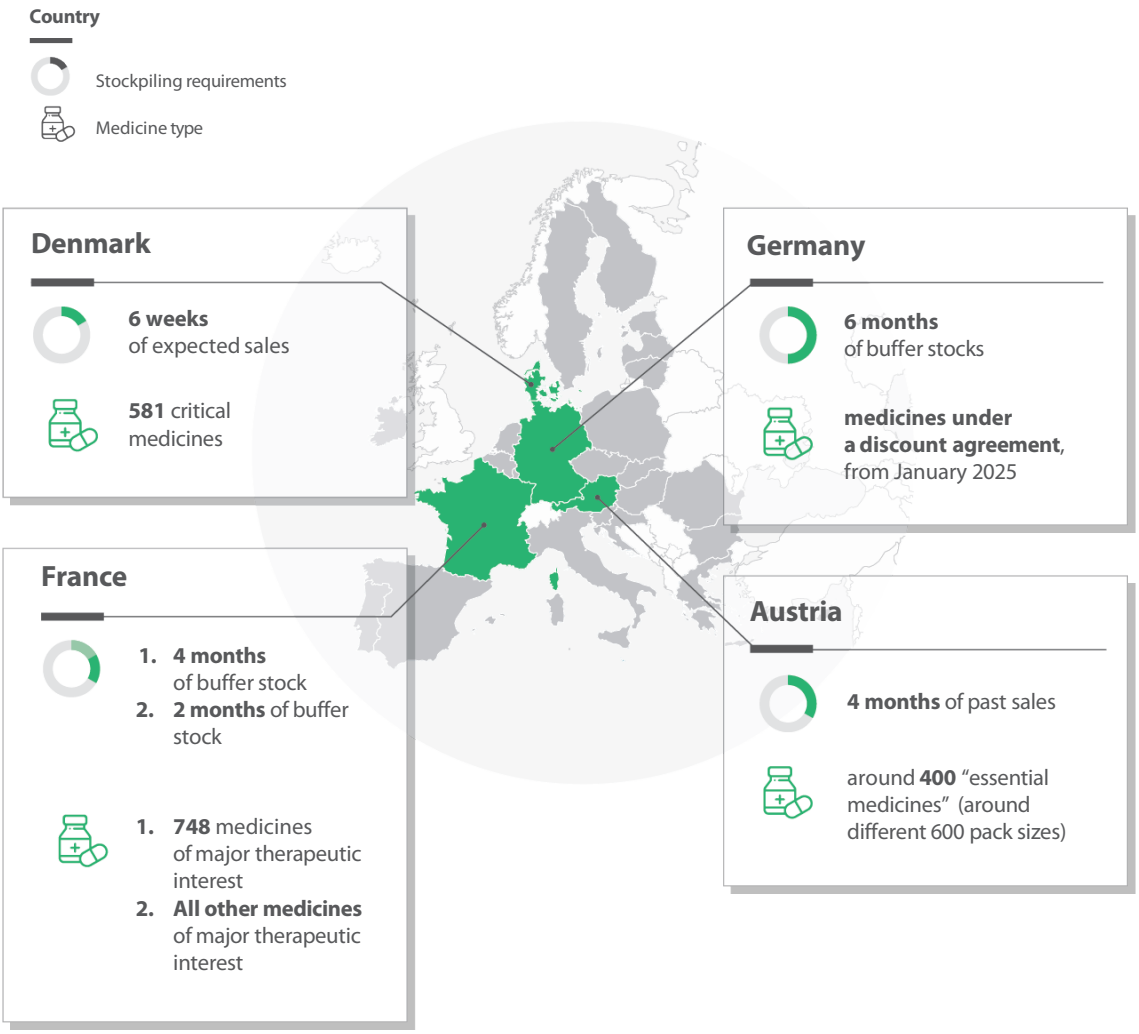
66 Without a properly functioning industry supply obligation and faced with rising shortages, many member states started to introduce unilateral national stockpiling measures, (see ***Figure 13*** and ***Annex III***) which were not coordinated with other member states. These included national stockpiles, contingency stocks to be held by industry and buffer stocks held in the distribution chain.

67 Such stockpiles can help to minimise shortages in a given member state and provide authorities with time to act. However, they may have spill-over effects and create or exacerbate shortages in other member states – in particular in the smaller ones[22] – as manufacturers might have to choose where to prioritise their limited capacity. This is especially true when stockpiles are built up for large amounts of medicines and within a short time. Furthermore, the Commission study on medicine shortages noted that stockpiled medicines cannot easily be redistributed within the EU due to country-specific packages and labelling requirements.

[21] Pharmaceutical Strategy for Europe, COM(2020) 761, p. 17.

[22] Medicines for Europe, *Medicine shortages and national stockpiling requirements in the EU*, 2024, p. 2.

Figure 13 | Differing stockpiling measures for medicines, end 2024



Source: ECA based on national legislation.

68 Member states have to notify the Commission through the Technical Regulation Information System (TRIS) about specific measures[23] that could affect the single market, such as stockpiling requirements. Some member states did so (e.g. Denmark and Austria) and the Commission managed to adjust the national stockpiling requirements and limit spill-over risks. For instance, the Commission asked Denmark to reduce its stockpiling list of medicines considered critical for patient care from 924 to 400-600, and extend the build-up period from 3 to 6 months. However, not all member states notified the Commission about new stockpiling obligations.

69 Some member states raised the issue of certain uncoordinated unilateral stockpiling requirements in the Employment, Social Policy, Health and Consumer Affairs Council, in June 2024. The proposed Critical Medicines Act would require member states to uphold

[23] Article 1 of Directive (EU) 2015/1535.

some general principles. However, it is not yet clear how this would overcome the coordination challenges, create synergies and avoid negative spillover effects.

Security of supply is not yet sufficiently considered in procurement procedures, but the Commission has started to push for change

70 When member states purchase medicines through public procurement, they have to apply EU procurement rules set out in Directive 2014/24/EU. The Directive and the Commission recommend using other criteria than just price and considering factors such as environmental impact of production or resilient supply, e.g. through production in the EU, geographical diversification of supply and reliability of the supply chain. A US report indicated that a lack of reward for reliable supply and mature quality management practices was a root cause of medicine shortages in that country[24].

71 We reviewed Commission documentation, such as a study from 2022, which noted that most contracts were awarded using price as the sole criterion. This was confirmed by our special report on public procurement[25]. Low level of reward for resilience in national procurement procedures has increased price pressure. At the same time, production costs in the EU are higher in comparison to Asia (where production costs are estimated to be 20-40 % lower[26]). This has contributed to significant outsourcing of production to Asia and concentration of manufacturers across the world to create economies of scale[27]. Both factors have resulted in lower costs for medicines but created dependencies and vulnerabilities for medicine supply.

72 The Commission stated in its October 2023 Communication that it intended to publish procurement guidance for medicines in early 2024 to ensure security of supply. By June 2025, no guidance had been published. However, the Commission coordinated useful meetings of the group of National Competent Authorities on Pricing and Reimbursement and Public Healthcare Payers.

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[24] U.S Department of Health and Human Services: White Paper on Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States, January 2024.

[25] Special report 28/2023, paragraphs 39-40.

[26] Medicines for Europe and European Fine Chemicals Group (EFCG), *The EU must stop the offshoring of essential medicines manufacturing investments: ambitious, open and coherent policies must support competitive, robust and sustainable production of APIs and medicines*, 2021.

[27] Potential measures to facilitate the production of active pharmaceutical ingredients (APIs), European Parliamentary Research Service, 2023, p. 9.

73 In 2020, the Commission highlighted that it considered joint procurement by member states as another powerful tool to ensure security of supply and intended to support member states in such procurement[28]. It also said that this could increase volumes and negotiating power, resulting in more competitive markets and disincentivising excessive supply chain consolidation. In its 2023 Communication, the Commission stated that it intended to organise joint procurement for critical medicines but had not organised such procurement by June 2025. However, with the Critical Medicines Act, the Commission proposed to extend its legal mandate for collaborative procurement of certain medicines. In our survey, 15 NCAs said that they were interested in participating in voluntary joint procurement, while 14 NCAs did not know whether their member state was interested in this option (see ***Annex III***).

Medicine supply chains remain vulnerable to disruption and member states have begun reshoring medicine production

74 In recent years, the manufacturing of many medicines and active pharmaceutical ingredients (APIs) has moved to locations outside the EU (see paragraph ***71***)[29]. This has been especially the case for antibiotics and painkillers. In addition, there has been significant concentration in the industry. For instance, APIs are often manufactured by few or only one company. At the same time, the supply chains of medicines have become more complex, longer, and distributed more widely across the globe (see ***Box 3***)[30]. While these developments have an economic rationale, they have also been a source of supply chain vulnerabilities in the market for medicines.

[28] Pharmaceutical Strategy for Europe, COM(2020) 761, p. 17.

[29] EFCG, Addressing the acute and complex challenge of medicine shortages, 2020.

[30] OECD, *Shortages of medicines in OECD countries*, 2022, p. 24.

Box 3

Supply chain vulnerabilities reported by industry in 2021

Source: ECA, based on European Fine Chemicals Group.

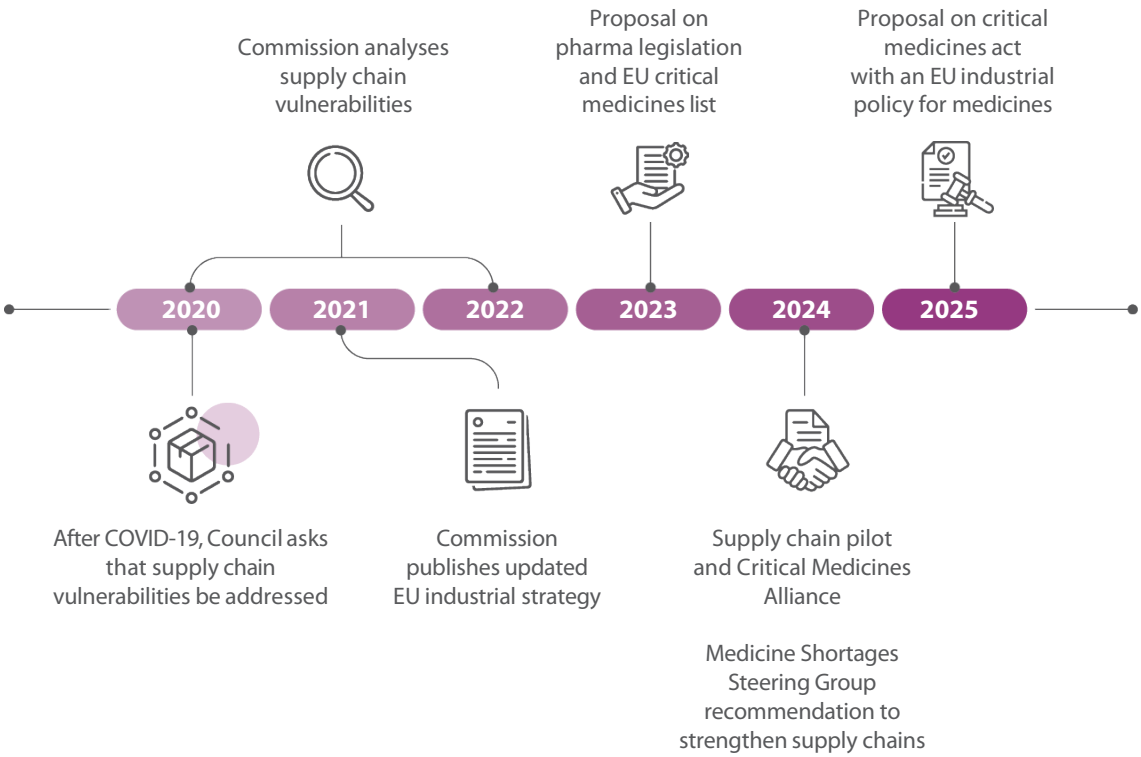
The analytics company IQVIA has estimated that the **EU depends on Asia for 70 % of its active pharmaceutical ingredients and 79 % of its medicine precursors (the biochemical substances from which they are formed)**. The same study indicates that the EU is fully dependent on Asia for active pharmaceutical ingredients of common painkillers (e.g. paracetamol and ibuprofen) and that dependency is around 80 % for other common medicines which have been in critical shortage in the EU, such as amoxicillin (an antibiotic) and salbutamol (a medicine needed for treating asthma).

Source: IQVIA study for the European Fine Chemicals Group, 11 December 2020.

75 During the COVID-19 pandemic, in late 2020, the Council asked the Commission to address weaknesses in the supply chain for medicines. The Commission committed to certain measures in its 2020 Pharmaceutical Strategy, such as increasing transparency of supply chains and increasing their resilience.

76 The Commission published an update to the EU's Industrial Strategy in 2021, calling for an active industrial policy for critical sectors, including medicines. It also conducted several studies on supply chain vulnerabilities for medicines[31]. However, it was not until April 2023 that the Commission proposed first measures to address these vulnerabilities through its 2023 proposals, such as new reporting obligations for industry. In May 2023, member states called for urgent additional measures. As a result, the Commission and EMA started further preparations (see ***Figure 14***).

Figure 14 | Main EU measures to support supply chain resilience



Source: ECA.

77 First, in December 2023, the Commission, EMA and NCAs published a first EU list of 268 critical medicines, mostly low-cost generics that should always be available to patients. We found that work so far has been focused on analysing supply chains and has not yet led to preventive action to ensure medicine availability, except for a voluntary pilot on shortage prevention and mitigation plans. Some medicines on the list, e.g. salbutamol (for asthma), methotrexate (for cancer and immune diseases) and amoxicillin (antibiotic), were in critical shortage throughout the EU during our audit, for which mitigating actions were taken (see paragraph ***44***).

[31] Vulnerabilities of the global supply – Structured Dialogue on the security of medicines supply, 2022.

78 Second, the Commission assessed the supply chains of eleven critical medicines, selected as a pilot. The assessment provided insights into the complexity of supply chains. For instance, it concluded that for four out of eleven APIs the EU depended on sources in non-EU countries and that there was an overreliance (> 30 %) on single manufacturers or individual countries for all eleven APIs[32]. The Commission then convened a Critical Medicines Alliance, to discuss how vulnerabilities in the supply chains could best be identified and addressed. It published recommendations in February 2025. The Commission also asked EMA to further develop the methodology to identify supply chain vulnerabilities.

79 In March 2025, the Commission proposed an EU industrial policy for medicines in a critical medicines act, building on the 2024 STEP Regulation. It proposes a framework to facilitate investment in manufacturing capacity for critical medicines, coordinate measures, and increase the resilience of supply chains. Concrete EU measures to address existing supply chain vulnerabilities will depend on the adoption and implementation of the legislation proposed by the Commission.

80 In the absence of an EU-level industrial policy for medicines, member states had begun relocating the production of critical medicines to the EU (reshoring), from 2021. In our survey, three NCAs said their country had started reshoring and six NCAs said that their country was planning to do so (see ***Annex III***). The International Monetary Fund and OECD have emphasised, however, that uncoordinated reshoring exposes the EU to risks and might result in duplication of effort and a significant cost for taxpayers. This was also highlighted by an assessment of the French reshoring initiative.

81 Some member states used national and EU funds to support reshoring. For example, France used the Recovery and Resilience Facility to relocate essential medicines to France, aiming to mobilise more than €800 million for 15 projects. Austria used national funds (€40-45 million) to support and extend existing local manufacturing of APIs. EU financial support is possible through multiple EU funding streams, such as EU4Health, Horizon Europe and the Recovery and Resilience Facility. The Commission has an insufficient overview of their use for reshoring, which reduces its ability to monitor progress and identify gaps and overlaps. The Commission proposed in the Critical Medicines Act to introduce a Critical Medicines Coordination Group, chaired by the Commission. This could provide the Commission with a better overview of projects and funding streams.

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[32] Assessment of the supply chain vulnerabilities for the first tranche of the Union list of critical medicines: Technical report, Health Emergency Preparedness and Response Authority, 2024, p. 16.

The single market for medicines is fragmented resulting in many availability challenges

82 The Commission is responsible for ensuring a well-functioning single market, which guarantees the free flow of goods within the EU. This is a prerequisite for availability of medicines[33]. EU action in this area relies on the single market for security of supply.

83 We were looking to find out whether the Commission had addressed barriers to a single market for medicines by:

- sufficiently harmonising regulatory procedures, standards and packages;
- ensuring transparent pricing and reimbursement;
- ensuring the free movement of medicines in the single market.

Despite efforts, insufficient harmonisation of the regulatory environment contributes to unequal access to medicines and trade barriers

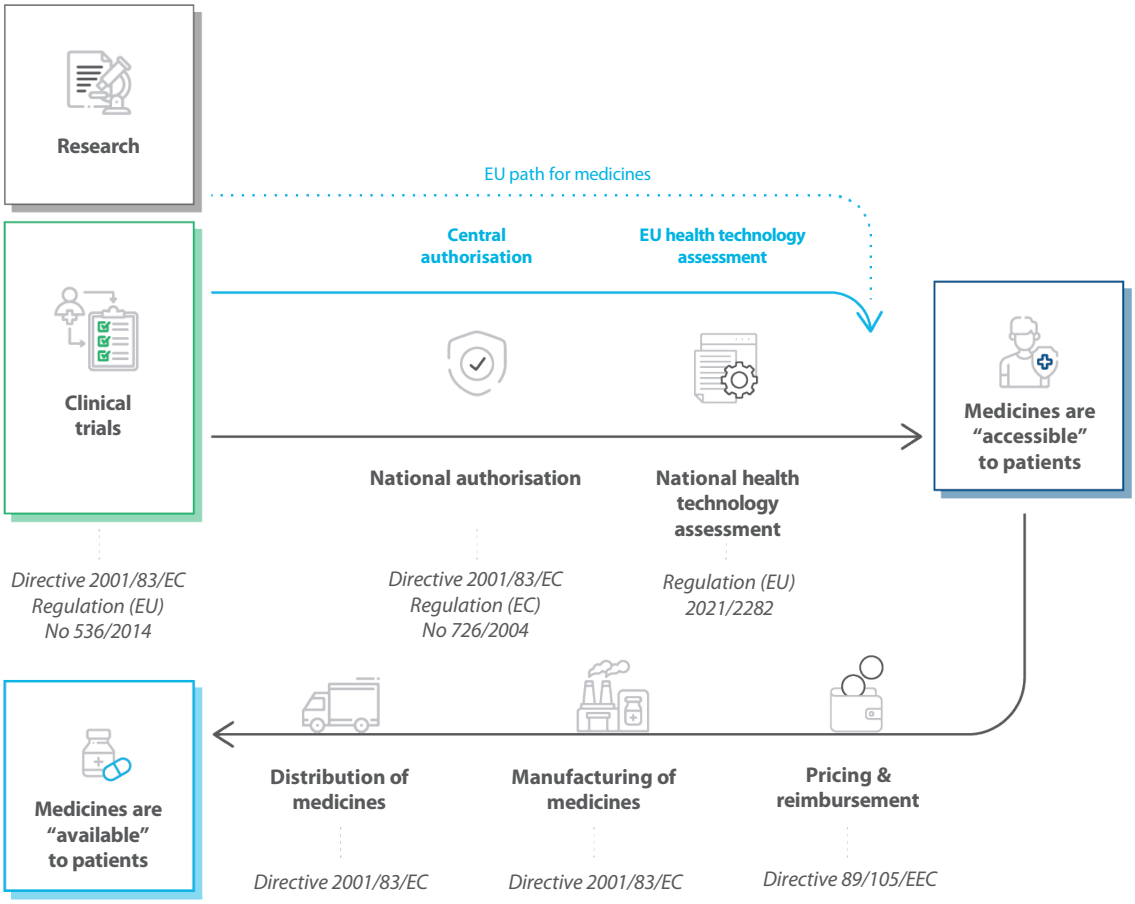
84 Harmonising regulatory procedures, standards and packages is vital for a single market in medicines that functions well and for medicine availability. We assessed the level of harmonisation achieved by the Commission in these areas.

Regulatory procedures have been harmonised partially, leading to different medicines authorised and marketed in member states

85 To become "accessible" to EU patients, new medicines need to be authorised to ensure their safety, quality and efficacy and may undergo a health technology assessment, to assess their added value. Harmonising such regulatory procedures allows NCAs and patients to trust in the safety and efficacy of medicines from other countries. This is a prerequisite for trade and hence for ensuring availability (see ***Figure 15***).

[33] OECD, Developing a set of indicators to monitor the performance of the pharmaceutical industry, 2023, p. 16, paragraph 2.

Figure 15 | Life cycle and EU legal framework for medicines



Source: ECA, based on Commission Impact Assessment.

86 There is an "EU path" for authorising medicines. This allows some medicines to be centrally authorised by the Commission, with the support of EMA. However, while industry must apply for EU-wide authorisation for certain medicines, it cannot apply for all medicines[34]. This means that most medicines in the EU are still authorised nationally.

87 Since 2025, under the EU Health Technology Assessment Regulation, member states can jointly undertake the clinical assessment of a medicine's added value. However, other aspects such as the cost-effectiveness of new medicines are still assessed nationally, and EMA can only facilitate these procedures.

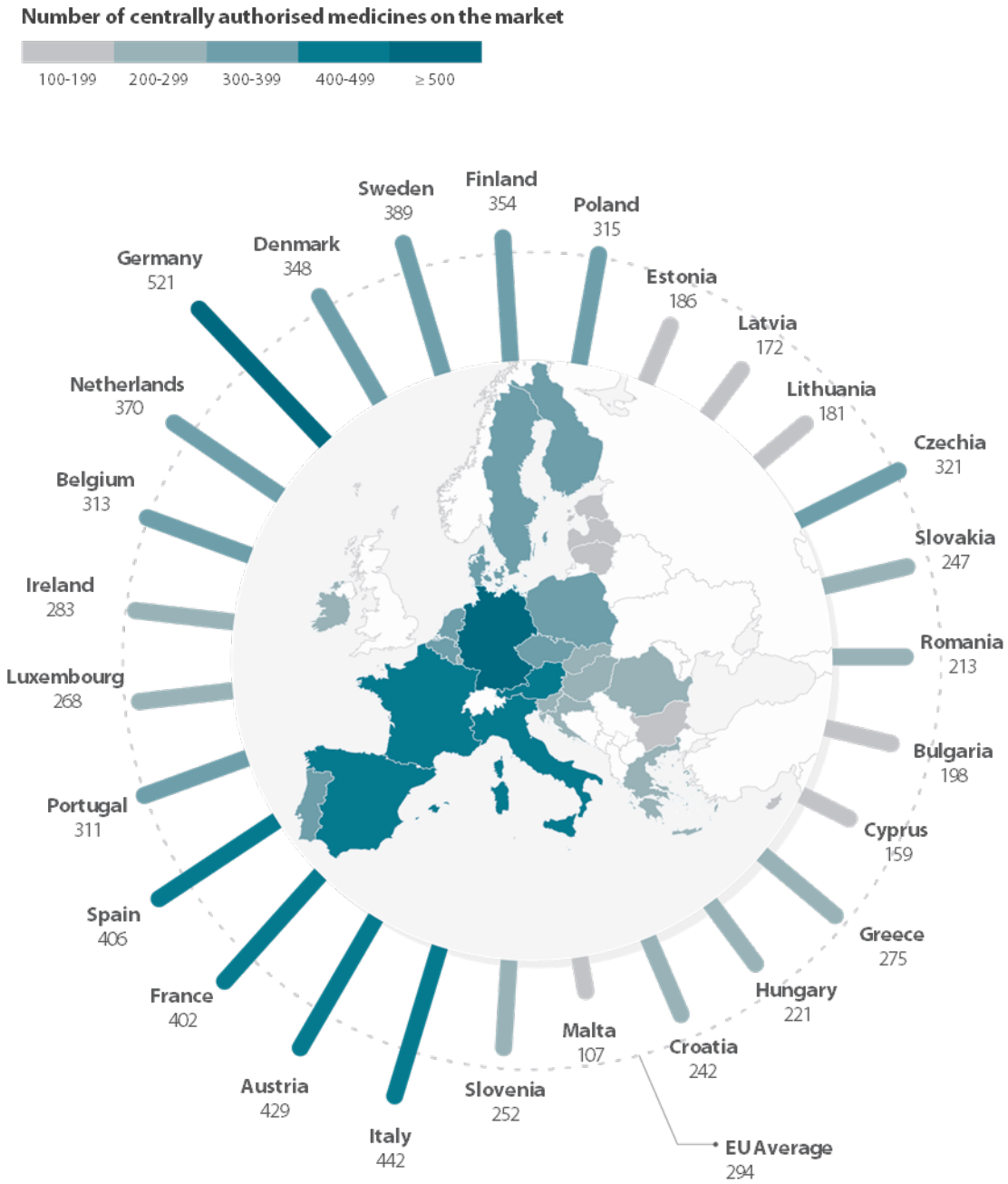
88 The subsequent medicine pricing and reimbursement are governed by national legislation. Thus member states have the right to choose which medicines they prefer to pay for. Industry is not obliged to market medicines everywhere in the EU. The WHO noted that

[34] Article 3 of Regulation (EC) No 726/2004.

industry considers the commercial size of a country when prioritising where to market its medicines, creating particular challenges for smaller countries.

89 As a result, medicines authorised for the entire EU are often not actually marketed in all member states. We found that of 629 centrally authorised medicines, between 107 and 521 were on the market in different member states, with the average of 294 (see ***Figure 16***). As different medicines are available in each member state, trading medicines in the single market and moving medicines to counter shortages is difficult.

Figure 16 | Number of centrally authorised medicines marketed per EU member state in 2025



Note: We used the marketing status of all centrally authorised medicines authorised as of 2015 that were marketed in at least one member state.

Source: ECA, based on data available to EMA for human medicines as of 10 January 2025.

While medicine safety and quality standards have been harmonised, the use of inspections to prevent and address shortages was insufficient

90 We found that the Commission had created harmonised EU-wide standards for the safety and quality of medicines. These include pharmacovigilance rules, a framework against falsified medicines and rules on good laboratory practice, good manufacturing practice and good distribution practice. Member states are responsible for implementation and enforcement, for instance, through inspections[35].

91 Inspections are a key tool to encourage high quality manufacturing and prevent quality defects. The United States Food and Drug Administration has used inspections as a way of addressing and preventing shortages[36]. For instance, inspections may discover actions or activities that could threaten availability early on. However, inspections of marketing authorisation holders by NCAs in relation to availability of supply are not possible in all member states, and the quality of imported APIs, especially from India and China, has been a concern for some years[37]. The Commission proposed in 2023 that EMA should have its own inspectors and coordinate national inspections. Together with recently reinforced international rules on quality risk management, this could significantly strengthen the oversight framework and help ensuring availability.

Medicine packages differ within the EU, hindering cost-effective trade

92 Medicine packages (medicine names, package sizes and labelling) differ significantly across the EU (see ***Box 4***). Different packages for different national markets make trading medicines in the EU complex and more costly. In our survey, 14 NCAs considered that different packages increased the cost of trading medicines in the EU (see ***Annex III***). The result has been reduced availability of medicines. Different packages are also a barrier to easy redistribution of medicines during a shortage.

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35 Article 111 of Directive 2001/83/EC.

36 US Food and Drug Administration, *Annual Report on Drug Shortages For Calendar Year 2023*, p. 11.

37 Pharmaceutical Committee on 7 November 2019, Agenda item 7.

Box 4

Varying names and package sizes

Salbutamol, a medicine in critical shortage, is marketed as **Ventolin** in the Netherlands but as **Ventilan** in Portugal.

Fexofenadine, a common antiallergic, is marketed as **Allegra tab** in Belgium and Luxembourg, but it is marketed as **Telfast** in Portugal and Ireland. The package sizes available in member states are different (10, 20 or 30 tablets).

Amoxicillin, a common antibiotic in critical shortage, is marketed by Sandoz in **package sizes of 2, 6, 8, 10, 12, 14, 16, 20, 24, 30, 100 and 1 000** in different member states. Sandoz asked regulators whether it could simplify packages and presentation and whether regulators would allow multi-country packages so as to increase supply.

Source: ©Sandoz.

Source: PGEU and EURIPID.

93 Key reasons for different packages include:

— EU requirements for labelling packages and paper leaflets in the official language(s) of each country;

— member states require national labelling, such as barcodes or national symbols;

— health systems in member states reimburse different package sizes;

— differing clinical practices, resulting, for example, in different treatment duration and package sizes.

94 The Commission proposed some measures to harmonise packages in its 2023 legislative proposals. These include multi-language packages and electronic package leaflets in all languages to address cross-border barriers to trade. However, differing names, package sizes and additional national labelling requirements may persist.

EU rules for transparent markets are outdated

95 While pricing and reimbursement policies for medicines are a national competence, the Commission considers cooperation in this area essential to avoid decisions in one member state creating shortages in other member states. The 1988 Transparency Directive requires member states to ensure a certain level of transparency in relation to medicine prices and reimbursement decisions, as differing measures can hinder trade within the EU.

96 The Commission stock-taking exercise of the Transparency Directive in 2022-2023 concluded that, in many cases, it was not applied appropriately by member states. Furthermore, medicine price transparency is low. Member states have introduced mechanisms like price-volume agreements, claw-back mechanisms, and managed entry agreements to ensure affordability of medicines in a given member state. In practice, these mechanisms often result in confidential contracts, with prices known only to contracting parties. Prices between member states differ significantly.[38] Furthermore, member states and industry only publish "list prices", which are often much higher than actual prices after discounts. The average discount on list prices, following negotiations, can be up to 50 %.

[38] European Parliament study on differences in cost of an access to pharmaceutical products in the EU, 2010.

97 The WHO and important stakeholders (e.g. doctors and public health insurers) have called for more medicine price transparency. In its 2020 Pharmaceutical Strategy, the Commission pledged to foster transparency of price information. The Commission has been funding a database (EURIPID) for member states to exchange information on list prices since 2010, which is restricted to NCAs. Despite the limited value of list prices, most NCAs do use the system. The OECD has found that member states would be interested in receiving information on actual prices but the appetite for sharing such information is low.

98 A revision of the 1988 Transparency Directive was planned as far back as 1992. It was to have "contained appropriate measures leading towards the abolition of any remaining barriers". This revision never occurred. The Commission made a proposal to revise the Directive in 2012 to ensure its effectiveness and prevent barriers to trade but it was not adopted. The Commission currently has no plans to evaluate or revise the legal framework despite the existing problems, citing insufficient support by member states.

The Commission has not sufficiently addressed barriers to trade in the single market

99 One of the main ways of mitigating medicine shortages is moving medicines from one member state to another (see paragraph ***44***). This should be guaranteed by the free movement of goods in the single market. We assessed how the Commission was identifying and addressing barriers to trade.

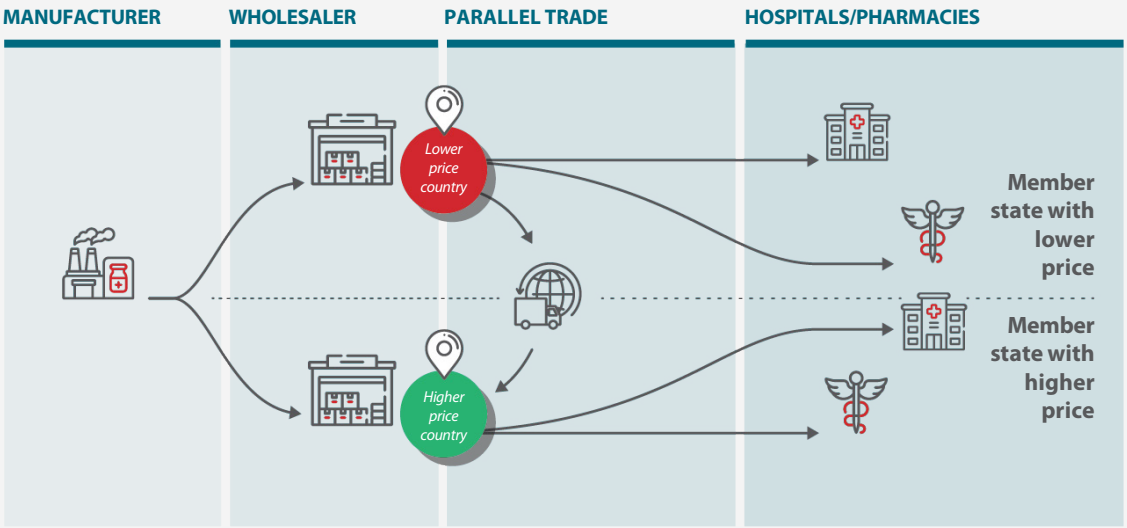
100 We found that some member states had created trade barriers to prevent shortages caused by industry supply quotas and parallel trade (see ***Box 5***). In 2017, the European Parliament had asked the Commission to assess the impact of supply quotas and parallel trade. The Commission's 2021 study on shortages recommended requiring greater transparency, in absence of reliable data on parallel trade and supply quotas. We note that the Commission did not further address these issues.

Box 5

Parallel trade and industry supply quotas

Parallel trade exploit different prices for medicines in the EU (see paragraph ***96***) by exporting medicines from member states with low prices and supplying member states with higher prices (see ***Figure 17***). It mainly concerns expensive branded medicines or medicines for which supply is limited, which can then be sold at a higher price.

Figure 17 | Parallel trade in medicines between member states



Source: ECA.

In 2022, medicines worth €6.4 billion were moved by parallel traders between member states. Industry data shows that parallel imports were especially large in Denmark (29.4 % of pharmacy sales) and Sweden (11.2 %).

While parallel trade can create shortages, it is also often used to prevent or mitigate them, increase access to medicines that are not marketed in a certain member state, and it can reduce medicine prices. A total of 12 NCAs reported that parallel trade had caused shortages in their member state and 15 NCAs reported that it had helped their member state mitigate shortages (see ***Annex III***).

As parallel trade can reduce industry profits, industry places a limit on supply to certain member states, based on estimated national demand. This is known as "supply quotas" and is considered legal. It may restrict the industry supply obligation (see paragraph ***64***).

101 Trade barriers, set up to protect citizens in one member state (see ***Figure 18***), can create shortages in other member states. While export bans are allowed under certain conditions for "the protection of health and life of humans", they were not always temporary and in some cases affected many medicines and were repeatedly renewed over many years. In the past, the Commission has launched infringement procedures against some export bans, for instance, against Poland, Romania and Slovakia. However, in 2018, it closed these proceedings, stating that it would need to find other ways to solve this complex issue. The Commission followed-up with, for example, a study on shortages, the structured dialogue and discussions in the Pharmaceutical Committee. However, it did not propose any solutions to the issues caused by trade barriers, parallel trade and supply quotas.

Figure 18 | Examples of trade barriers for medicines in certain member states at different times between 2019 and 2024

Source: ECA.

102 In principle, any measures that might restrict trade need to be notified to the Commission via its Technical Regulation Information System (TRIS) before being adopted[39]. This allows the Commission to respond and take action to prevent member states from erecting trade barriers. Some member states that imposed restrictions relating to medicines did report them (e.g. Belgium, Bulgaria and Greece) while others did not. This limits the Commission's overview of such restrictions. We found that the Commission assessed the notifications received and asked notifying member states to limit their restrictions, such as by reducing the number of medicines concerned.

[39] Article 5 of Directive (EU) 2015/1535.

This report was adopted by Chamber I, headed by Mrs Joëlle Elvinger, Member of the Court of Auditors, in Luxembourg at its meeting of 14 July 2025.

For the Court of Auditors

Tony Murphy
President

Annexes

Annex I – About the audit

Introduction

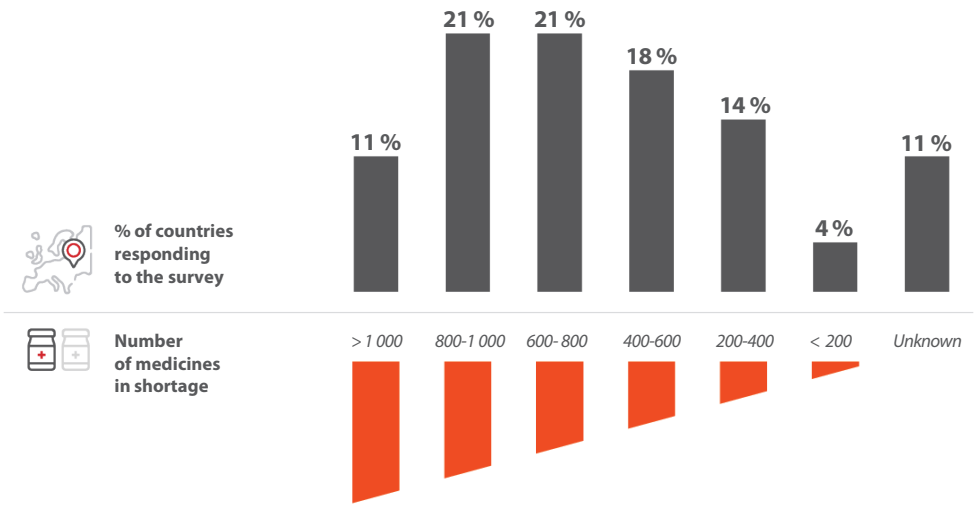
Medicine shortages in the EU

01 Medicines are often referred to as “medicinal products”[1], “pharmaceuticals” or “drugs”. In this report, we use the term “medicines” for simplification.

02 Shortages of medicines have been a significant issue throughout the EU for a long time. Hospital pharmacies and community pharmacies have reported an increasing number of medicines “in shortage” during the last decade and record levels for 2023 and 2024. For 2024, 53 % of community pharmacy groups in 25 EEA countries, the United Kingdom and North Macedonia reported shortages of more than 600 medicines (see ***Figure 1***). This was despite measures by the EU and member states to prevent and mitigate shortages.

[1] Article 1 of Directive 2001/83/EC.

Figure 1 | Number of medicines in shortage reported by pharmacies, end 2024



Note: Data from community pharmacy organisations in 25 EEA countries, the United Kingdom and North Macedonia as at the end of 2024.

Source: PGEU Medicine Shortages Report 2024.

03 Medicine shortages compromise patient health and can also pose a significant threat to public health (see ***Box 1***). Furthermore, they cause significant additional costs for doctors, pharmacies, and the health system. Doctors and pharmacists need to spend a lot of time managing shortages and finding alternative treatments.

Box 1

EU wide critical shortages and impact on patients

Amoxicillin is a common antibiotic used to treat many infections. When social distancing measures of the COVID-19 pandemic were lifted in late 2022, respiratory infections, and therefore demand for antibiotics, surged. At the same time, manufacturing problems resulted in a critical shortage of amoxicillin. As a result, many patients, especially children, could not receive the most effective treatment and broad-spectrum antibiotics had to be used instead, which can result in more antimicrobial resistance.

Since 2021, a **shortage of verteporfin**, an essential medicine for treating a broad range of eye conditions, has had significant adverse effects on patient care in all member states. As a result of the shortage, a number of patients have suffered significant and irreversible vision loss.

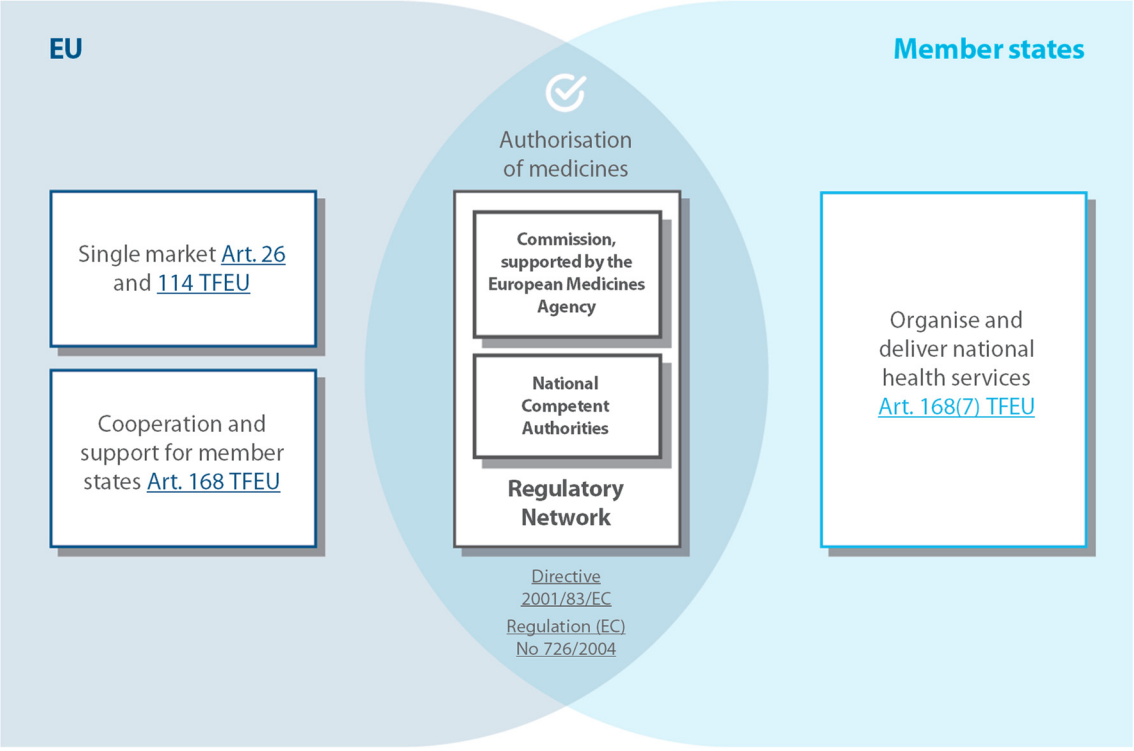
At the end of 2024, both critical shortages were still on-going.

04 Shortages can affect all categories of medicines including innovative patented medicines, off-patent generics, or vaccines. They can also affect all formulations, such as pills, intravenous or oral formulations, and all treatment areas.

Roles and responsibilities

05 Medicines are a shared responsibility of the EU and member states (see ***Figure 2***). The Commission is responsible for "establishing and ensuring the functioning" of the single market, including for medicines. Furthermore, the Commission must consider health in all its policies, encourage cooperation between member states in the area of public health, and support member states in this area. The Commission is supported by the European Medicines Agency (EMA) to carry out its tasks.

Figure 2 | Responsibilities for medicines at EU and member-state level



Source: ECA, based on the Treaty on the Functioning of the European Union.

06 The authorisation of medicines is based on EU legislation but there are EU and member state responsibilities. The Commission, supported by EMA, is responsible for authorising

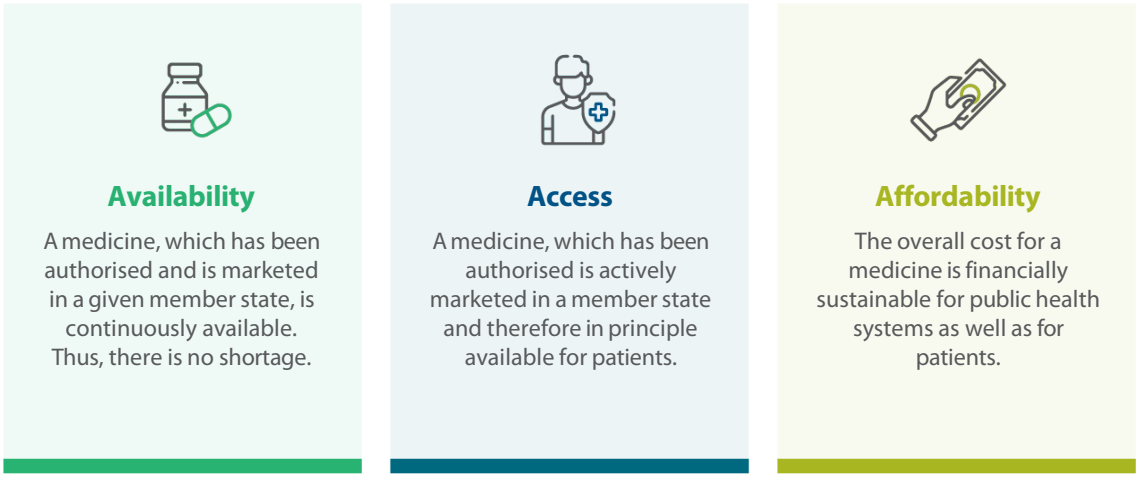
certain medicines centrally. However, most medicines are authorised nationally through the member states' national competent authorities (NCAs). For each authorised medicine, there is one marketing authorisation holder (in this report, we refer to these authorisation holders as the "industry"). Industry is responsible for ensuring continuous supplies of medicines. Together, EMA, NCAs and the Commission cooperate in the European Medicines Regulatory Network.

07 Member states are responsible for organising, financing, and delivering health services and medical care. Their health systems differ significantly, and their expenditure on healthcare ranges from 5.5 % to 12.6 % of GDP. Their total healthcare expenditure in 2022 was €1 648 billion[2]. Member states are the main purchasers of medicines in the EU.

Relevant EU objectives

08 EU citizens have a fundamental right of access to preventive healthcare and medical treatment[3]. Access to healthcare and medicines is also a core objective of UN Sustainable Development Goal 3. Accordingly, "availability", "accessibility" and "affordability" of medicines are important EU objectives, guiding the work of the Commission and supported by the EU budget (see ***Figure 3***)[4].

Figure 3 | Definitions used by the European Commission



Source: Commission.

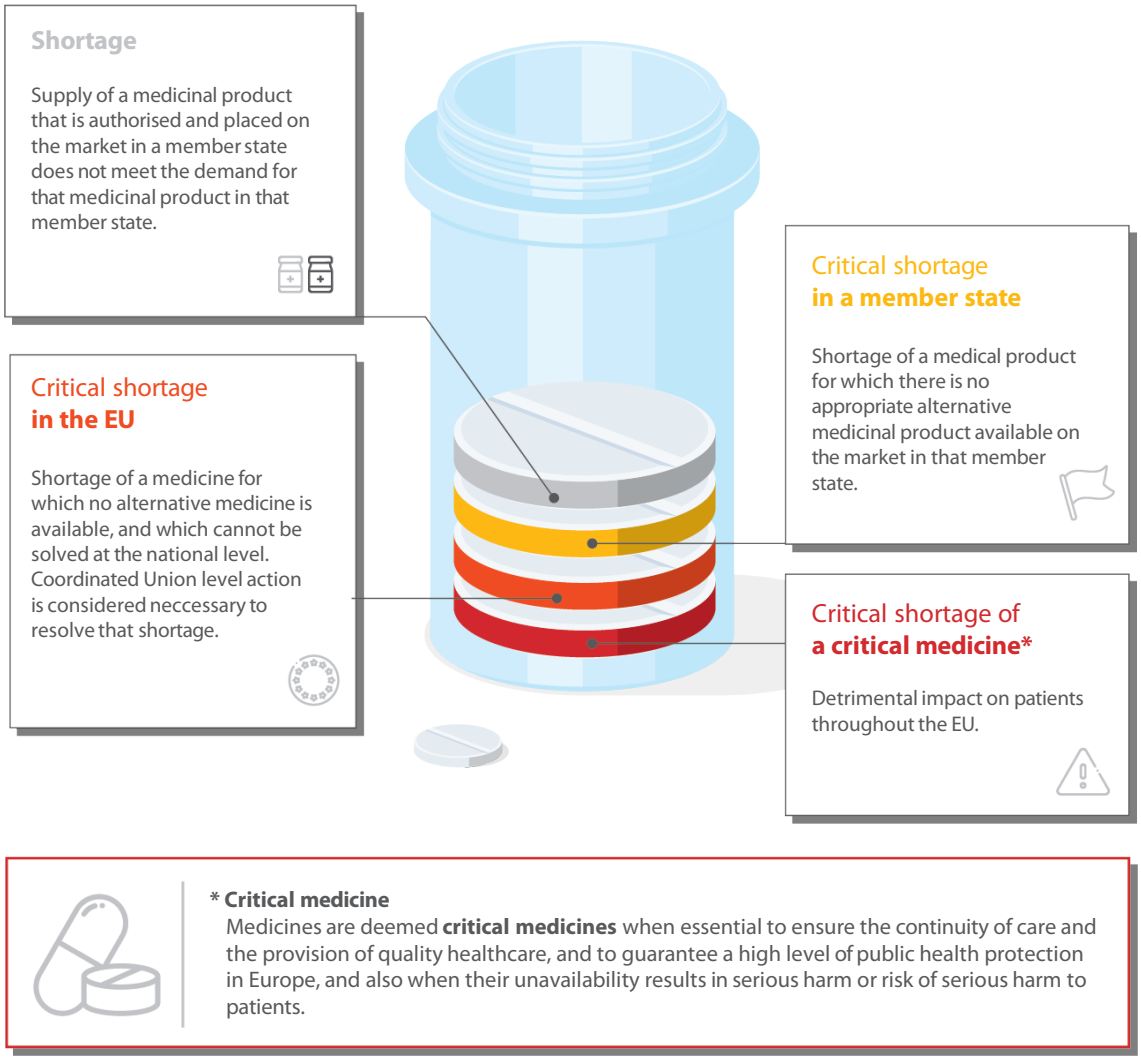
[2] Healthcare expenditure statistics, Eurostat, 2022 data.

[3] Article 35 of the Charter of Fundamental Rights of the European Union.

[4] Article 4c of Regulation (EU) 2021/522.

09 The Commission has defined different levels of shortage (see ***Figure 4***).

Figure 4 | Commission definitions for shortage levels



Source: Commission Communication on addressing medicine shortages in the EU, 24 October 2023, p. 3.

Key EU measures related to medicine shortages.

10 The Council[5] and the European Parliament[6] have called on the Commission to address medicine shortages on many occasions. The Commission has responded with a number of measures (see ***Figure 5***) such as new legislative proposals in 2023 and 2025.

[5] E.g. in 2016, 2020, 2021 and 2023.

[6] E.g. in 2017, 2020 and 2021.

Figure 5 | Timeline of events and publications related to medicine shortages

Source: ECA.

11 EU action to ensure the availability of medicines can be divided into three categories:

(1) Since 2011, in response to increasing shortages, various building blocks have formed an **EU system to prevent and mitigate critical shortages** when they happen.

(2) Since 2018, the Commission has worked on analysing and addressing **root causes of medicine shortages**.

(3) The Commission has worked on **creating a functioning single market**, formally established in 1993, including **for medicines**.

Audit scope and approach

12 The objective of our audit was to assess whether EU measures to ensure medicine availability were effective. We examined whether the Commission and the European Medicines Agency had:

(1) established and implemented an effective framework to prevent and mitigate critical shortages;

(2) identified and addressed the root causes of shortages;

(3) addressed market barriers to ensure a functioning single market for medicines.

13 While availability, accessibility, and affordability of medicines go hand in hand, we focused mainly on availability, given the severe impact of frequent and critical shortages of medicines in the EU. We did not audit individual member states. We also did not cover EU action in related areas such as antimicrobial resistance, or shortages of medical devices or veterinary medicines. We covered the period from 2019 until 31 October 2024. We considered some earlier Commission work where necessary, for example, on the single market for medicines.

14 *Figure 6* shows how we obtained evidence for our observations.

Figure 6 | Audit work carried out

We examined

- the legal framework applicable to the 30 countries of the European Economic Area
- responsibilities related to the availability of medicines

We analysed

- Commission's work and internal documentation on establishing a system for addressing shortages, root causes and barriers to a functioning Single Market for medicines

- EMA's documentation related to preventing and mitigating shortages, including its work in:
  - the task force on availability of authorised medicines
  - the Medicine Shortages Steering Group (MSSG)
  - the Medicines Shortages Single Point of contact (SPOC) working party

  We also analysed:
  - a sample of critical shortages which had been addressed

We interviewed

- representatives of the **European Commission** (DG SG, DG SANTE, DG GROW, DG HERA and DG ECHO)
- representatives of the **EMA**

- representatives from a **sample* of three member states** (Denmark, Greece and France) including medicine regulators and ministries of health

* **Sample selection criteria:** severity of shortages, experience in managing shortages, country size, problems with parallel trade

We consulted

key stakeholders, including:
- organisations representing patients, doctors, pharmacists, traders, and the industry
- international organisations (e.g., WHO Europe and the OECD Health Division)
- key US authorities

Our survey covered

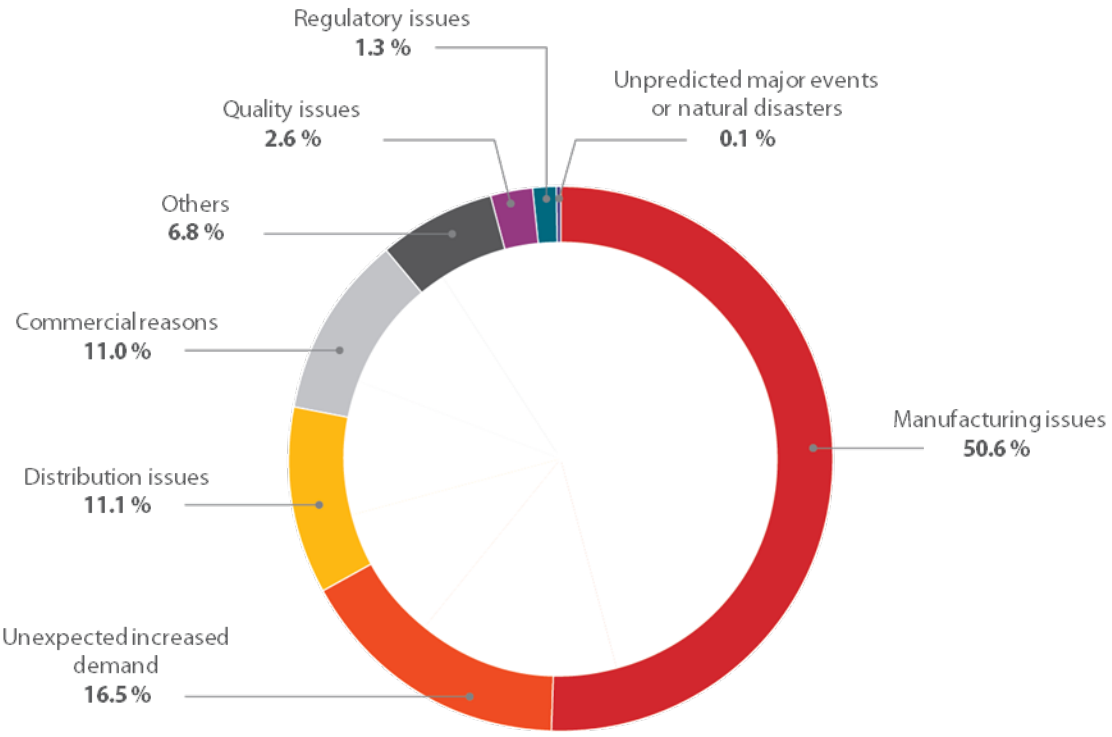
- member state representatives, participating in the SPOC working party

Source: ECA.

Annex II – Root causes analysed by National Competent Authorities

NCAs analysed 83 266 shortage notifications from 24 EEA countries during 2022-2023 (see ***Figure 1***). The analysis was performed through the join action CHESSMEN, funded by the EU4Health programme 2021-2027.

Figure 1 | Root cause analysis of medicine shortages in the EEA based on 2022-2023 data



Source: ECA based on CHESSMEN.

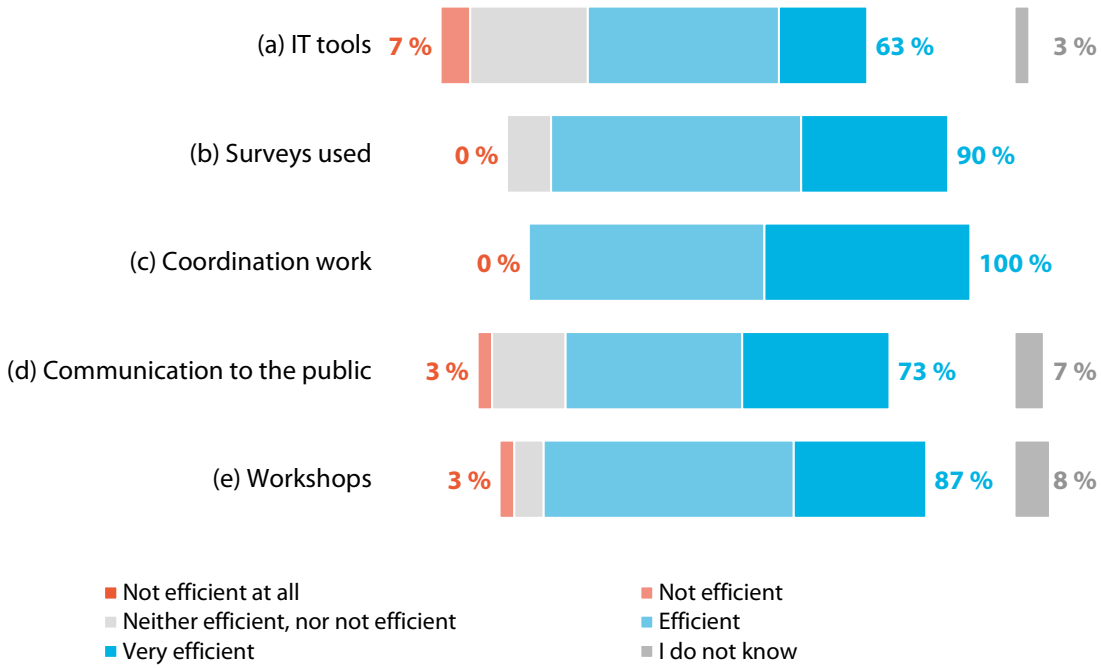
Annex III – Survey of member states

01 We used EUSurvey to collect the views of national competent authorities (NCAs) for human medicines on the Commission's and EMA's action to tackle medicine shortages, and to find out about the situation in member states.

02 We asked 30 NCAs that were part of the Single Point of Contact (SPOC) working party for information. These NCAs are responsible for mitigating medicine shortages in the 30 countries of the European Economic Area of 27 EU member states, plus Norway, Iceland and Liechtenstein. However, we had no NCA respondent from Liechtenstein as it has no representative in the SPOC, but two NCA respondents from Germany from its two SPOC representatives. Responses from all 30 NCAs were collected between 9 December 2024 and 15 January 2025.

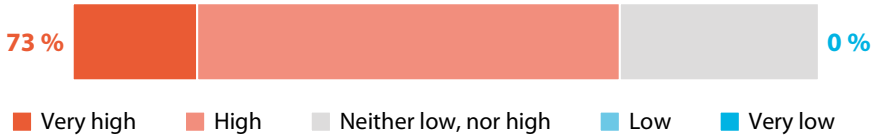
03 The charts below show the cumulated responses to the survey.

(1) How would you rate EMA's tools and processes to manage shortages?



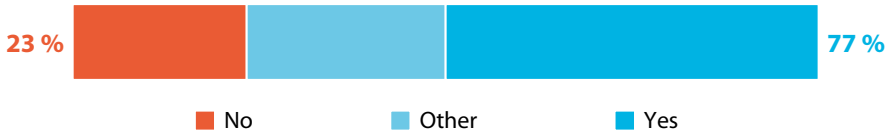
(2) Overall, how useful was EMA's work on shortages for the prevention and management of shortages for your country?

(3) How would you assess the workload resulting from the activities of the SPOC and MSSG on your authority?

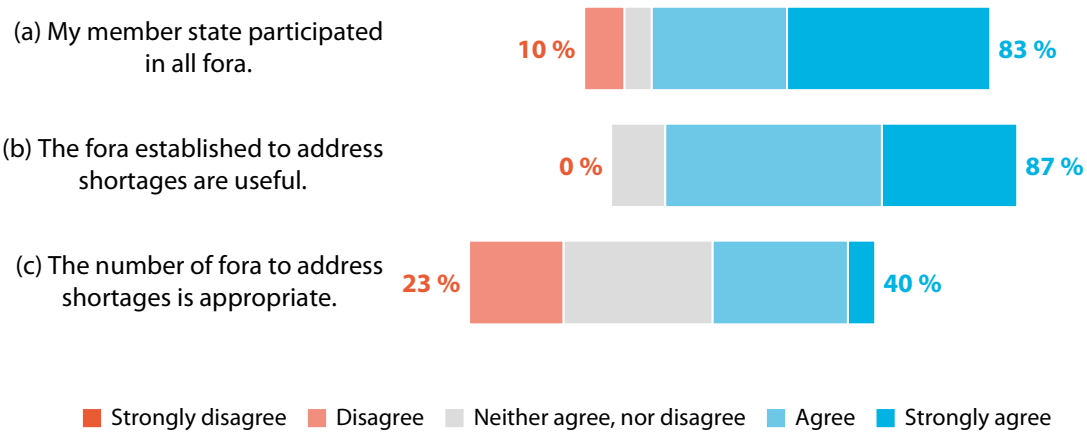


(4) How much did the joint exercise by EMA and the Commission (HERA) help to minimise shortages of antibiotics during winter 2023-2024?

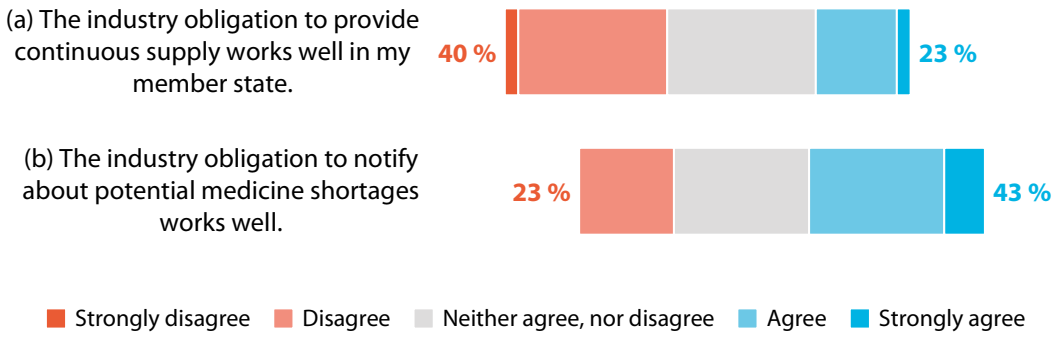
(5) Does the national legislation in your country allow inspections of marketing authorisation holders to check compliance with Good Manufacturing Practices and/or Good Distribution Practices in relation to availability of supply?



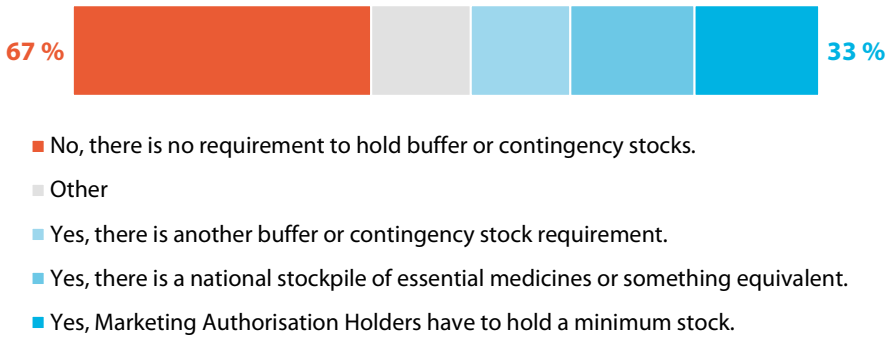
(6) The issue of medicines shortages is being discussed in different fora and initiatives set up by the EU and Member States. This includes the Pharmaceutical Committee, Task Force AAM, MSSG, SPOC, JA CHESSMEN and the Critical Medicines Alliance. Do you agree to the following statements?



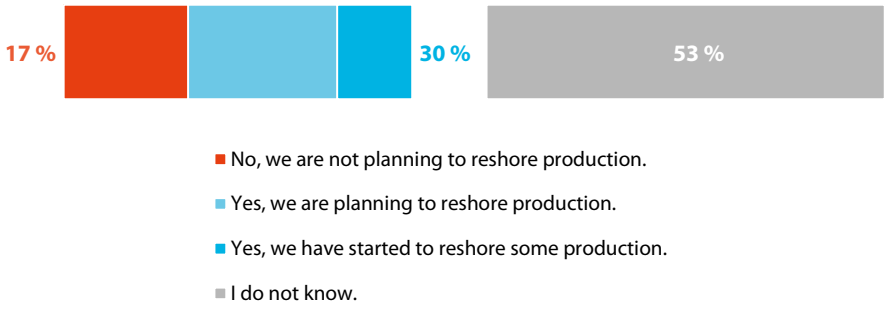
(7) Articles 23a and 81 of Directive 2001/83/EC specify obligations of marketing authorisation holders. Do you agree to the following statements?



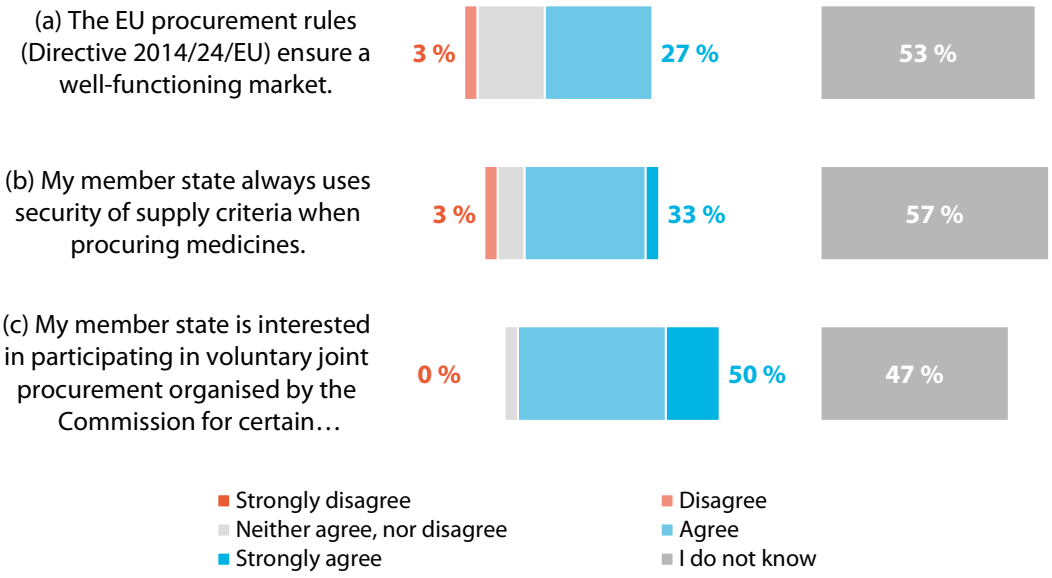
(8) Does your Member State have a legal requirement to stockpile essential/critical medicines (whether buffer/contingency stocks or national stockpiles)?



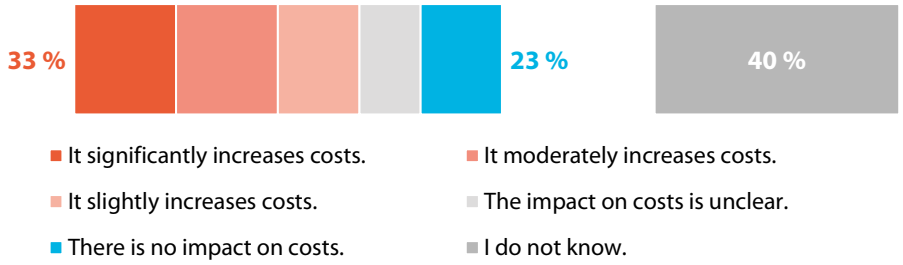
(9) Did your Member State reshore the production of essential medicines or active pharmaceutical ingredients during the last 5 years or is it planning to do so?



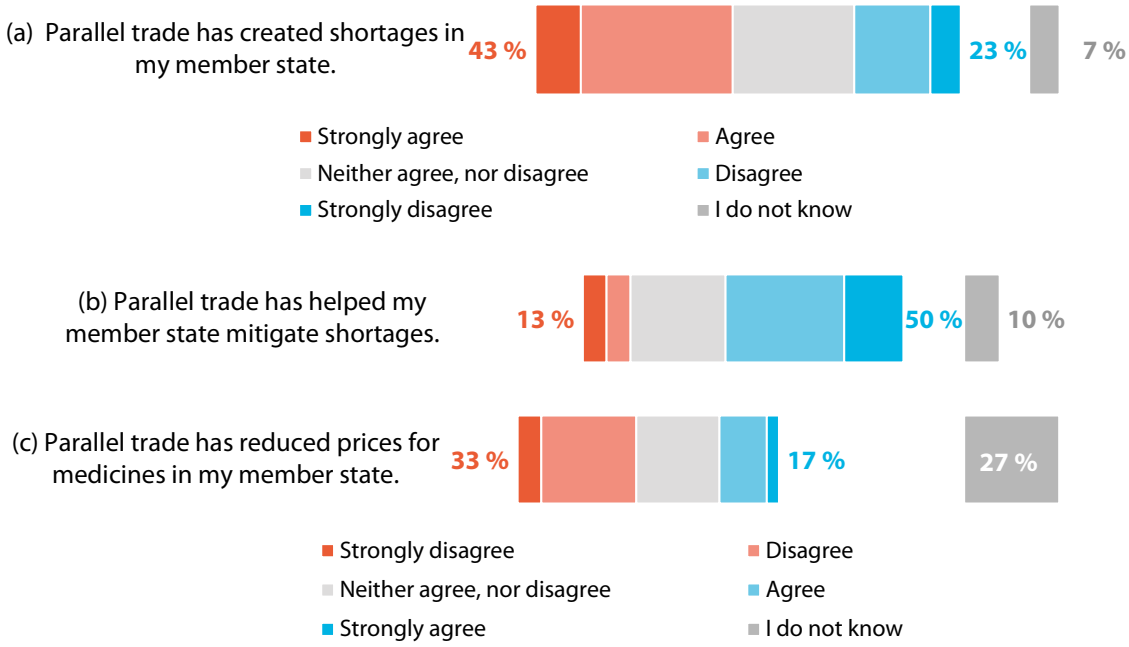
(10) The Commission considers procurement key for a functioning market and security of supply. Do you agree to the following statements?



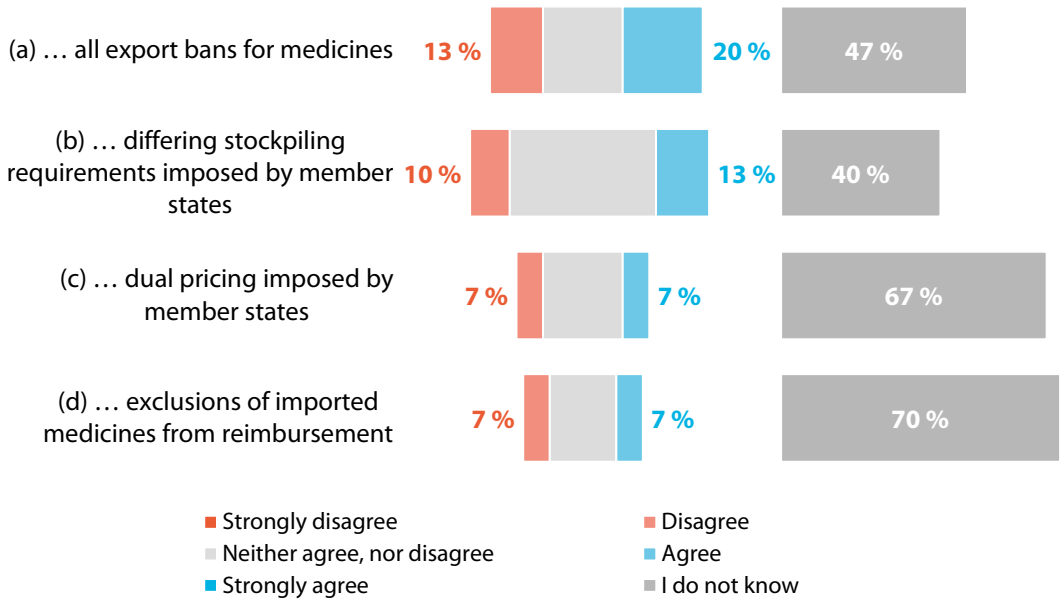
(11) There are different medicine names, packaging sizes, and labelling requirements in the EU. What is their impact on the cost of importing/exporting medicines within the EU, in your experience?



(12) Parallel trade is considered to create shortages of medicines but also used as a tool to mitigate shortages. Do you agree to the following statements?



(13) Based on the Treaty, the Commission should address relevant cross-border barriers to trade within the Single Market. Do you agree to the following statements? The Commission appropriately addressed...



Abbreviations

API	Active pharmaceutical ingredient
CHESSMEN	Coordination and Harmonisation of the Existing Systems against Shortages of Medicines – European Network
EEA	European Economic Area
EMA	European Medicines Agency
MSSG	Executive Steering Group on Shortages and Safety of Medicinal Products (Medicine Shortages Steering Group)
NCA	National competent authority
OECD	Organisation for Economic Co-operation and Development
SPOC	Single Point of Contact
WHO	World Health Organization

Glossary

Access	Access exists when a medicine which has been authorised, is actively marketed in a member state and therefore in principle available for patients.
Active pharmaceutical ingredient	Component of a medicine that provides its therapeutic effect.
Availability	A situation in which a medicine which has been authorised and is marketed in a given member state, is continuously available. Thus, there is no shortage.
Claw-back mechanism	Provision requiring a pharmaceutical company to repay to a health insurance provider any amounts it has received in excess of its individual reimbursement budget.
Critical medicine	Medicine that is essential to ensure the continuity of quality healthcare or public health protection in Europe, failing which there is a risk of serious harm to patients.
Critical shortage	A shortage of any medicine for which no alternative medicine is available, and which cannot be resolved by national measures only but requires coordinated action at EU level.
Declared health crisis	The Commission can declare a public health emergency or a major event, which activates additional powers and responsibilities.
European Economic Area	The EU member states, plus Iceland, Liechtenstein and Norway.
IRIS	Online platform of the European Medicines Agency on which the pharmaceutical industry can submit certain kinds of information, such as the marketing status of medicines.
List price	Initial price of a medicine set by its manufacturer before any discounts, rebates or negotiations.
Managed entry agreement	Arrangement between a manufacturer and a payer/provider opening access to (coverage/reimbursement of) a health technology under specific conditions.
Marketing authorisation holder	Company or other legal entity that has authorisation to market a medicine in one, several or all EEA member states.
Parallel trade	Cross-border sale of goods within the EU by traders outside the manufacturer's distribution system.
Pharmacovigilance	Constant monitoring of the safety of medicines during clinical trials and after authorisation.
Public procurement	Purchase by a public body or other authority of goods, works or services.
Reshoring	Relocation of the production of critical medicines to the EU.

Supply obligation	Legal requirement for industry and distributors to ensure an appropriate and continuous supply of medicines to meet patients' needs.
Supply quota	Restriction imposed by a marketing authorisation holder on the volume of supplies to wholesalers.

Replies of the Commission

https://www.eca.europa.eu/en/publications/sr-2025-19

Replies of the European Medicines Agency

https://www.eca.europa.eu/en/publications/sr-2025-19

Timeline

https://www.eca.europa.eu/en/publications/sr-2025-19

Audit team

The ECA's special reports set out the results of its audits of EU policies and programmes, or of management-related topics from specific budgetary areas. The ECA selects and designs these audit tasks to be of maximum impact by considering the risks to performance or compliance, the level of income or spending involved, forthcoming developments and political and public interest.

This performance audit was carried out by Audit Chamber I – Sustainable use of natural resources, headed by ECA Member Joëlle Elvinger. The audit was led by ECA Member Klaus-Heiner Lehne, supported by Thomas Arntz, Head of Private Office and Marc-Oliver Heidkamp, Private Office Attaché; Florence Fornaroli, Principal Manager; Matthias Blaas, Head of Task; Monika Dedicova and Vasileia Kalafati, Auditors. Jennifer Schofield provided linguistic support. Dunja Weibel provided graphical support.

From left to right: Dunja Weibel, Florence Fornaroli, Vasileia Kalafati, Marc-Oliver Heidkamp, Klaus-Heiner Lehne, Matthias Blaas, Monika Dedicova and Thomas Arntz.

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European Court of Auditors, special report 19/2025: “Critical shortages of medicines: EU measures were of added value, but structural problems remain”, Publications Office of the European Union, 2025.

Critical shortages of medicines have become a frequent threat to public health throughout the EU. We assessed EU measures to ensure medicine availability.

We conclude that there is not yet an effective framework for critical shortages of medicines. While the European Medicines Agency has provided valuable support to member states, and the Commission has taken initial steps by proposing legislative changes, efforts to tackle the underlying causes of these shortages remain at an early stage. In addition, fragmentation within the single market continues to hinder the availability of medicines across the EU. We recommend that the Commission further improve the system to address critical shortages, launch coordinated action to address root causes and improve the functioning of the single market for medicines.

ECA special report pursuant to Article 287(4), second subparagraph, TFEU.

EUROPEAN COURT OF AUDITORS

Publications Office of the European Union

EUROPEAN COURT OF AUDITORS
12, rue Alcide De Gasperi
1615 Luxembourg
LUXEMBOURG

Tel. +352 4398-1

Enquiries: eca.europa.eu/en/contact
Website: eca.europa.eu
Social media: @EUAuditors