



Thank you for participating in the study on medicine shortages for the European Commission (DG SANTE). This study is being conducted by a consortium led by Technopolis Group. In this stage of the study, potential solutions to the problem of medicine shortages in Europe will be assessed. This will serve to inform future EU policy in this area.

Your participation in the first survey has been of pivotal value to our study. We have now analysed your responses and filtered out several solutions that had been initially proposed in the first survey.

To further appraise and develop the remaining solutions, we would welcome your professional judgment against five new statements:

The proposed solution yields more value if implemented at EU level than at Member State level (*EU-added value*) The proposed solution complements other solutions and does NOT create unnecessary duplication (*coherence*) The proposed solution does NOT pose major risks of unintended negative effects (*unintended consequences*) There are NO major obstacles to the implementation of the proposed solution (*ease of implementation*) The proposed solution should be implemented as a matter of priority (*urgency of implementation*)

We kindly ask you to indicate your agreement with each of these statements for all solutions on a five point scale ranging from “Disagree” to “Agree”. Additional feedback can be provided in open comment boxes.

To provide you with sufficient context, each solution is described in brief ‘fiches’. These include a description of the underpinning problem and rationale for the solution, its objectives, foreseen added value and how it may impact different stakeholder groups. Please understand that these fiches are necessarily short and thus somewhat reductive; they cannot capture the full range of considerations or implications. Rather, the development of such nuance will be supported by your input and will be part of the final set of proposed solutions. In a like manner, we fully acknowledge that this survey format only gives limited room for feedback and is reductionist in its nature. This is intended as we aim to increase the level of detail with which we appraise the solutions per assessment stage. The third stage (panel discussion) will give sufficient room to discuss the solutions extensively and reflect stakeholders’ impressions, opinions and contexts.

This survey, and thereby the second stage of the consultation, will be closed on 29th May 23:59 CET.



Section A: Introduction

We kindly ask you to provide basic information about the stakeholder type and organisation you represent. Your responses will be treated confidentially and fully in line with GDPR. We collect this information to better contextualise responses from different stakeholder groups. Please note that only those participants who have filled in this survey are invited for the next stages of consultation.

A1. Please indicate the stakeholder type that describes the organisation that you represent best

National Competent Authority

Industry

Health Professional

Civil Society Organisation

Other

Other

A2. Please indicate the name of the organisation that you represent

A3. Please indicate your name (optional)



Section B: Definition

Proposed Solution(s)

i) Establish and follow a centralised and harmonised EU-wide definition of medicine shortages

Description

Currently, definitions of a medicine shortage differ between Member States as well as between stakeholders. The lack of a unified definition hampers the coordination of a common approach across the EU, which is crucial for many of the solutions presented in the following.

A centralised and harmonised definition of shortages across the EU could improve understanding of the scope and nature of shortages in the EU and provide a better basis for the development of policy solutions.

General objectives

Create and follow a centralised and harmonised EU-wide definition of medicine shortages that enables a common understanding of the issue and facilitates the development of policy solutions.

Value added

Establishing and mainstreaming a standardised definition has the potential to improve the handling and mitigation of shortages. For instance, standardised definitions may enable standardised reporting and monitoring standards, which can facilitate the communication and monitoring of shortages across the EU.

B1. i) Establish and follow a centralised and harmonised EU-wide definition of medicine shortages

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EU-added value The proposed solution yields more value if implemented at EU level than at Member State level	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Coherence The proposed solution complements other solutions and does NOT create unnecessary duplication	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unintended consequences The proposed solution does NOT pose major risks of unintended negative effects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ease of implementation There are NO major obstacles to the implementation of the proposed solution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Urgency of implementation The proposed solution should be implemented as a matter of priority	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>



B2. If you wish to elaborate on your response, you may add clarifying comments.

The definition should include a length of time during which the medicine is missing (72h for example as in France) and also include the impact on the patients, no matter the cause.

Amandine.Courtin
2021-05-27 14:54:21

The definition should include a length of time which the medicine is missing (72h for example) and also include the impact on the patients. It is a matter of high priority to have an EU wide definition.



Section C: Monitoring & Notification (1/4)

Proposed Solution(s)

- i) Establish and mainstream centralised reporting criteria for shortages

Description

At present, the criteria for reporting shortages differ greatly between European Member States. This hinders the comprehensive understanding of the issue. It also creates inefficiencies in the national reporting systems. Whilst harmonised and centralised reporting will not prevent the occurrence of shortages per se, improved information sharing through timely and standardised reporting may improve understanding of the nature and causes of shortages.

Standardised reporting requirements for shortages could thus be agreed on and implemented. Reporting criteria to consider could involve the (expected) duration of a shortage, the criticality of a medicine, availability of alternatives and the relation between supply and demand. The reporting process should ultimately avoid duplication of reporting and be concise and consistent in the data required.

General Objectives

Better exchange of information and interoperability thereof through centralised and harmonised reporting criteria. National reporting systems may therefore be streamlined and fed into, bundled or centralised in an EU-wide interface.

Value added

Similar to a centralised definition of shortages addressed previously, agreed reporting criteria can foster communication, system reliability, functionality and resilience. Downstream benefits, such as higher predictability or better-informed decision making in case of a shortage, are further anticipated.

C1. i) Establish and mainstream centralised reporting criteria for shortages

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EU-added value The proposed solution yields more value if implemented at EU level than at Member State level	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Coherence The proposed solution complements other solutions and does NOT create unnecessary duplication	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unintended consequences The proposed solution does NOT pose major risks of unintended negative effects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Ease of implementation There are NO major obstacles to the implementation of the proposed solution	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Urgency of implementation The proposed solution should be implemented as a matter of priority	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>



C2. If you wish to elaborate on your response, you may add clarifying comments.

It would enable better information, better reporting and result in better information for patients.

Centralised and harmonised reporting criteria would enable smoother information sharing, a clearer understanding of the information being reported, and it would ultimately result in better treatment management for patients.



Section D: Monitoring & Notification (2/4)

Proposed Solution(s)

i) Increase the transparency of supply chains by use of appropriate systems and tools

Description

Currently, the systems and tools used by authorities in Member States differ greatly in their level of sophistication. The information contained in systems thus varies in both content and quality. As a result, it is difficult to get a good and full understanding of the issue of shortages at the level of the EU. To improve this understanding and facilitate greater collaboration between Member States in preventing and mitigating shortages, systems could be centralised or their interoperability improved. This requires development of standards for data reporting (e.g. what data to provide, in which formats) and a technical interface that allows systems to be connected. The system could further benefit from the incorporation of analytical tools and platforms for communication between authorities.

Feeding into this technical interface is a supply chain monitoring and tracking system. This may include transparent supply registers or contracts, for instance. Attention needs to be paid to greatest possible transparency for all stakeholders, while respecting General Data Protection Regulations (GDPR).

In addition to the infrastructure needed to implement such technical systems (both, hard- and software), staff maintaining these interfaces (e.g. databases) is necessary, and different stakeholders need to be trained on how to report information to ensure coherence and workability.

General Objectives

The aim is to improve the quality and quantity of data available regarding shortages and improve information sharing between Member States, as well as between different groups of stakeholders. Through this, strategies to prevent and mitigate shortages can be improved and evaluated.

Value added

The timely adoption of measures and subsequent identification of disruptions along the supply chain is key for health authorities to mitigate the impact of shortages or prevent them altogether.

D1. i) Increase the transparency of supply chains by use of appropriate systems and tools

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EU-added value The proposed solution yields more value if implemented at EU level than at Member State level	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Coherence The proposed solution complements other solutions and does NOT create unnecessary duplication	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Unintended consequences The proposed solution does NOT pose major risks of unintended negative effects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Ease of implementation There are NO major obstacles to the implementation of the proposed solution	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Urgency of implementation The proposed solution should be implemented as a matter of priority	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>



D2. If you wish to elaborate on your response, you may add clarifying comments.

Information sharing is key. To be efficient, reporting for the MAH should be made compulsory and not voluntary in order to ensure that all stakeholders alongside the chain have the correct info. This is crucial for to ensure continuity of treatments for patients.

Timely information sharing is key. The MAH should be obliged to report information about shortages before the problem occurs. Currently, it is voluntary and it is not sufficient to tackle shortages. This would ensure that all stakeholders alongside the chain have the correct information and this would contribute to the continuity of treatments for patients.



Section E: Monitoring & Notification (3/4)

Proposed Solution(s)

i) Strengthen and enforce notification obligations

Description

Member States typically have requirements in place for marketing authorisation holders and wholesaler-distributors to report any shortage at the national level. The advance warning of a shortage they are expected to give may vary. However, in most cases shortages are only notified at the time of their first occurrence or even after. Consequently, prescribers and pharmacists have not had time to prepare for mitigation of the impact of shortages. Existing notification requirements are typically not enforced in the sense that penalties are levied when notification is delayed. The information provided with the reported shortage may also be complete.

To improve information sharing and preparedness against shortages, additional notification obligations – both voluntary and compulsory – could be introduced and enforcement of existing obligations improved. These may include earlier notification requirements or standardised reporting mechanisms.

General Objectives

Identify (prospective) shortages as early as possible to better prepare for their consequences. Create a better and more stringent reporting compliance by effectively enforcing obligations.

Value added

Monitoring, identifying, reacting to, and effectively mitigating or preventing prospective shortages is one of the key aspects in dealing with medicine shortages. Having reliable and timely information from relevant supply chain stakeholders is a prerequisite for effective monitoring. The sooner this information can be gathered, the greater the options for corrective measures.

E1. i) Strengthen and enforce notification obligations

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EU-added value The proposed solution yields more value if implemented at EU level than at Member State level	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Coherence The proposed solution complements other solutions and does NOT create unnecessary duplication	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unintended consequences The proposed solution does NOT pose major risks of unintended negative effects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Ease of implementation There are NO major obstacles to the implementation of the proposed solution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Urgency of implementation The proposed solution should be implemented as a matter of priority	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>



E2. If you wish to elaborate on your response, you may add clarifying comments.

Transparency should be made compulsory. A system of obligations and sanctions need to be fostered.

Notification obligations should be only compulsory or we would continue to have in Europe different reporting systems. A system of obligations and sanctions should be in place as this would increase the accountability and responsibility across the supply chain. Earlier notification requirements and standardised reporting mechanisms should be fostered also by using the European Health Data Space. It will be therefore critical to equip member states with the right competencies and capabilities to made the system work.



Section F: Monitoring & Notification (4/4)

Proposed Solution(s)

i) Develop an EU-wide list of medicines for which shortages are the most critical and develop policies and/or regulations to improve their availability

Description

Most shortages can usually be resolved at the level of the pharmacy, either by sourcing the medicine through other channels (such as parallel import) or by dispensing an alternative medicine. Whilst such shortages create a lot of hassle costs for pharmacists and physicians and substitutes may pose risks for reduced treatment adherence or decreased effectiveness, the consequences are usually not critical. Shortages of potentially life-saving medicines, particularly when there are no suitable alternatives, may have far greater impact. In this sense, not all shortages are equal. To prevent or mitigate the effects of shortages of such critical medicines, separate mechanisms could be introduced to safeguard their supply. Possible measures include strategic stockpiling, joint procurement or other legislative measures to improve availability.

As a first step, agreement is needed on which medicines should be included in such mechanisms. Therefore, a central list of most critical medicines could be developed for all EU Member States. Criteria to consider for determining criticality may include the size of the potentially affected patient population, the vulnerability of supply, the complexity of production, medical necessity, and the ability to substitute.

General Objectives

Member States share information to identify and prioritise critical medicinal products. The resulting list or database would then serve as a basis for addressing shortages and ensuring a tailored approach with reasonable and appropriate mitigation measures.

Value added

Having a centralised list of critical medicines across all EU Member States enables better screening and oversight of medicine shortages that could have a particularly detrimental impact on the health of patients. Mitigatory efforts can be coordinated in a more comprehensive manner between Member States as a result.

F1. i) Develop an EU-wide list of medicines for which shortages are the most critical and develop policies and/or regulations to improve their availability

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EU-added value The proposed solution yields more value if implemented at EU level than at Member State level	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Coherence The proposed solution complements other solutions and does NOT create unnecessary duplication	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unintended consequences The proposed solution does NOT pose major risks of unintended negative effects	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ease of implementation There are NO major obstacles to the implementation of the proposed solution	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Urgency of implementation The proposed solution should be implemented as a matter of priority	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>



F2. If you wish to elaborate on your response, you may add clarifying comments.

As a matter of coherence with others solutions suggested in this document, these medicines could be qualified as medicines as major therapeutic interests. Specific regulations should be linked to these medicines: stockpiling obligations, specific prevention and mitigations plans. Because these medicines are of major therapeutic interests, sanctions should be applied when obligations from the MAH are not met.



Section G: Prevention / Mitigation Plan

Proposed Solution(s)

i) Require suppliers to have adequate shortage prevention or mitigation plans in place

Description

Marketing authorisation holders and wholesalers have a responsibility to ensure the continued supply of medicines to the best of their ability. As part of this responsibility, they could be required to submit shortage mitigation and prevention plans to the regulatory authorities. Such strategies could outline, for example, approaches to handling a shortage, steps to mitigate the core issue, prospective action-timelines or information on alternatives in case a shortage occurs. Furthermore, they could include clear communication guidelines and channels which can become activated in case of a shortage (e.g. how will NCAs, practitioners or other stakeholders be informed?). Legal obligations on MAHs to develop shortage mitigation or prevention plans already exist in several countries, e.g. France.

Pharmacists are the final link in the supply chain and connect directly to the patient. As such, they have a large role to play in mitigating the impact of a shortage at the patient level. To assist them in such efforts, they could be encouraged and equipped to develop prospective risk assessments, considering the potential impact of a shortage and any actions that could be taken to either obtain a product another way or offer appropriate substitutes. For this, they will require access to clear communication and notification channels through which they can signal (impending) shortages to responsible authorities and receive intelligence and insight for their own practices.

The development of appropriate shortage mitigation strategies, whether by pharmacists, manufacturers or national authorities, requires insight into expected and realised demand and supply throughout the supply chain. This insight would allow shortages to be observed – and potentially prevented – in real-time and potentially even show where a product could still be sourced. To achieve this, more use could be made of national and EU competent authorities’ data repositories. One such data repository that has been suggested is the European Medicines Verification System, which was set up in the context of the EU Falsified Medicines Directive.

General Objectives

A clear placement of responsibility is sought so that shortages can be anticipated and handled systematically, efficiently, and urgently.

Value added

With more mitigation and prevention mechanisms in place, the entire supply chain could become more robust. The mechanisms devised should follow streamlined principles, be interoperable and cascade into each other. Information from forecasts and assessments is crucial for all stakeholders along the supply chain to ensure supply and facilitate planning of aspects such as manufacturing capacity and distribution arrangements.

G1. i) Require suppliers to have adequate shortage prevention or mitigation plans in places

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EU-added value The proposed solution yields more value if implemented at EU level than at Member State level	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Coherence The proposed solution complements other solutions and does NOT create unnecessary duplication	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unintended consequences The proposed solution does NOT pose major risks of unintended negative effects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ease of implementation There are NO major obstacles to	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



G2. If you wish to elaborate on your response, you may add clarifying comments.

Mitigation and prevention plan should be public, compulsory and with sanctions attached if not done



Section H: Supply Chain Resilience

Proposed Solution(s)

i) Introduce measures to create an economic and regulatory framework incentivising the diversification of production of APIs, raw materials and medicines

Description

Even in a market where there are multiple suppliers of a (generic) medicinal product, these suppliers frequently rely on raw materials and active pharmaceutical ingredients from a very limited number of sources. Any disruptions to the operations of these upstream suppliers thus can have large scale domino effects on the manufacturers who rely on their products. Insufficiently diversified supply chains are thus much more vulnerable to disruption and may result in shortages.

Furthermore, at present a large part of all APIs and raw materials are produced in non-EU countries, which leads to limited oversight and control over supply chains. Non-EU based production also means that the supply of medicines to the EU is at increased risk from export bans or from events and policies that affect operations elsewhere. This was illustrated by the COVID-19 pandemic when API production in China was suspended due to local lock-downs.

A possible strategy to reduce the risk of shortages is thus to introduce measures that incentivise the diversification of the production of APIs, raw materials and medicines. These measures could be both economic and legislative nature. Economic measures may involve subsidies, grants or tax breaks, whilst regulations could be introduced to mandate MAHs to source materials from multiple suppliers.

General Objectives

The objective is to ensure the supply and supply chain resilience of APIs, raw materials and medicines to the greatest extent possible.

Value added

More diverse supply sources may enable greater shock resilience and flexibility in preventing and mitigating shortages. This effect could be boosted through increased local production of APIs, reducing the dependency on third markets, and minimising the length and complexity of supply chains.

H1. i) Introduce measures to create an economic and regulatory framework incentivising the diversification of production of APIs, raw materials and medicines

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EU-added value The proposed solution yields more value if implemented at EU level than at Member State level	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Coherence The proposed solution complements other solutions and does NOT create unnecessary duplication	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Unintended consequences The proposed solution does NOT pose major risks of unintended negative effects	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ease of implementation There are NO major obstacles to the implementation of the proposed solution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Urgency of implementation The proposed solution should be implemented as a matter of priority	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>



H2. If you wish to elaborate on your response, you may add clarifying comments.

Incentives must be used for medicines in shortages and not high price innovative medicines
Strong conditions should be linked to these incentives.

It is important to differentiate medicines into different categories (generics, biosimilar, small molecules, etc). Incentives should be foreseen for medicines that are oftentimes in shortage for the reasons that the previous survey identified. High-priced medicines are produced largely already in Europe and do not suffer from shortage per se. the problem with their availability is around their high prices. If MAHs are provided with incentives to strengthen the supply chain, strong conditions should be linked to these incentives.

Section I: Supply Obligation

Proposed Solution(s)

- i) Introduce a ‘PSO-responsible-pay’ principle and grant a right to be supplied to wholesalers who are under a PSO**

Description

A Public Service Obligation (PSO) specifies that there should be an “obligation placed on wholesalers to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question.” PSO-responsible pay defines an obligation for suppliers to pay the price difference (if positive) between emergency or parallel imports and the normal reimbursement price for products in shortage.

Whether suppliers are required to pay this difference may depend on the specifics of the situation that led to the shortage and on the efforts made by the supplier to prevent or mitigate the situation. A more measured approach may also help to prevent situations in which any potential risk margins and penalty fees will be included in the medicinal products’ retail price and thereby be shifted onto the health insurers and patients.

- i) Introduce a ‘PSO-responsible-pay’ principle and grant a right to be supplied to wholesalers who are under a PSO**

Disagree Somewhat Disagree Neither Disagree nor Agree Somewhat Agree Agree Don't Know

EU-added valueThe proposed solution yields more value if implemented at EU level than at Member State level

CoherenceThe proposed solution complements other solutions and does NOT create unnecessary duplication

Unintended consequencesThe proposed solution does NOT pose major risks of unintended negative effects

Ease of implementationThere are NO major obstacles to the implementation of the proposed solution

Urgency of implementationThe proposed solution should be implemented as a matter of priority



I2. If you wish to elaborate on your response, you may add clarifying comments.



Section J: Supply Quota

Proposed Solution(s)

i) Require greater transparency of industry supply quotas as well as parallel traders' and wholesalers' transactions

Description

Supply quotas are set by marketing authorisation holders to define the quantity of a certain medicine with which they supply a wholesaler or other relevant actor throughout the supply chain. Marketing authorisation holders state that supply quotas allow them to better regulate the distribution of medicines across countries to ensure that patient demands are met. In doing so, supply quotas have the effect of limiting parallel exportation from certain countries. Supply quotas are thus seen as contrary to the functioning of the internal EU market. They could be justified only if there is a clear and justified reason, such as production problems, that would warrant rationing. In such circumstances quotas should be sufficiently transparent and flexible to account for normal market fluctuations. However, in practice, wholesalers are not always informed of how much stock they will receive per week or month, so-called 'black-box quotas'.

Supply quotas have been linked to shortages, when wholesalers are not able to fulfil orders because their quotas have been reached. These types of shortages are usually resolved relatively quickly, as the manufacturer can resupply wholesalers-distributors at the start of the next supply period.

General Objectives

When supply quotas are not transparently defined and communicated, wholesaler-distributors are not able to foresee supply problems or inform pharmacies and authorities of their inability to supply in a timely way. Greater transparency on quotas would enable wholesaler-distributors to predict shortages and inform pharmacies accordingly, so that they may take timely action to mitigate the impact of the expected shortage.

Value added

Greater transparency is expected to translate into better predictability and planning, which, in turn, is expected to prevent shortages more systematically.

J1. i) Require greater transparency of industry supply quotas as well as parallel traders' and wholesalers' transactions

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EU-added value The proposed solution yields more value if implemented at EU level than at Member State level	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Coherence The proposed solution complements other solutions and does NOT create unnecessary duplication	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unintended consequences The proposed solution does NOT pose major risks of unintended negative effects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ease of implementation There are NO major obstacles to the implementation of the proposed solution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Urgency of implementation The proposed solution should be implemented as a matter of priority	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



J2. If you wish to elaborate on your response, you may add clarifying comments



Section K: Parallel Trade

Proposed Solution(s)

- i) Allow for greater flexibilities for emergency imports of specific products in case of market withdrawals and other critical shortages
- ii) Adopt common principles for the introduction of national restrictions on export

Description

The parallel exportation of medicines from one Member State to another is often considered a contributor to the occurrence of shortages. However, under the right circumstances, emergency imports can also be used to mitigate shortages when medicines are moved from a country where they remain in surplus to one where there is an acute and critical shortage. Hence, policymakers may consider making use of the parallel import framework provided by the EU and national legislation. Practical evidence suggests that in case of shortages, excess stocks of the medicine in question are typically available elsewhere.

To prevent excessive stock held in some EU Member States while others are experiencing shortages, common principles may be adopted that lay the foundation for export restrictions or the reduction thereof. Member States may therefore be requested to abolish the distortive effects of national schemes incentivising parallel imports and instead promoting the application of the non-extraterritoriality principle.

General Objectives

Reach better control over, and greater transparency of supply and stocks and the management thereof between Member States.

Value added

In the context of parallel trade, a functioning and efficient framework between EU Member States has the potential to alleviate shortages in a short timeframe or prevent them in the first place. The quantities of parallelly traded medicines are usually not traceable; introducing shared liability could therefore serve as an effective control mechanism.

K1. i) Allow for greater flexibilities for emergency imports of specific products in case of market withdrawals and other critical shortages

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EU-added value The proposed solution yields more value if implemented at EU level than at Member State level	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Coherence The proposed solution complements other solutions and does NOT create unnecessary duplication	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Unintended consequences The proposed solution does NOT pose major risks of unintended negative effects	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ease of implementation There are NO major obstacles to the implementation of the proposed solution	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Urgency of implementation The proposed solution should be implemented as a matter of priority	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



K2. ii) Adopt common principles for the introduction of national restrictions on export

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EU-added valueThe proposed solution yields more value if implemented at EU level than at Member State level	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
CoherenceThe proposed solution complements other solutions and does NOT create unnecessary duplication	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unintended consequencesThe proposed solution does NOT pose major risks of unintended negative effects	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ease of implementationThere are NO major obstacles to the implementation of the proposed solution	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Urgency of implementationThe proposed solution should be implemented as a matter of priority	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

K3. If you wish to elaborate on your response, you may add clarifying comments



Somewhat Disagree

Neither	Somewhat	D
r	Agree	Agree
Disagree		n
e nor		'
Agree		t
		K
		n
		o
		w



L2. ii) Develop EU legislation allowing for greater flexibility of Member States to impose financial sanctions if notification requirements are not met

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EU-added valueThe proposed solution yields more value if implemented at EU level than at Member State level	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CoherenceThe proposed solution complements other solutions and does NOT create unnecessary duplication	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unintended consequencesThe proposed solution does NOT pose major risks of unintended negative effects	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ease of implementationThere are NO major obstacles to the implementation of the proposed solution	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Urgency of implementationThe proposed solution should be implemented as a matter of priority	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

L3. If you wish to elaborate on your response, you may add clarifying comments.

Whilst the objective is noble, the flexibility allowed across the EU could increase inequalities in the availability of medicines for the level of flexibility that would differ from country to country.
The EU legislation should push MS to put in place financial sanctions.
Overall, we disagree with the proposed solutions.



Section M: Procurement & Tendering (1/2)

Proposed Solution(s)

i) Incorporate requirements for having more diversified, multiple tenderers and thereby supply sources in public procurement tenders

Description

Procurement practices can have a major impact on the medicines supply chain. Some current practices, aimed primarily at reducing healthcare expenditure on medicine, can directly affect market dynamics and the level of competition. For instance, tenders that are evaluated primarily on price, without due consideration for other issues such as multi-sourcing, may force prices down to the level where it is no longer attractive for potential bidders to remain in a market. This reduces the competition and leaves markets vulnerable when remaining suppliers experience disruptions.

A similar effect can be seen with “winner-takes-all” tenders, whereby the winning bidder becomes the sole supplier to a market for a given time period for a specific product. Losing tenderers may decide to stop production (and potentially not renew the marketing authorisation) for that medicine all together as their overall market has become too small to be economically attractive. This again has the effect of thinning out competition, leaving the market dependent on a single or only few suppliers and reduces the absorptive capacity in case of demand shocks or production problems.

Potential solutions thus lie in smaller and more frequent tenders and reduced use of ‘winner-takes-all’ tenders. Procurers could furthermore be encouraged or even obligated to evaluate tenders not only on price but also on criteria such as supply chain robustness. Procurement contracts could have built in security provisions, specifying how the provider intends to protect against the risk of shortages and how these would be mitigated should they occur.

General Objectives

More holistic tendering practices, greater efficiency and supply reliability. Centralised/pooled procurement, is set to maximise the bargaining power which is expected to facilitate a more resilient supply chain and less frequent shortages.

Value added

More strategic and fair procurement is expected to translate into less dependency on single manufacturers and wholesalers and thereby greater supply chain resilience, which is complemented by a generally more strategic approach to tendering.

M1. i) Incorporate requirements for having more diversified, multiple tenderers and thereby supply sources in public procurement tenders

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EU-added value The proposed solution yields more value if implemented at EU level than at Member State level	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Coherence The proposed solution complements other solutions and does NOT create unnecessary duplication	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Unintended consequences The proposed solution does NOT pose major risks of unintended negative effects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Ease of implementation There are NO major obstacles to the implementation of the proposed solution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Urgency of implementation The proposed solution should be implemented as a matter of priority	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



M2. If you wish to elaborate on your response, you may add clarifying comments.

Centralised/pooled procurement, is set to maximise the bargaining power which is expected to facilitate a more resilient supply chain and less frequent shortages.



Section N: Procurement & Tendering (2/2)

Proposed Solution(s)

i) Introduce legal obligations for MAHs and wholesalers to maintain a safety stock for medicines of major therapeutic interest at EU-level

Description

Efforts to prevent or respond to shortages in one country may have the unwanted by-effect of increasing (the risk of) shortages in another. Excessive stockpiling of medicines at national or sub-national levels represents perhaps the clearest example of how actions by individual Member States can impact on product availability elsewhere. Whilst a certain level of stockholding is a normal aspect of responsible supply chain management, countries also engage in building up greater stock of critical medicines to prepare for unexpected events, such as sudden supply chain disruptions or surge demand (e.g. as part of epidemic preparedness).

When there is a limited overall supply of such medicine, national stockpiling could mean that other countries, in particular those with lower purchasing and negotiation power, cannot be sufficiently supplied anymore. Products that are kept in national (or regional) stockpiles cannot easily be redistributed to other markets in need, due to country-specific packaging and labelling requirements. The normal relation between supply and demand can also be distorted when countries procure a product well in excess of estimated demand for other reasons, such as for parallel exportation. For equitable product availability between Member States, it is thus important that there is a clear and transparent relation between supply and demand and that individual Member States are discouraged from locking in critical supplies through excessive stockpiling.

Although excessive national or regional stockpiling is counter to equitable access, holding sufficient stock of medicines of major therapeutic interest can be an effective tool to protect against shortages, if done at a sufficiently high level (such as at EU-level) and when managed properly. Marketing authorisation holders and/or wholesalers could be obligated to hold sufficient stock, not only of finished products but potentially also of raw materials and of unfinished/unpackaged products that can be prepared to meet specific national requirements. Stockholding can also be centrally coordinated at the EU-level for particular products. In 2020, against the backdrop of COVID-19, the Commission introduced the first strategic EU-coordinated stockpile (rescEU) for medical equipment, vaccines and therapeutics. For other medicinal products thus far a coordinated approach to stockpiling at the EU-level does not exist.

General Objectives

Build strategic stockpiles for medicines of major therapeutic interest that ensure sufficient product availability but without increasing unequitable distribution between Member States.

Value added

A coordinated stockpiling obligation for certain raw materials, active pharmaceutical ingredients and critical medicines may enhance the EU's preparedness for unexpected supply disruptions

N1. i) Introduce legal obligations for MAHs and wholesalers to maintain a safety stock for medicines of major therapeutic interest at EU-level

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EU-added value The proposed solution yields more value if implemented at EU level than at Member State level	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Coherence The proposed solution complements other solutions and does NOT create unnecessary duplication	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Unintended consequences The proposed solution does NOT pose major risks of unintended negative effects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ease of implementation There are NO major obstacles to the implementation of the proposed solution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



N2. If you wish to elaborate on your response, you may add clarifying comments

This solution should be linked to the one about critical medicines. The mandatory constitution of safety stocks of medicines by market authorisation holders is an important measure. They should go hand in hand with a closer cooperation and coordination among Member States, and with the transparency of available stocks proposed in the Pharmaceutical Strategy to guarantee a fair distribution of medicines across the EU.



Section O: Pharmacies' Role

Proposed Solution(s)

- i) Allowing pharmacies to substitute medicines (generics or more expensive INNs) or supply a part of a unit pack to avoid waste in case of shortages
- ii) Include information about available alternative medicines in shortage databases

Description

In many cases, if a prescribed medicine is not available in the exact strength and formulation indicated on the prescription, pharmacists do not have the authority to instead issue another variation of the product. Moreover, they usually cannot issue a therapeutic alternative (i.e. a medicine with the same or a similar therapeutic profile but containing a different active ingredient). In such cases, the pharmacist needs to contact the prescriber to discuss an appropriate alternative and a new prescription needs to be issued. This creates significant additional work for both the pharmacist and the prescriber and can result in delays in dispensing of the medicine to the patient.

A potential solution to mitigate the impact of shortages, is to enable pharmacists to independently decide on appropriate substitutions for a medicine in shortage and dispense this directly to the patient without further consultation with a prescriber. This would decrease the administrative and cost burden on the involved health professionals and decrease the impact on the patient. Competent authorities could thus consider extended the mandate for pharmacists to independently issue substitutions, whilst clarifying the conditions under which such substitution would and would not be allowed.

To enable these mitigative measures, more systematic and better information is needed about the availability and suitability of substitutes. Therefore, shortage databases could also provide information about available alternative medicines that may be dispensed if a shortage occurs. These alternatives will be decided upon a-priori by competent authorities.

Besides dispensing available substitutes, it is also possible for pharmacists to produce medicines that are in shortage directly or to have these produced in compounding pharmacies. For patented medicines, this is allowed only under a prescribed set of conditions and only for the pharmacy's own patient population. Expanding the regulatory framework to increase the scope for use of pharmacy preparations could help reduce shortages provided raw materials are still available.

General Objectives

The aim is to have a more efficient and resilient mitigation infrastructure in place at the very end of the supply chain, at the interface between pharmacies and patients.

Value added

Granting pharmacists greater flexibility in case of a shortage helps them address shortages more directly and mitigate them efficiently, thereby enhancing the capacity to respond to shortages.

Evidence (optional)

The British Medical Association recently adopted a policy proposing that pharmacists should be given the mandate to dispense an "equivalent dose of an appropriate and available alternative medicine" if the initially prescribed medicine is not available. In a similar vein, pharmacists are allowed to perform therapeutic interchanges in several jurisdictions in Canada as well as in several other countries worldwide.

- 01. i) Allowing pharmacies to substitute medicines (generics or more expensive INNs) or supply a part of a unit pack to avoid waste in case of shortages**



O2. ii) Include information about available alternative medicines in shortage databases

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EU-added value The proposed solution yields more value if implemented at EU level than at Member State level	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Coherence The proposed solution complements other solutions and does NOT create unnecessary duplication	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Unintended consequences The proposed solution does NOT pose major risks of unintended negative effects	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Ease of implementation There are NO major obstacles to the implementation of the proposed solution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Urgency of implementation The proposed solution should be implemented as a matter of priority	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

O3. If you wish to elaborate on your response, you may add clarifying comments

The latest solution should not be applied to medicines of major therapeutic interest.

The latest solution should not be applied to medicines of major therapeutic interest. It is also true that currently pharmacists cannot substitute the medicine prescribed should this be in shortage. A database with suggestions for substitutions would speed up the process. Nevertheless, this should also come with legal protection for pharmacists should an adverse effect occur otherwise the pharmacist is not likely to substitute the medicines prescribed even if allowed. Also, it is important to consider that the substitute medicine is intended in the first place for another category of patients which should not risk having their medicine in shortage (e.g., during the covid-19 crisis a large number of corticosteroids were used in ICUs to treat patients but these, normally, are produced in certain amount to fulfill certain needs).



Section P: Authorisation, Approval & Recognition (1/2)

Proposed Solution(s)

- i) Enable a (more) efficient Repeat Use Procedure
- ii) Enable an accelerated mutual recognition procedure within the EU

Description

The Repeat Use Procedure is defined as “the use of the Mutual Recognition Procedure (MRP) after the completion of a first MRP or Decentralised Procedure (DCP) for the recognition of a marketing authorisation by other Member States. This means that a marketing authorisation holder may use the MRP several times for the same marketing authorisation, once the first MRP is complete, to include additional Member States that were not involved in the initial MRP” (CMDh, 2020).

The MRP is a European marketing authorisation procedure based on the principle of recognition of the evaluation performed by the reference Member State. If a European Member State has already issued a marketing authorisation, other Member States may refer to, and rely on this authorization instead of having to run their own authorisation procedures.

General Objectives

Avoiding lengthy procedures and double testing through Repeat Use and / or Mutual Recognition Procedures.

Value added

Greater efficiency in authorisation procedures, which may, for instance, facilitate emergency imports while reducing costs.

P1. i) Enable a (more) efficient Repeat Use Procedure

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EU-added valueThe proposed solution yields more value if implemented at EU level than at Member State level	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
CoherenceThe proposed solution complements other solutions and does NOT create unnecessary duplication	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Unintended consequencesThe proposed solution does NOT pose major risks of unintended negative effects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Ease of implementationThere are NO major obstacles to the implementation of the proposed solution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Urgency of implementationThe proposed solution should be implemented as a matter of priority	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>



P2. ii) Enable an accelerated mutual recognition procedure within the EU

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EU-added valueThe proposed solution yields more value if implemented at EU level than at Member State level	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CoherenceThe proposed solution complements other solutions and does NOT create unnecessary duplication	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unintended consequencesThe proposed solution does NOT pose major risks of unintended negative effects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ease of implementationThere are NO major obstacles to the implementation of the proposed solution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Urgency of implementationThe proposed solution should be implemented as a matter of priority	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

P3. If you wish to elaborate on your response, you may add clarifying comments



Section Q: Authorisation, Approval & Recognition (2/2)

Proposed Solution(s)

i) EU authorities reduce the administrative and cost burden submission of post-approval changes

Description

Any time a manufacturer changes the production of a medicine, for instance because ingredients are sourced from new suppliers or because the production method has changed, they need to submit an application for a post-approval change (PAC). Delays in obtaining PAC approval have been linked to the occurrence of shortages. More efficient handling of PACs, such as through expedited review, is thus seen as a way to prevent shortages.

General Objectives

Ensuring the supply of older molecules which may still have high therapeutical but limited commercial relevance. In addition, to initiate further cost-reducing procedural adjustments that in turn serve as incentives for multiple stakeholders throughout the supply chain, particularly MAHs, wholesalers or manufacturers.

Value added

Greater commercial incentives for the abovementioned stakeholder groups may translate into greater supply reliability

Q1. i) EU authorities reduce the administrative and cost burden submission of post-approval changes

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EU-added value The proposed solution yields more value if implemented at EU level than at Member State level	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Coherence The proposed solution complements other solutions and does NOT create unnecessary duplication	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Unintended consequences The proposed solution does NOT pose major risks of unintended negative effects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Ease of implementation There are NO major obstacles to the implementation of the proposed solution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Urgency of implementation The proposed solution should be implemented as a matter of priority	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Q2. If you wish to elaborate on your response, you may add clarifying comments

Any changes in the production of a medicine need to be proofed with robust evidence and justifiable . The impact on the production chain and potential disruptions should be clearly communicated to all stakeholders in order for the patients to have the correct information



R2. If you wish to elaborate on your response, you may add clarifying comments

Digital leaflets can be an addition to the traditional leaflet in paper but they cannot substitute them. Patients, especially the elderly, are not acquainted enough to retrieve information online if needed

Digital leaflets can be an addition to the traditional leaflet in the paper but they cannot substitute them. Patients, especially the elderly, are not acquainted enough to retrieve information online if needed. Digitalisation is too fragmented in Europe and this would bring major issues in geographical areas where the internet is not common. The covid-19 pandemic showed how some regions in Europe do not have access to the internet for studying from home, for instance. The EU should not take the risk of putting patients health and safety in danger by looking only at digital leaflets.



Section S: Dialogue

Proposed Solution(s)

i) Set up stakeholder dialogue platforms for/between supply chain stakeholders, patients and healthcare providers, respectively at Member States level

Description

Information sharing is crucial in solving the problem of medicines shortages. This includes information sharing between Member States but also between regulators, supply chain actors, pharmacists and patients, both at national and EU level. These stakeholders need to continuously share information and perspectives on the issue to discuss and plan the response to national and European shortages. To do so, coordination platforms should be set up by the national/European health authorities responsible for shortage mitigation and response.

General Objectives

To improve information sharing between the various actors in the supply chain as well as the national authorities, prescribers, and patients.

Value added

Greater communication between the supply chain actors as well as national and healthcare stakeholders could help create a greater sense of shared responsibility, ultimately leading to improved understanding of mutual issues and challenges in relation to shortages. This in turn, will lead to a more coherent response to and mitigation of shortages.

S1. i) Set up stakeholder dialogue platforms for/between supply chain stakeholders, patients and healthcare providers, respectively at Member States level

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EU-added value The proposed solution yields more value if implemented at EU level than at Member State level	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Coherence The proposed solution complements other solutions and does NOT create unnecessary duplication	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unintended consequences The proposed solution does NOT pose major risks of unintended negative effects	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ease of implementation There are NO major obstacles to the implementation of the proposed solution	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Urgency of implementation The proposed solution should be implemented as a matter of priority	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>



S2. If you wish to elaborate on your response, you may add clarifying comments

These dialogue platforms should not be in competition with the already existing ones. Best practices could be exchange between these different dialogue platforms.

Section T: Before you Leave

You have now almost reached the end of this survey. Please note that your responses have not been submitted yet. If you wish, you may now go through your responses again by using the “Previous” button at the bottom of each page. However, if you do so, please make sure to return to this page and select “Submit” to submit your responses. Unless you have submitted your responses, your input will not be recorded.

On the following page, after having submitted your responses, you have the option of saving a record of your responses by selecting “Print your answers.”

Thank you very much for your participation.

Your input is greatly appreciated and very valuable to the study’s success, and further decision making at the European level. We will now analyse your responses to prioritise solutions and further develop them.