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European Federation of Pharmaceutical Industries and Associations

MEDICINE SHORTAGES
EFPIA PROPOSAL FOR ACTION

July 2022

Medicine shortages[1]

EFPIA proposal for action

Executive summary

1) The research-based pharmaceutical industry is committed to the supply of medicines to the patients that need them, and therefore supports EU-coordinated efforts to improve the resilience of supply chains and reduce the risk of shortages at European (EU) level.

2) The root cause of a supply shortage varies from case to case and is often multiple, covering regulatory, manufacturing & quality, economic, and supply chain considerations. There is no simple solution, and the way forward consists more in a blend of adjusted measures than a one-size-fits-all approach:
   - Shortages affect both innovative and generic medicines but are more likely to affect off-patent products.
   - Resilience is based on robust and agile global supply chains. Global supply chains have demonstrated that they are a strength during the COVID-19 pandemic.
   - There is common agreement that lack of transparency in any part of the supply chain (for example the lack of visibility on demand) can increase the risk of supply shortages However, improvements in transparency should be developed through a collaborative process, focusing on areas that would reduce the risk of supply shortages by increasing visibility of drivers of demand, allowing earlier notification, reducing risks or allowing a greater understanding of the root causes.

   To address these different root causes, manufacturers can design Shortage Prevention Plans matching the specifics of each product.

3) EFPIA calls on any future policy solution to be designed and implemented proportionally to the risk, giving due consideration to the unintended effects brought by the measure and above all supported by strong evidence on the nature of shortage. This is a delicate balance to achieve in a complex milieu where information is scarce, and where any well-intended measure also has the potential to hinder access of patients to medicines.

4) EFPIA has 9 concrete proposals to address the Commission's objective to enhance security of supply articulated around 5 salient points:

   A. **A harmonised EU prevention and mitigation system, based on a standard definition of a shortage[2], and an interoperable IT European monitoring/notification system.** It is key to adequately deploy innovative technologies to ensure interoperability of existing data (European Medicines Verification System (EMVS), Management services for Substances, Products, Organisations and Referential terms (SPOR), European Medicines Agency IRIS platform, etc.) on the basis of European standards (definition) to avoid duplication and leverage the wealth of information available. This will be instrumental in achieving the much-needed improved transparency in supply chains.
      I. Endorse a harmonised definition of a shortage
      II. Develop a European state-of-the-art, interoperable IT monitoring/prevention tool.

[1] This White Paper only focuses on medicines. Specific considerations for vaccines can be found in papers prepared by Vaccines Europe.

[2] A shortage of a medicinal product for human use occurs when supply does not meet patient need at a national level for a period of more than two weeks.

B. **Transparency-based resilience**. Improved transparency across the supply chain has the potential to increase resilience and prevent shortages. Leveraging data available from other systems such as the National Medicines Verification Systems (NMVS), IRIS, SPOR and other sources into the European monitoring system will dramatically expand authorities' visibility and thereby their capacity to take appropriate action.

III. Improve transparency and understanding of patient demand, through timely (current and forward looking) epidemiological data.

IV. Ensure more transparency of the supply chain including thanks to the use of European Medicines Verification System (EMVS).

C. **A risk-based approach focussing on critical products / critical shortages.** Not all products need the same level of attention (one-size-does-not-fit-all), and the variety of situations require adapted responses. Products with high risk of shortage, and/or which shortages have a high potential negative impact for patients should be differentiated, and subject to preventive measures such as different safety stocks requirements and/or Shortage Prevention Plans made available upon request from the authorities.

V. Implement targeted shortage prevention plans (SPP) for critical products through a collaborative process.

VI. Manage safety stocks on a risked-based approach.

D. **Flexibility** should be applied as a principle, translating through the implementation of specific regulatory provisions where appropriate.
For example, the use of electronic Patient Information Leaflet (ePIL) for hospital products would allow greater flexibility and faster allocation of supplies to the countries that need medicine and contribute to the reduction of shortages (subject to local market process and approvals).

VII. Regulatory mitigation measures for shortages.

E. **Maintain resilient global supply chains**. European supplies can rely on the strong EU manufacturing and R&D footprint as well as open trade with reliable partners.

VIII. Strengthen EU resilience building on the very strong existing EU manufacturing and R&D footprint while keeping the benefits of global open supply chains.

IX. Targeted incentivisation for diversification of supply chains (without discrimination and in compliance with international law)

5) Some proposals could exacerbate rather than reduce the risk of shortages:
   - Neither mandatory dual sourcing for medicines nor mandatory safety stocks are efficient or effective ways to prevent shortages.
   - Forced repatriation of API and medicine manufacturing to the EU is neither feasible nor beneficial to the EU.
   - Supply quotas are not a root cause of supply shortages but part of the solution.

Context

In its November 2020 Pharmaceutical Strategy for Europe, the Commission announced a series of legislative[3] and non legislative initiatives aimed at building up EU's open strategic autonomy in the area of medicines and minimising the impact of medicine shortages on patient care. In this respect, the Commission stated its intent "*to revise the pharmaceutical legislation to enhance security of supply and address shortages through specific measures including stronger obligations for supply and transparency, earlier notification of shortages and withdrawals, enhanced transparency of stocks and stronger EU coordination and mechanisms to monitor, manage and avoid shortages*". This paper summarizes the research-based industry's proposals to minimise the impact of medicine shortages in the context of the anticipated revision of the EU pharmaceutical legislation.

Ensuring the supply of medicines to patients who need them remains a core priority for EFPIA and its members. Throughout the Covid-19 pandemic, the pharmaceutical industry has acted as a responsible partner working together with relevant EU and national authorities. The COVID-19 crisis has highlighted five key issues to be addressed in order to minimise any shortages of critical medicines both within Europe and globally: 1) The importance of a preparedness plan for critical medicines and the need for regulatory flexibility; 2) The need for understanding and transparency of patient demand at national/subnational level; 3) the need for timely (current and forward looking) epidemiological data; 4) the need for transparency of the supply chain; and 5) the need for solidarity between Member States. This led EFPIA to issue a position paper in May 2020 summarising industry's challenges in securing supply of crucial medicines during the COVID-19 crisis and putting forward a set of policy recommendations to help ensure that patients across Europe get the medicines they need[4].

General policy principles

Any work aimed at better understanding the causes of shortages in the supply chain and aspiring to propose meaningful solutions should start from the premises of the most correct measurement of the phenomena. The December 2021 report on medicine shortages released by the European Commission highlights that proper understanding of the root causes of shortages remains substantially challenged by a lack of high-quality, standardised information about shortage monitoring at national level. The study also confirms that shortages are often not so much a problem of *whether* a medicine is available but one of *where* it is available.

The forthcoming revision of the EU pharmaceutical legislation provides a unique opportunity to simplify, harmonise and modernise the current system relying on the use of new technologies to better understand and anticipate demand as well as to strengthen supply chain resilience, all of which will help to anticipate and address shortages. EFPIA's policy proposals for minimizing medicine supply shortages in Europe outlined in this paper build on EFPIA's longstanding experience in the

[3] On 11 November 2020 the European Commission released the European Health Union package as the first step of a structural approach aimed at increasing EU's preparedness and resilience to cross-border health threats. The European Health union package is mainly composed of three legislative proposals i.e. a revision of the mandates of the mandates i) of the European Centre for Disease Prevention and Control (ECDC) and ii) of the European Medicines Agency (EMA) to provide stronger surveillance, scientific analysis and guidance before and during a crisis; and iii) the launch of a new European Health Emergency Preparedness and Response Authority (HERA) for health emergencies to develop, produce and procure medical countermeasures before and during a health crisis.

[4] See Policy proposals to minimise medicine supply shortages in Europe, Lessons from COVID-19 crisis: https://www.efpia.eu/media/554682/covid-19-drug-shortages-efpia-position-paper.pdf

supply of medicines and integrate the learning from the COVID19. They are based on the following observations and principles:

- **Cooperation**. COVID19 has vividly demonstrated, that only cooperation can achieve the best outcomes. Today's global health challenges and priorities require complex new approaches, including innovative supply chain technologies and data-driven solutions. This can only be achieved with the active involvement and support of all actors involved in the supply chain.

- **Flexibility**. The causes of shortages are multifactorial and include production disruptions, limited resilience of certain supply chains, unintended impact of pricing, reimbursement, and procurement policies, stronger and/or unexpected demand due to public health emergencies or poor public forecasting, as well as supply chain problems and bottlenecks. Shortage mitigation and management measures need to be adapted to the specifics of each particular situation, e.g. therapeutic area, category of product and presence of alternatives on the market, etc. As shortages result from a variety of root-causes, and apply in a variety of conditions for a variety of medicines, one-size-fits-all measures are unlikely to succeed.

- **Risk-based approach**. Shortage prevention and mitigation efforts should be proportionate to the risk incurred by patients. Further preparedness efforts should be deployed on critical medicines, i.e. the more medicines are likely to face shortages, and the bigger the patient impact of a medicine shortage, the more precautionary measures are needed to prevent a negative impact.

- **Proportionality and sustainability.** Legislative amendments to be considered should be proportionate to the aimed objective and provide efficient, workable, and sustainable solutions that serve patient needs. Lessons from COVID19 are key here. Global supply chains for medicines have been a source of strength during the pandemic; supporting them is critical to ensure supply chain resilience.

- **Transparency-based resilience.** EFPIA supports measures to improve end-to-end transparency that lead to greater supply chain resilience and lead to faster notifications of potential shortages based on information available. This includes increasing visibility of drivers of demand, a strengthened notification regime based on a harmonised EU-definition of medicine shortages – and greater clarity on when a shortage should be notified to the authorities.

9 EFPIA proposals for action (I to IX)

A. A harmonised EU prevention and mitigation system, based on a standard definition of a shortage, and an interoperable IT European monitoring/notification system.

I. **Endorse a harmonised definition of a shortage**, to serve as a basis for a European reporting system based on a standardised format.

The common definition of a shortage is the cornerstone of EU coordination and cooperation. This definition should be workable and designed with the purpose of serving as a meaningful basis for the entire shortage prevention/mitigation system, and needs to include a clear definition of demand and timelines. EFPIA proposes the following definition: 'the shortage of a medicinal product for human use occurs at country level when supply does not meet patient need at a national level for a period

of more than two weeks'[5]. It would be beneficial to complement this definition with a measurement unit, that would help specifying the magnitude of the shortage, e.g. reflecting the patient population likely to be affected[6].

II. Develop a European state-of-the-art, interoperable IT monitoring/prevention tool.

Shortage information should be uploaded onto a common IT portal to ensure a streamlined and effective alert system as well as an alignment across the data provided from different sources and based on a consistent and workable definition of medicine shortages. For optimal efficiency and result, the system should be interoperable with existing databases such as IRIS, EMVS (European Medicines Verification System) and SPOR. The lack of interoperability will result in duplication, which is a waste of resources and source of errors. Both EMA and national authorities should have access to the European database information in order to mitigate shortages. The reporting requirement should also be optimised for the sake of efficiency and to ensure the sustainability of the system.

Note on the level of demand to be taken in consideration to consider shortages: the most relevant basis to assess demand is the patient (medical) need. Wholesalers' orders are sometimes considered, since they reflect the economic demand for medicines, which is based on a number of factors beyond local patient needs, such as precautionary orders (hoarding), demand for re-exportations (intra-community trade), or simply fluctuations in the safety and working stock of an economic operator. Wholesalers' orders do not constitute a satisfying and workable proxy for the management of shortages of medicinal products, since some circumstances will disconnect them from the reality of medical and patient needs and introduce economic considerations that should be left to a normal customer-supplier relationship. Such a proxy will induce a bias that might lead to an overreporting of shortages, and thereby weaken the shortage management and mitigation system entirely. In practical terms, patient demand should be estimated on the basis of actual consumption and forecasts based on epidemiology data.

B. Transparency-based resilience. Improved transparency across the supply chain has the potential to increase resilience and prevent shortages. Transparency can be improved at the level of patient demand and within the supply chain.

III. Improve transparency and understanding of patient demand, through timely (current and forward looking) epidemiological data.

As the COVID-19 crisis vividly evidenced, the opacity of the supply chain downstream from manufacturers prevents the allocation of demand where patient needs are. This constitutes a major weakness of the system, which EU should address by building an integrated system allowing for the supply of medicines at the right place and in the right moment, connecting upstream supply with patient demand. This would involve not only the European Centre for Disease Control (ECDC)

[5] EFPIA notes that the definition included in the regulation on the extended mandate of EMA (EU regulation 2022/123 of 25 January 2022) provides a good basis, but fails to introduce a timeline: "'shortage' means a situation in which the supply of a medicinal product that is authorised and placed on the market in a Member State (…) does not meet demand for that medicinal product (…) at a national level, whatever the cause;"

[6] For example: "a unit of shortage of a medicinal product for human use occurs at a country level when supply does not meet patient need at a national level for the typical dispensed timeframe (1 month, 1 week, 1 day) per 100,000 citizens impacted". This would allow authorities to provide an objective measurement of the magnitude of a shortage, to be interpreted in light of other information available including the nature of treatment or vaccine.

releasing modelling data covering patient needs and hospital capacity in the Member States, but also combining any such forecasting data with real data on usage (consumption), and other relevant data that can provide information on supply. Information on patient needs and a coordination mechanism for allocation of medicines are crucial for manufacturers to adequately forecast demand and make the necessary planning in terms of manufacturing capacity and detailed distribution arrangements to supply those medicines to the right regions at the right time.

IV. Ensure more transparency of the supply chain, including thanks to the use of EMVS data

Supply chain operators and authorities need better visibility on available stocks of medicines throughout the supply chains, in an integrated system. Competent authorities could use the EMVS (European Medicines Verification System) data repositories set up in the context of the EU Falsified Medicines Directive to monitor, at aggregate level[7]. This information is readily available to authorities.

EMVS data has the potential to follow when and how various medicinal products/INNs are placed on which markets as well as the rate of their consumption at national level. The confidential use and analysis of this data by competent authorities would also allow them a better understanding of the root-causes of shortages, to develop adequate responses, as required by the specific situation observed, and to proactively mitigate risks of shortage in the future. More specifically, the data stored in the National Medicines Verification Systems could provide useful intelligence regarding the number of packs for all prescription products being supplied by manufacturers on the various EU markets, number of packs dispensed in national pharmacies, number of packs exported (and/or imported), as well as on the level of stocks present in the supply chain at country level. The real time information in the repositories can be analysed according to very granular time frames (per day, per week, per month etc.) as well as per region (postal codes). That wealth of data would supplement information already provided by Marketing Authorisation Holders on manufacturing and quality related supply disruption to National Competent Authorities and, in providing information on causes and extent of shortages beyond manufacturing related issues, would greatly facilitate the detection and mitigation of genuine shortages. The use of the repositories systems for the monitoring of shortages would benefit from further discussion between National Competent Authorities and relevant supply chain stakeholders with the goal of using every tool available to protect patient safety and public health[8].

C. A risk-based approach focussing on critical products / critical shortages.

Not all products need the same level of attention (one-size-does-not-fit-all), and the variety of situations require adapted responses. Products with high risk of shortage, and/or which shortages have a high potential negative impact for patients should be differentiated, and subject to additional preventive measures such as different safety stocks requirements and/or Shortage Prevention Plans made available upon request from the authorities.

A clear harmonised list of critical products is needed to ensure a consistent approach at EU level.

[7] Medicines Shortages: From Assumption to Evidence to Action: A Proposal for Using the Data Repositories for Shortages Monitoring, Frontiers in Medicine, January 2021

[8] No less than 9 countries have already stated that they plan to use the repository systems developed in the scope of the Falsified Medicines Directive to monitor shortages whilst 8 other countries consider doing it. See response to Question 10.b in the Summary of Responses to the Questionnaire on the Measures implemented in the Member States territories in the context of Article 81 of Directive 2001/83/EC.

V. Implement targeted shortage prevention plans (SPP) for critical products through a collaborative process.

EFPIA fully supports the development of a fit-for-purpose shortage prevention plan (SPP) in a common format for a risk-based selection of medicines, i.e. history of supply issue and patient impact. They should be kept by the marketing authorisation holder and made available upon request by authorities during inspections, and kept confidential given the sensitive information they include. Imposing such a requirement to medicines that are not at risk of shortage might prove too resource-intensive for both manufacturers and national competent authorities and be disproportionate (the level of effort should be commensurate with the level of risk). It is vital that any planned EU reform harmonises the existing patchwork of SPP requirements proliferating across the EU Member States to facilitate interoperable use of data.

VI. Manage safety stocks on a risk-based approach

Safety stocks are only one of an array of remediation strategies that can be deployed to prevent shortages. They should be designed to respond as exactly as possible to the perceived risk induced by shortages and the specificities of product. This will optimise shortage prevention while limiting associated constraints to the minimum and make sure the overall model is sustainable. There could be serious unintended consequences to patient access in Europe and globally if several countries decided to introduce safety stocks obligations at the same time. We need to prioritise solutions that ensure solidarity and sustainability of supply and do not discriminate against patients on a geographical basis. Stronger visibility of demand, through establishing improved dialogue across supply chain stakeholders, and a European approach favouring the harmonization and modernization of current processes including digital solutions, are more likely to have a sustainable impact allowing manufacturers to plan supply according to patient needs.

Safety stocks cannot be the general rule, and if requested, this should be done **only on an exceptional and targeted basis following a risk based approach,** avoiding any discrimination among European patients:

- EU level safety stocks should focus on a limited number of critical products of major therapeutic interest that are at risk of shortages. This is in line with the recommendation included in the study conducted by Technopolis for the European Commission, which also supports the stocks to be kept at unfinished/regional level. Any volumes requested should be proportionate and limited in time buffering a specific risk, to ensure this does not lead to unfair and unintended negative consequences that would limit patient access in other countries.
- Moreover safety stocks requirements need to take in consideration the specificities of each product categories. Vaccines for example are subject to different procurement rules, typically have longer manufacturing lead time and will require different stocks requirements. Other categories of medicines will also require different safety stocks modalities, e.g. personalised medicines, immunotherapy treatments.
- Any request for additional safety stocks to the ones already being built by companies should be managed preventively to allow a more optimal management of stocks through demand variability risk pooling, economies of scale, decreased waste, and the possibility to allocate products where the needs are. Across the board stock requirements at national level or in hospitals are particularly disruptive and may exacerbate shortages. These should be avoided unless absolutely needed. Furthermore, we strongly advise against any stock requirements at raw material level since they might be difficult to implement, significantly increase production costs, and have a limited impact on supply increase.
- Any preventive safety stocks policy should be deployed at European level rather than national level. The multiplication of national safety stocks requirements in Europe would be the least

efficient architecture, multiplying several folds the constraints associated to safety stocks, i.e. cost potential waste without being even as efficient as a European reserve allowing optimisation of supply allocation through cross-border flows to meet local demand.

In the cases where safety stocks held by the manufacturer were considered as an appropriate tool to prevent/mitigate shortages, EFPIA recommends the following conditions:

- Scope: critical medicinal products only (excluding certain categories of products like, for example, vaccines/immunization therapies, personalised medicines or products with fast track approval, because of their manufacturing/distribution specificities). The definition of critical products should take into account the patient impact and the likelihood of a shortage to happen for a specific product.
- Amounts: Demand should be calculated on European sales and forecasts, and distinction made between what needs to be available in the companies' manufacturing cycle and what needs to constitute a potential strategic reserve owned by public authorities.
- Form: finished or unfinished level depending on MAH's preference.
- Standstill: an EU mandatory safety stock requirement must be associated with a standstill on national measures (no additional national requirement on top of EU requirements)
- Implementation: manufacturers should be provided sufficient time to implement changes in their organisation and manufacturing to increase minimum stock levels.

While safety stocks[9] at European/regional level are preferable over national initiatives, supply is not unlimited, and this will still impact supply in other countries outside Europe. We therefore ask for a cooperative, efficient, solidarity-based and responsible approach to this kind of short-term solution.

It is essential that any European requirement is associated with a standstill on national measures, i.e. no new national measures with safety stocks requirements should be introduced in addition to the European requirements. The proliferation of national measures can have a very harmful impact on the availability of medicines.

D. Flexibility should be applied as a principle, with the implementation of specific regulatory provisions where appropriate.

For example, the use of electronic Patient Information Leaflet (ePIL) for hospital products would allow greater flexibility and faster allocation of supplies to the countries that need medicine and contribute to the reduction of shortages.

VII. **Regulatory mitigation measures for shortages**. EFPIA has developed a reflection paper on regulatory flexibilities that can help mitigate shortages[10]. EFPIA believes that this should include

i. Electronic product information and use of common EU packs in order to improve supply chain efficiency and agility.
ii. Simplification of post approval changes and accelerating Mutual Recognition Procedures within the EU.

[9] European safety stock: stocks kept at European level, that can be allocated where there is need.

[10] See Reflection Paper on Regulatory Mitigation Measures for Shortages of Medicinal Products, September 2020, https://www.efpia.eu/media/554740/reflection-paper-on-regulatory-mitigation-measures-for-shortages-of-medicinal-products.pdf

iii. Harmonized procedure on life cycle management of ICH Q12. ICH12 is an important tool that will provide flexibility and reduce post-approval change burden associated with continual improvement of manufacturing and supply, and the introduction of innovative manufacturing technologies. It should be implemented as soon as possible.

Regulatory flexibilities will be important, allowing inventory to be redeployed where appropriate in response to critical needs. In the short term, the use of electronic Patient Information Leaflet (ePIL) for products administered by healthcare professionals (e.g. hospital products, vaccines) would allow greater flexibility and faster allocation of supplies to the countries that need medicines and contribute to the reduction of shortages. The replacement of paper leaflet by electronic leaflet would allow optimal packaging size and patients to have access to up-to-date information in their language.

The future EU framework should provide an expedited approval process for innovative manufacturing solutions and support process and product innovations that aim to reduce lead times (e.g. decentralised supply chains with local "finishing" plants). It should also allow for expedited variations and procedural simplification for alternative sites / sources / logistics partners and facilitate the use of digital information and "big data".

Also, we should work towards global regulatory convergence and Mutual Recognition Agreements with other global partners that have high-quality regulatory systems.

E. Maintain resilient global supply chains.

European supplies can rely on the strong EU manufacturing and R&D footprint as well as open trade with reliable partners.

VIII. Strengthen EU resilience building on the very strong existing EU manufacturing and R&D footprint while keeping the benefits of global open supply chains.

Significant efforts have been made over the past years by the innovative industry to successfully put in place global, diverse supply chains to meet the needs of patients. At the same time the EU, enormous pharmaceutical manufacturing base, has seen considerable growth in exports, being the largest exporter of medicines globally[11]. It is important to avoid moving backwards with measures that could compromise the supply chain integrity and future sustainability. Mandatory dual sourcing for medicines or national safety stocks are not efficient or effective ways to prevent shortages, and could increase risk of shortages. Forced repatriation of API and medicine manufacturing to the EU is neither feasible nor beneficial to the EU. All such approaches could also trigger reciprocal measures by countries outside Europe. Instead a holistic approach is required, including making an environment where the research-based pharmaceutical industry can develop solutions to today's unmet needs, and ensure that Europe continues to be an attractive location for R&D investment and industrial development to respond to tomorrow's patients' needs. A strong life science ecosystem encourages innovation for life-saving medicines, attracts strategic investments, promotes collaboration, and strengthens pandemic preparedness. We therefore support policies that enable a strong innovation ecosystem from Europe with Global partners. This includes public-private partnerships, a robust intellectual property framework, skills and workforce training, an agile and modern regulatory system, and progressive market conditions such as quality and security of supply criteria in public tenders and pricing and reimbursement systems that recognise and reward innovation. It also includes government incentives to expand R&D and manufacturing, such as economic, tax, and trade policies that incentivise companies to invest in Europe. We consider this

[11] https://ec.europa.eu/eurostat/web/products-eurostat-news/-/ddn-20220406-1

more efficient than government mandates to produce in Europe. Patient access to medicines & treatments should not be jeopardised by where a medicine is manufactured.

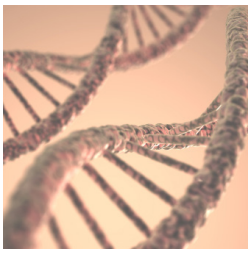
Alongside this, dialogue on open supply chains with like-minded countries, at the WTO or bilaterally, will be critical in driving sustainable and globally aligned approaches to the common goal of patient access. Ensure open global, diversified supply chains to allow the free flow of critical material and goods is essential to ensure supply chain resilience and secure flow of medical goods to all patients globally. EU should leverage its multilateral & bilateral trade negotiations to support open trade flows and a more resilient supply chain at global level (e.g. EU-US Trade and Tech Council, Free Trade Agreements, Trade in Healthcare Initiative at the WTO). This includes ruling out import/export bans of medicines and ingredients.

IX. **Targeted incentivisation for diversification of supply chain (without discrimination and in compliance with international law)**

Support targeted incentives for the diversification of supply chains where it is appropriate and feasible, including the number of key suppliers of medicines and components, for critical medicines in dialogue with Marketing Authorisation Holders.

Diversification is only possible and desirable for some products, and should never be a source of discrimination, e.g. in tender. Mandating diversification for all products without distinction of their status and environment is likely to affect availability. EFPIA warns against the across-the-board obligation to diversify suppliers of raw materials, as it could play against the availability of certain medicines. Whereas dual sourcing[12] is an option and a reality already today for many medicines with high volumes and with established technologies, it might not be a feasible option for some medicines, including, but not limited to, innovative low-volume medicines or vaccines where the technology either does not exist in a second manufacturing facility, pose further quality issues, or may be very costly to maintain, or complex and difficult from a regulatory point of view to build and sustain over time leading to output inconsistencies and hence an increased risk of shortage. Mandatory diversification of suppliers might constitute a serious obstacle or at best considerably extend the timeline for the launch of innovative products, which production is generally scaled up from a very small basis started during clinical development. Industry calls for EU to remain aligned with global standards in terms of quality and registration requirements. Without this the EU runs the risk of getting access to new products significantly later than other regions globally. Effective Business Continuity Plans on products at risk of supply disruption could be an effective alternative where supplier diversification is not suitable.

[12] Dual sourcing refers to the use of two suppliers for a given component or raw material, which has the potential to lower the risk of shortage resulting from the failure of a single supplier.



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