



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. Based on data collected in the preceding phases of the study, a large number of potential solutions, aimed at preventing or mitigating the impact of shortages, have been identified. To further appraise and develop these solutions, a three-stage consultation is being conducted with key stakeholders. We kindly ask you for assistance in this consultation process by completing the assessment of the solutions through completing two surveys, first of which is presented to you below.

This survey, and thereby the first stage of the consultation, will be closed on 19th May 23:59 CET. In this first stage, we would welcome your professional judgment of the proposed solutions against the following four statements:

The proposed solution leads to a reduction in the occurrence and/or impact of shortages (*effectiveness*) The value that may be gained from this solution justifies the effort and resources needed for its implementation (*efficiency*) The proposed solution has a clear logical link to preventing and/or mitigating shortages (*relevance*) The proposed solution is feasible, realistic and can be implemented by relevant stakeholders (*feasibility*)

We 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’.

This includes 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. Hence, in the 1st stage (this survey), we assess a large set of solutions on a limited number of criteria, while in the 2nd stage (2nd survey), we assess a refined, smaller set of solutions against a greater number of criteria (e.g. including criteria such as coherence, value added,



## 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
<b>Effectiveness</b> The proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Efficiency</b> The value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Relevance</b> The proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b>Feasibility</b> The proposed solution is feasible, realistic and can be implemented by relevant stakeholders.	<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 of shortage is relevant as long as it is connected with obligations and sanctions should the phenomenon occur. The definition of shortage would create a predictable pharmaceutical supply chain and there would be consequences should a marketing authorisation holder not fulfill its responsibilities or cause shortages for withdrawal reasons. The definition should include a length of time during which the medicine is missing (72h for example) and also include the impact on the patients.

**Commented [AC1]:** Should the definition include a length of time during which the medicines is missing (72h for example) and also includes the impact on the patients, potentially life threatening.



## 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
<b>Effectiveness</b> The proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Efficiency</b> The value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b>Relevance</b> The proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b>Feasibility</b> The proposed solution is feasible, realistic and can be implemented by relevant stakeholders.	<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.**

The application of digital tools would surely streamline communication channels, reduce time-consuming procedures, make the system more transparent, increase accountability and not only address shortages but it would prevent them. Marketing authorisation holders would also benefit from a centralised reporting system as long as the information requested at EU level is the same requested from national authorities. The SPOC and i-SPOC system should converge to the benefit of all stakeholders.



## Section D: Monitoring & Notification (2/4)

### Proposed Solution(s)

- i) Establish and mainstream centralised and/or interoperable interfaces for monitoring shortages
- ii) 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 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) Establish and mainstream centralised and/or interoperable interfaces for monitoring shortages

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
Effectiveness The proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Efficiency The value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Relevance The proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Feasibility The proposed solution is feasible, realistic and can be implemented by relevant stakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



**D2. ii) 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
Effectiveness The proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Efficiency The value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Relevance The proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Feasibility The proposed solution is feasible, realistic and can be implemented by relevant stakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

**D3. If you wish to elaborate on your response, you may add clarifying comments.**

The objective of making the systems and tools more sophisticated in member states where this is needed, should be supported with funding opportunities foreseen with Cohesion Funds and EU4Health Programme. Funding digitalization and training of the workforce to address medicines shortage would be an investment since shortages bear a vast impact on the quality of care and it is detrimental for the healthcare system with increased hospitalization rate. Perhaps a joint action could be considered so that more advanced countries can support those that are lagging behind.



## 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	Know
<b>Effectiveness</b> The proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b>Efficiency</b> The value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b>Relevance</b> The proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Feasibility</b> The proposed solution is feasible, realistic and can be implemented by relevant stakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



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

A system of obligations and sanctions need to be fostered.



## 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
Effectiveness The proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Efficiency The value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Relevance The proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Feasibility The proposed solution is feasible, realistic and can be implemented by relevant stakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



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

Recent news reports that parallel trade impact on shortages. Moreover, the fact that physicians or pharmacist can find a solution is cumbersome, time consuming and a lack of responsibility of the marketing authorization holder should not damage other stakeholders. Joint procurement can be a way for national government to increase their bargaining power and reduce the price. Lessons can be learnt from the joint negotiation of COVID-19 vaccines. The creation of a list of critical medicines can be useful to closely monitor a set of pharmaceuticals but this doesn't necessarily address disruption of the supply chain. Looking at the size of the population possibly affected would raise ethical questions and discrimination issues. A list of critical medicines would give a basis to act and apply sanctions should shortages occur.

**Commented [AC2]:** Totally agree. For example, in France, we have this list of critical medicines (Médicaments d'Intérêts thérapeutiques Majeurs) but we still have shortages for this medicines. However, it is a good start to have this critical medicines lists (defined in the French law) as it give a basis to act. So I would push for a definition of critical medicines with sanctions applied when they are in shortages.



## Section G: Prevention / Mitigation Plan

### Proposed Solution(s)

- i) Require suppliers to have adequate shortage prevention or mitigation plans in place
- ii) Encourage pharmacists to increase the use of prospective risk assessments for the mitigation of medicines shortages
- iii) Support cooperation on national strategies for demand forecasting, planning, and shortage mitigation across the Member States

### 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

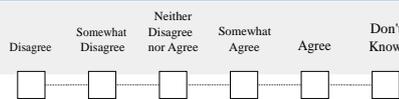
A clear placement of responsibility is sought so that shortages can be anticipated and handled systematically, efficiently, and urgently.

### Value added

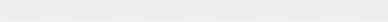
With more mitigation and prevention mechanisms in place, the entire supply chain could become more robust. The mechanisms devised should follow streamlined principles, be interoperable and cascade into each other. Information from forecasts and assessments is crucial for all stakeholders along the supply 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

Effectiveness The proposed solution leads to a reduction of shortages.



Efficiency The value gained through this solution



**Commented [AC3]:** It could help reducing shortage  
Pretty relevant measure too  
Pretty feasible also



**G2. ii) Encourage pharmacists to increase the use of prospective risk assessments for the mitigation of medicines shortages**

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
Effectiveness The proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Efficiency The value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Relevance The proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Feasibility The proposed solution is feasible, realistic and can be implemented by relevant stakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Commented [AC4]:** I don't think it is up to pharmacists to do this and I am not sure it will leads to a significant reduction of shortages.

**G3. iii) Support cooperation on national strategies for demand forecasting, planning, and shortage mitigation across the Member State**

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
Effectiveness The proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Efficiency The value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Relevance The proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Feasibility The proposed solution is feasible, realistic and can be implemented by relevant stakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Commented [AC5]:** It could lead to reduction of shortages

**G4. If you wish to elaborate on your response, you may add clarifying comments.**

Legal obligations on MAHs to develop shortage mitigation AND prevention plans should be in place. ECL wants to put an emphasis on the importance of preventing shortages and address possible causes before the disruption occurs. Mitigation plans should be accompanied by prevention plans and these should be public, compulsory and with sanctions attached if not fulfilled.

**Commented [AC6]:** Yes, and this shortage 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
- ii) Create incentives for the local production of APIs

### 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.

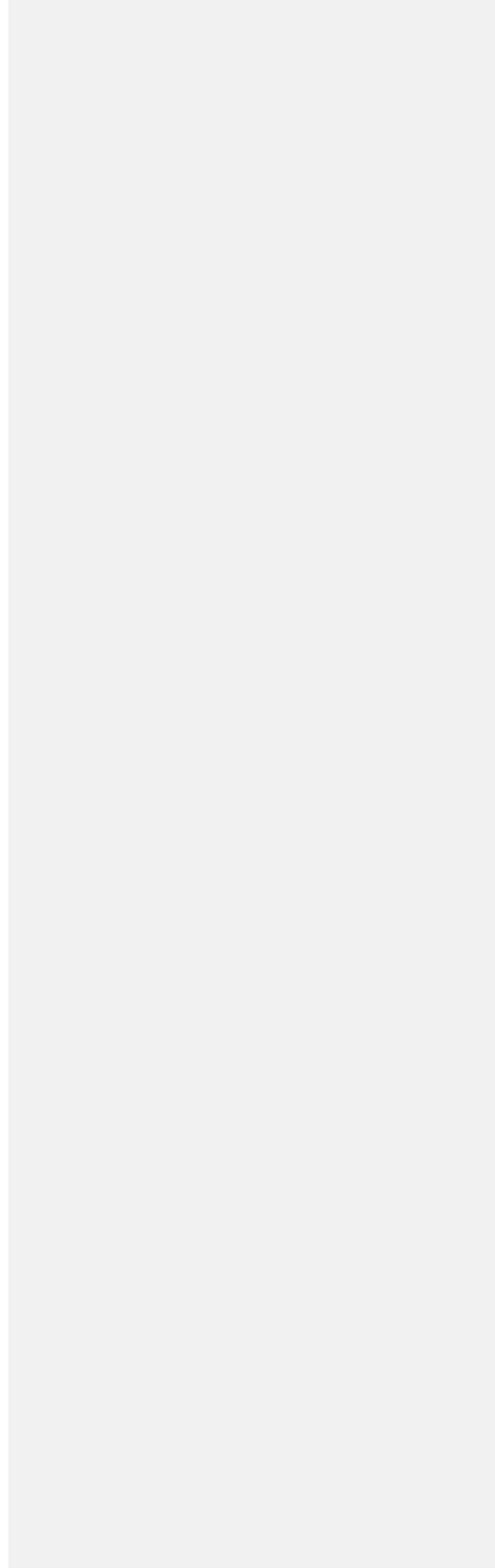
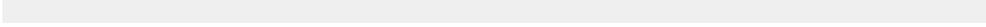
### Value added

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
<b>Effectiveness</b> The proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Efficiency</b> The value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Relevance</b> The proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Feasibility</b> The proposed solution is feasible, realistic and can be implemented by relevant stakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Commented [AC7]:** Big warning here, incentives must be used for medicines in shortages and not high price innovative medicines  
I am not sure this solution would reduce shortages without strong, very strong conditions attached to these incentives.





**H2. ii) Create incentives for the local production of APIs**

	Disagree	Somewhat Disagree	Neither Disagree	Somewhat Agree	Agree	Know
<b>Effectiveness</b> The proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Efficiency</b> The value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Relevance</b> The proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b>Feasibility</b> The proposed solution is feasible, realistic and can be implemented by relevant stakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Commented [AC8]:** The ones which are used to make medicines in shortages...

**H3. If you wish to elaborate on your response, you may add clarifying comments.**

Diversification of the production sites is needed especially for those components (active ingredient or raw material or any component of the packaging) that are produced by few manufacturers. An increased local production of pharmaceuticals should be however carefully assessed considering the impact on the economy, environment, health, labor market. Mindful of the position of the European Commission, an open strategic autonomy should be the ultimate objective to avoid protectionist measures from China and India that would hamper the single market also in sector different from the pharmaceutical one. The production of API should target API affected by shortages and specifically used to develop critical medicines.

**Commented [AC9]:** The production of API should target API involved in medicines in shortages and specifically the critical medicines



## Section I: Supply Obligation

### Proposed Solution(s)

- i) Introduce a 'PSO-responsible-pay' principle
- ii) Wholesalers who are under a PSO obligation should have a right to be supplied
- iii) Enforcement of the commitment to supply by manufacturers / wholesale suppliers

### Description

A Public Service Obligation (PSO) specifies that a "holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered." 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.

### General Objectives

Ensure supply and strengthen supply chains through actionable and enforceable tools that hold Wholesalers and Manufacturers accountable within the limits of a Public Service Obligation.

### Value added

Greater responsibility and accountability are expected to trickle down throughout the supply chain. Preventive measures may be implemented more strategically by wholesalers and manufacturers to make sure PSO responsibilities are met and potential penalties avoided.

## II. i) Introduce a 'PSO-responsible-pay' principle

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
<b>Effectiveness</b> The proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Efficiency</b> The value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<b>Relevance</b> The proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<b>Feasibility</b> The proposed solution is feasible, realistic and can be implemented by relevant stakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>



**I2. ii) Wholesalers who are under a PSO obligation should have a right to be supplied**

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EffectivenessThe proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
EfficiencyThe value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
RelevanceThe proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
FeasibilityThe proposed solution is feasible, realistic and can be implemented by relevantstakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

**I3. iii) Enforcement of the commitment to supply by manufacturers / wholesale suppliers**

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EffectivenessThe proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EfficiencyThe value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RelevanceThe proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FeasibilityThe proposed solution is feasible, realistic and can be implemented by relevantstakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**I4. If you wish to elaborate on your response, you may add clarifying comments.**



## Section J: Supply Quota (1/2)

### 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
Effectiveness The proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Efficiency The value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Relevance The proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Feasibility The proposed solution is feasible, realistic and can be implemented by relevant stakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



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



## Section K: Supply Quota (2/2)

### Proposed Solution(s)

- i) Restrict Direct-to-Pharmacy (DTP) Schemes
- ii) Set quotas for delivery to pharmacies in case of shortages

### Description

Direct-to-Pharmacy Schemes (DTP) entail the direct and exclusive sales by manufacturers to selected wholesalers or pharmacies. This means that a specific wholesaler or pharmacy may become the sole supplier of a specific medicine. This has several implications: while it is easier to ship medicines from the manufacturer to only one wholesaler rather than multiple ones, the dependency on this one wholesaler increases, making the supply chain more susceptible to disruptions. Moreover, prescribers may have to invest more time in identifying and ordering from the specific wholesalers offering a specific medicine and thereby have less time for other measures preventing / mitigating shortages, and prices for the medicine in question may rise due to decreased competition.

At the same time, in case of (potential) shortages, manufacturers may set quotas for deliveries to wholesalers / pharmacies based on historical deliveries. They can do so to prevent stockpiling by pharmacies and/or patients, and ensure fair distribution among pharmacies and patients.

### General Objectives

The overall objective is to promote equitable distribution among pharmacies.

### Value added

An equitable distribution may, in turn, allow for better and fairer distribution. This is believed to prevent or mitigate particularly those shortages arising due to logistical issues.

### K1. i) Restrict Direct-to-Pharmacy (DTP) Schemes

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
Effectiveness The proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Efficiency The value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Relevance The proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Feasibility The proposed solution is feasible, realistic and can be implemented by relevant stakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>



**K2. ii) Set quotas for delivery to pharmacies in case of shortages**

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EffectivenessThe proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EfficiencyThe value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RelevanceThe proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FeasibilityThe proposed solution is feasible, realistic and can be implemented by relevantstakeholders.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input 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**



## Section L: 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.

### L1. 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
Effectiveness The proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Efficiency The value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Relevance The proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Feasibility The proposed solution is feasible, realistic and can be implemented by relevant stakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



**L2. 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
EffectivenessThe proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EfficiencyThe value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RelevanceThe proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FeasibilityThe proposed solution is feasible, realistic and can be implemented by relevantstakeholders.	<input type="checkbox"/>	<input checked="" 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**

More transparency also from national government would be necessary to monitor the level of stock in the countries. It also depends on the type of medicines and the amount of the production. European wide stockpiling would or could prevent MS to stock individually.

**Commented [AC10]:** Maybe we could add our demand for European wide stockpiling which would ou could prevent MS to stock individually



## Section M: Sanctions

Proposed Solution(s)

- i) Develop EU legislation allowing for greater flexibility of Member States to impose financial sanctions if supply responsibilities are not met
- ii) Develop EU legislation allowing for greater flexibility of Member States to impose financial sanctions if notification requirements are not met

### Description

Procurement contracts can, and often do, include financial sanctions in case a supplier does not meet its stipulated supply obligations and/or does not notify authorities in time in case of inability to supply according to the terms of the contract. Whether sanctions are imposed depends on a range of “penalty steps”. For instance, extenuating circumstances (e.g. the duration of a violation, culpability, etc.), aggravating circumstances (such as recidivism / repeated occurrence) and the size of the company may be taken into consideration. Purely commercially motivated decisions that result in a shortage (or permanent discontinuation) may be reflected in different sanctions than if the supplier has acted in good faith but experiences a disruption caused by events outside their responsibility.

With regard to notification requirements, suppliers often point out that there is frequently little advance warning for the occurrence of shortages. Pre-emptive notification could also create unnecessary unrest and costs as the supply disruption may be resolved before a shortage happens. As such, enforcing fines for not meeting notification requirements can be fraught with difficulties.

While several responsibilities and requirements are already specific and in place nowadays (see below), procurement agencies often do not enforce such sanctions at all or not to the full extent either because the tools to do so are missing or they fear a backlash (e.g. market withdrawal) that could be detrimental. Penalties could also have the undesirable effect of suppliers prioritising supply against contracts that include penalties over those without such penalties.

A more systematic and EU-wide approach to the imposition and enforcement of sanctions could enhance the bargaining power of procurers and minimise or avoid potential adverse effects.

### General Objectives

Similar to the previously introduced PSO, supply ought to be ensured and supply chains strengthened through actionable and enforceable tools that hold suppliers accountable within the limits defined under the relevant legislative measures.

### Value added

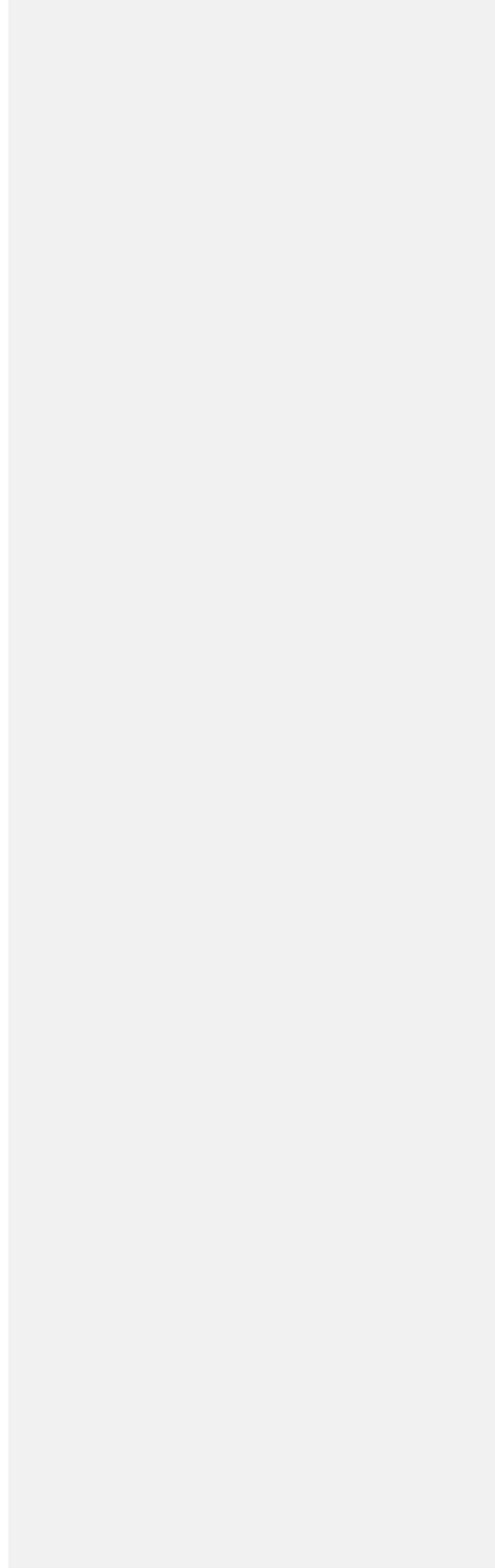
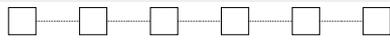
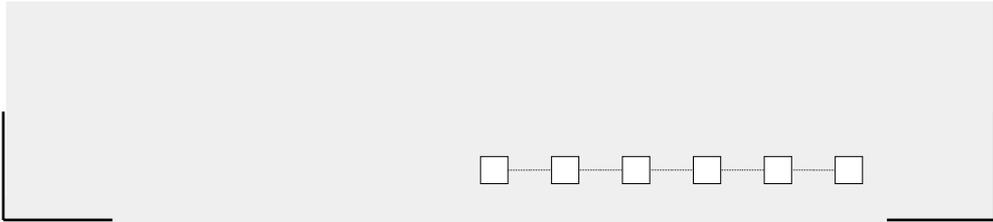
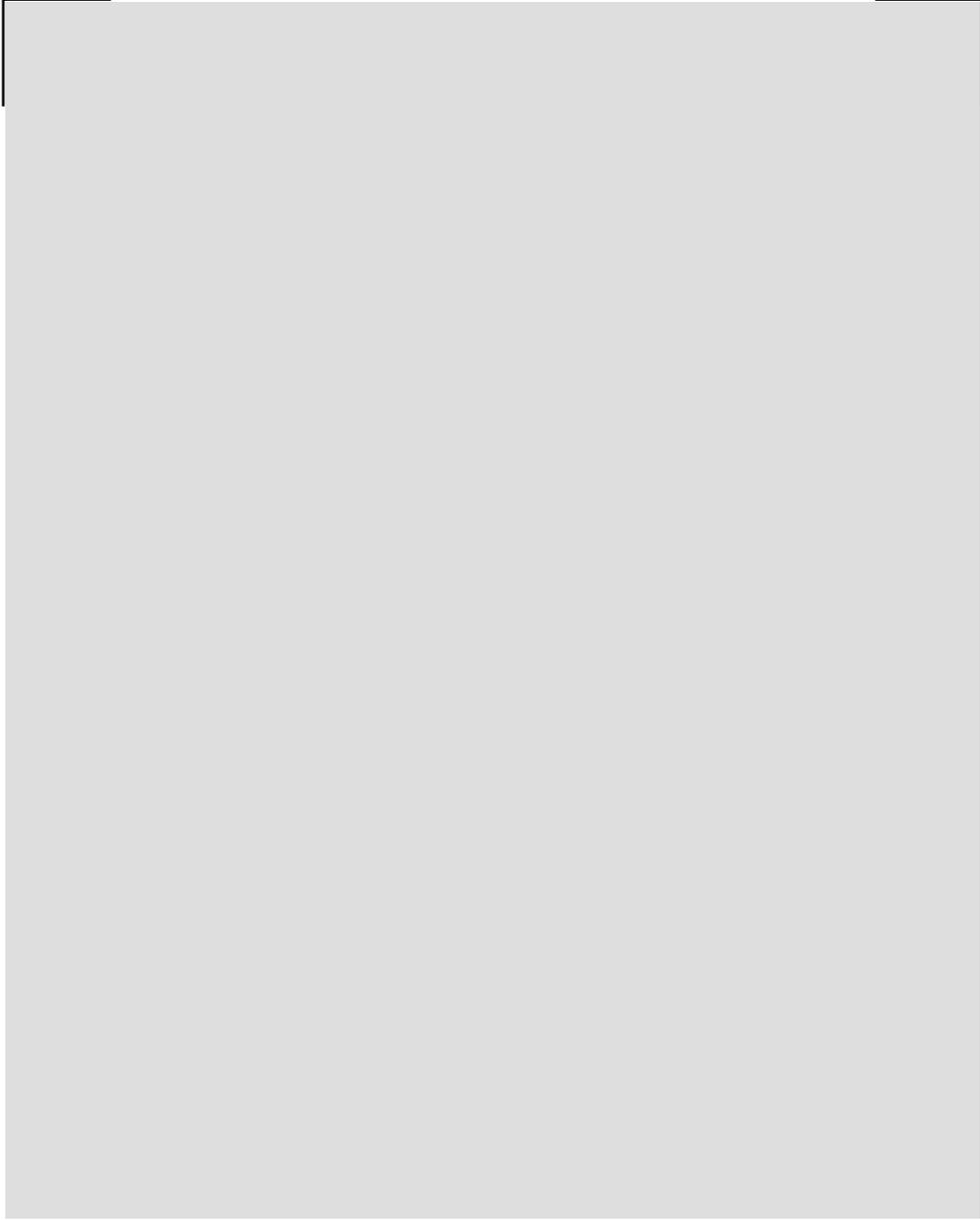
Greater responsibility and accountability is expected to trickle down throughout the supply chain. Suppliers could be expected to implement or strengthen preventive measures strategically to avoid penalty fees.

**M1. i) Develop EU legislation allowing for greater flexibility of Member States to impose financial sanctions if supply responsibilities are not met**

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

Effectiveness The proposed solution leads to a reduction of shortages.

Efficiency The value gained through this solution outweighs the effort and resources needed for the implementation thereof.





**M2. 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
<b>Effectiveness</b> The proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Efficiency</b> The value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Relevance</b> The proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b>Feasibility</b> The proposed solution is feasible, realistic and can be implemented by relevant stakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**M3. 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.

**Commented [AC11]:** Agree, not very much in favor of flexibility on that point





**N2. ii) 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
EffectivenessThe proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
EfficiencyThe value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RelevanceThe proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FeasibilityThe proposed solution is feasible, realistic and can be implemented by relevantstakeholders.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**N3. iii) Anchor supply security provisions in procurement contracts**

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EffectivenessThe proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
EfficiencyThe value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
RelevanceThe proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FeasibilityThe proposed solution is feasible, realistic and can be implemented by relevantstakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

**N4. iv) Adjust national tendering procedures so as to include criteria other than price**

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EffectivenessThe proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EfficiencyThe value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
RelevanceThe proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FeasibilityThe proposed solution is feasible, realistic and can be implemented by relevantstakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**N5. If you wish to elaborate on your response, you may add clarifying comments.**



## Section O: Procurement & Tendering (2/3)

### Proposed Solution(s)

- i) Make greater use of centralised and/or pooled procurement

### Description

In the EU, the responsibility for healthcare remains with the Member States and each country (or regional authority) is responsible for its own procurement. Further fragmentation can be found when procurement is managed regionally or at the level of hospitals or pharmacies.

Such fragmentation reduces procurers' negotiation power to set the terms of procurement contracts and effectively enforce these. It also makes it harder to redistribute medicines in case of local shortages as there is limited transparency at this point in the supply chain to see where medicines are still available. More centralised and/or pooled procurement could increase bargaining power, improve the ability to set and enforce supply obligations, and provide more flexibility to redistribute medicines when needed.

### 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.

### O1. i) Make greater use of centralised and/or pooled procurement

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
<b>Effectiveness</b> The proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b>Efficiency</b> The value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b>Relevance</b> The proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b>Feasibility</b> The proposed solution is feasible, realistic and can be implemented by relevant stakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>



**O2. If you wish to elaborate on your response, you may add clarifying comments.**



## Section P: Procurement & Tendering (3/3)

### Proposed Solution(s)

- i) Producers should avoid excessive national- or region-level stockpiling and avoid procurement in excess of regular demand
- ii) Introduce legal obligations for MAHs and wholesalers to maintain a safety stock for medicines of major therapeutic interest at EU-level
- iii) Introduce EU-coordinated strategic stockpiling

### 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

### P1. i) Producers should avoid excessive national- and regional-level stockpiling and avoid procurement in excess of regular demand

Effectiveness The proposed solution leads to a reduction of shortages.

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

Efficiency The value gained through this solution



**P2. ii) 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
EffectivenessThe proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
EfficiencyThe value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
RelevanceThe proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FeasibilityThe proposed solution is feasible, realistic and can be implemented by relevantstakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

**P3. iii) Introduce EU-coordinated strategic stockpiling**

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EffectivenessThe proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EfficiencyThe value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
RelevanceThe proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FeasibilityThe proposed solution is feasible, realistic and can be implemented by relevantstakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**P4. If you wish to elaborate on your response, you may add clarifying comments**



## Section Q: 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
- iii) Allow the use of pharmacy preparations as alternatives

### 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.



**Q2. ii) Include information about available alternative medicines in shortage databases**

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EffectivenessThe proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
EfficiencyThe value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
RelevanceThe proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FeasibilityThe proposed solution is feasible, realistic and can be implemented by relevantstakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

**Q3. iii) Allow the use of pharmacy preparations as alternatives**

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EffectivenessThe proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EfficiencyThe value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RelevanceThe proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FeasibilityThe proposed solution is feasible, realistic and can be implemented by relevantstakeholders.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Q4. If you wish to elaborate on your response, you may add clarifying comments**

While hospital pharmacists can prepare medicines as alternatives and putting aside time for this, community pharmacists play a different role in the society and in their daily activities which is mostly about providing to patients industry-prepared pharmaceutical. Not all pharmacies have the instrument and laboratory and safety equipment to manage and produce alternative medicines. This would also hamper their first duties. Sharing information and monitoring in database is instead an efficient way of monitoring shortages.

**Commented [AC12]:** It is also very costly in time for hospital pharmacies for example and it is not the heart of their mission



## Section R: 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.

### R1. i) Enable a (more) efficient Repeat Use Procedure

	Disagree	Somewhat Disagree	Neither Disagree / Agree	Somewhat Agree	Agree	Don't Know
Effectiveness The proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Efficiency The value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Relevance The proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Feasibility The proposed solution is feasible, realistic and can be implemented by relevant stakeholders.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



**R2. ii) Enable an accelerated mutual recognition procedure within the EU**

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EffectivenessThe proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
EfficiencyThe value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
RelevanceThe proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FeasibilityThe proposed solution is feasible, realistic and can be implemented by relevantstakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**R3. If you wish to elaborate on your response, you may add clarifying**

**comments**



## Section S: 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

### S1. 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
EffectivenessThe proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EfficiencyThe value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RelevanceThe proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FeasibilityThe proposed solution is feasible, realistic and can be implemented by relevantstakeholders.	<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

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

**Commented [AC13]:** 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



## Section T: Packaging & Labelling

### Proposed Solution(s)

- i) Greater flexibility of multi-country/-language packaging and labelling
- ii) Develop EU-wide medicines packaging and labelling regulation, including flexibilities for digital leaflets

### Description

Medicine shortages rarely affect more than a few EU Member States at the same time. However, the current requirement of national labelling on packaging restricts the ability of marketing authorisation holders and Member States to respond to shortages by moving supplies of medicines between countries to relieve local shortages in a timely manner.

An approach allowing for multi-language packaging would be to implement labelling that refers to an online, electronic version of the full package labelling and/or patient information via a code on the pack. During the dispensing process, the pharmacist provides details of the dose regimen that needs to be followed in the national language thereby ensuring that the medicine is taken correctly: the rest of the information could then be accessed electronically. For those patients that cannot access online labelling, the pharmacist would be able to print out the needed material in the local language.

The ultimate goal could be the mainstreaming of Electronic Product Information Leaflets (ePIL), which would provide additional options to improve patient understanding of their medicines and how they should be used, for instance in the form of videos included in the ePIL demonstrating their correct use (e.g. correct use of an inhaler).

### General Objectives

Efficiency gains and greater flexibility in preventing shortages in the first instance, as well as greater flexibility in mitigating them (e.g. through emergency imports) in the second instance

### Value added

Smaller markets could particularly benefit from these solutions as their relative commercial viability and attractiveness towards MAHs, wholesalers and manufacturers may improve

### T1. i) Greater flexibility of multi-country/-language packaging and labelling

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EffectivenessThe proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
EfficiencyThe value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
RelevanceThe proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
FeasibilityThe proposed solution is feasible, realistic and can be implemented by relevantstakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>



**T2. ii) Develop EU-wide medicines packaging and labelling regulation, including flexibilities for digital leaflets**

	Disagree	Somewhat Disagree	Neither Disagree nor Agree	Somewhat Agree	Agree	Don't Know
EffectivenessThe proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
EfficiencyThe value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RelevanceThe proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
FeasibilityThe proposed solution is feasible, realistic and can be implemented by relevantstakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**T3. 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.



## Section U: 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.

### U1. 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
<b>Effectiveness</b> The proposed solution leads to a reduction of shortages.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b>Efficiency</b> The value gained through this solution outweighs the effort and resources needed for the implementation thereof.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Relevance</b> The proposed solution is relevant in light of the root causes of shortages that you observe in your work.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b>Feasibility</b> The proposed solution is feasible, realistic and can be implemented by relevant stakeholders.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>



U2. **If you wish to elaborate on your response, you may add clarifying comments**

Information flow is key and highly needed.

**Commented [AC14]:** Information flow is key and highly needed.

**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 European level. We will now analyse your responses to prioritise solutions and further develop them. Please stay tuned for the second survey, which will be sent out on 21st May.**