Medicines Procurement Reform:

Strengthening Supply Security through EU Guidance

POSITION PAPER

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Executive Summary

This paper explores how the design of off-patent multisource, generic medicines procurement can be restructured to ensure greater security of supply of medicines while supporting broader policy objectives for more economically, environmentally, and socially sustainable development.

Due to pressure on healthcare budgets, EU Member States have introduced procurement rules that aim exclusively to reduce costs of acquiring medicines. As a result, this has led to the consolidation of supply and an increased risk for supply security. Incorporating security of supply as an objective in the tender design and the inclusion of pro-competitive Most Economically Advantageous Tender (MEAT)[1] criteria can incentivise manufacturers to make strategic investments in more robust supply chains. For a more successful demand-side policy over the longer term, there must be **an alignment across the EU**, especially for criteria that impact supply chains and manufacturing processes of companies operating globally. We strongly support the ambition of the European Commission, described in the communication *Addressing medicine shortages in the EU*[2], to **issue an EU guidance on procurement**, which is in our view one of the key actions that would contribute to greater security of supply.

This paper provides concrete proposals on how to better design tenders, namely around five main points:

- ➔ **Secure Diversity of Suppliers:** Design multiple winners in tenders or ensure several suppliers are active on the market
- ➔ **Increase demand predictability:**
  - ✓ Sufficient lead-time (at least 6 months between tender awarded and first supply)
  - ✓ Realistic Volume estimates, commitments and guarantees
- ➔ **Prevent disproportionate penalties for suppliers:** More bidders when penalties do not exceed business opportunity

[1] *Directive 2014/24/EU on public procurement introduced the concept of most economically advantageous tender (MEAT) criteria, which take into consideration aspects other than the lowest price, such as security of supply, environmental investments and long-term sustainability.*

[2] Published 24 October 2023, https://ec.europa.eu/commission/presscorner/detail/en/ip_23_5190

- **Introduce the possibility of adjusting pricing, in duly justified cases:** e.g. adjust pricing according to inflation or changed market conditions
- **Introduce Most Economically Advantageous Tender (MEAT) criteria:** Based on the EU priorities, aforementioned proposals provide concrete examples on how to incorporate MEAT criteria such as environmental sustainability and supply chain reliability, resilience and transparency in procurement, while still nurturing and maintaining fair competition and avoiding unnecessary administrative burdens for procurers and suppliers.

Role of procurement in achieving wider policy objectives

Healthcare budgets have been under significant pressure in recent years. With ageing populations and the rising cost of healthcare, governments, insurers, and healthcare providers are constantly facing the challenge of allocating limited resources effectively. The ever-increasing prices of new pharmaceutical products, especially for innovative and specialty drugs, pose a significant strain on these budgets. The need for healthcare systems to provide access to life-saving medications and treatment while limiting costs has led to various cost-containment measures, such as clawback schemes, restrictive pricing systems, and reimbursement restrictions, potentially leading to under treatment in several treatment areas. Striking a balance between affordability and availability remains a complex task.

According to an IQVIA report[3], the competition for small molecules in Europe between 2016 and 2021 has resulted in significant reductions in the cost of these medicines, making them more affordable. The report indicates that the cost of small molecules, for which generic competition has kicked in upon the loss of patent protection, has decreased by approximately 40% during this time. This competition has also led to increased accessibility to these medicines, as the volume of small molecule sales has grown by around 27% over the same period. These findings highlight the positive impact of patent expiries and

[3] IQVIA report Patent expiry and Journey into the market , September 2022

competition on the affordability and accessibility of small molecule medicines in Europe, ultimately resulting in improved patient access.

On the other hand, generic medicine manufacturers have faced growing expenses, during the COVID-19 pandemic, and more recently, as a consequence of the war in Ukraine, the gas crisis, high inflation and increase in cost of goods and regulation within a tightly regulated pricing framework.

In most EU Member States, procurement is used to ensure cost savings for healthcare systems. As procurement of generic medicines is primarily based on the lowest price criteria, this has resulted in further significant pressure on generic medicines pricing, which in turn has led to consolidation and an increased risk to supply security[4]. Therefore, procurement processes must be reevaluated and restructured to prioritise value, sustainability, and the long-term viability of healthcare systems.

The Public Procurement Directive[5] encourages public procurers to make use of the Most Economically Advantageous Tender (MEAT) criteria, going as far as recommending that Member States limit the use of price-only tenders to encourage greater quality of public procurement. Since the publication of Directive 2014/24/EU, the European Commission has published several communications aimed at improving procurement practices by Member States reinforcing the idea that MEAT criteria should be part of the practices of Member States.[6,7]

Even though the EU Procurement Directive encourages a strategic approach to procurement through MEAT award criteria, this has not transposed into medicines procurement on a large scale. As shown by many recent studies[8], most medicine tenders are awarded based solely on the lowest price. This practice has been employed by procurers to steer sharp and swift price decreases for off-patent medicines. At the same time, procurement practices have contributed to the consolidation of both supply and

[4] European Commission, Directorate-General for Health and Food Safety, Jongh, T., Becker, D., Boulestreau, M. et al., *Future-proofing pharmaceutical legislation – Study on medicine shortages – Final report (revised)*, Publications Office of the European Union, 2021, **https://data.europa.eu/doi/10.2875/211485**

[5] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 - *OJ L 94, 28.3.2014, p. 65–242*

[6] C(2018) 3051 - Commission notice Guidance on Innovation Procurement

[7] C(2019) 5494 - Guidance on the participation of third country bidders and goods in the EU procurement market

[8] European Commission, European Health and Digital Executive Agency, Vogler, S., Salcher-Konrad, M., Habimana, K., *Study on best practices in the public procurement of medicines – Final report*, Publications Office of the European Union, 2022, **https://data.europa.eu/doi/10.2925/044781**

manufacturing chains[9] and led to market withdrawals[10] and supply insecurity. In recognition of the shortcomings of price-driven procurement, several attempts have been made recently[11] by public procurers to diversify supply and recognise value of generic medicines beyond savings.

Incorporating security of supply as an objective in the tender design and introduction of pro-competitive MEAT criteria enable procurers to align their tendering with wider public health objectives. This approach can incentivise manufacturers to further make strategic investments in areas like supply security and environmental sustainability, while ensuring they are appropriately rewarded for their efforts. Creating the necessary structures and procedures to routinely include criteria in multisource medicines procurement will allow for consistent application of the MEAT principle to support and be adjusted to policy objectives as priorities for procurers evolve with time.

In this paper, we provide concrete proposals for generic medicines procurement[12] on how procurers can better design tenders with the objective of ensuring greater security of supply and include MEAT criteria such as environmental criteria and security of supply criteria in their procurement processes. We aim to demonstrate how to implement these in such a way that ensures fair competition and does not create unnecessary administrative burden for procurers.

[9] Ferrario et al. (2020). Strategies to achieve fairer prices for generic and biosimilar medicines. BMJ, l5444. https://doi.org/10.1136/bmj.l5444

[10] Study The case of Europe's dissapearing medicines cabinet

[11] Fare for antibiotikamangel gjer at Noreg må ta grep - Sykehusinnkjøp HF (sykehusinnkjop.no)

[12] The criteria provided in the suggestions are primarily focused on generic molecules and may not fully encompass the specific requirements and considerations for biosimilar medicines. Biosimilars, being a distinct category of pharmaceutical products, may have certain specificities in terms of manufacturing and supply security. Therefore, when evaluating and implementing procurement strategies for biosimilars, it is essential to consider those specificities.

Improving tender design

The design of a tender is important because it sets the foundation for a fair, transparent, and efficient procurement process. A well-designed tender should encourage competition among suppliers by clearly defining the requirements, specifications, and evaluation criteria. This ensures that multiple suppliers can participate, stimulating short- and medium-term competition and delivering higher-quality bids at good prices.
An efficient tender design can also achieve broader policy objectives beyond cost optimisation. We recommend that procurers adopt the following principles that should govern competitive medicines procurement:

1. Secure diversity of suppliers

Multi-winner tenders should be preferred to guarantee multiple manufacturers are active in the market/INN and prevent medicine shortages.

For instance, the market of paediatric antibiotics is highly consolidated, with a very limited number of suppliers, increasing the risk of medicine shortages. When a sole winning manufacturer experiences supply issues, the remaining manufacturers (if any) might not always be able to remedy a potential medicine shortage in a timely manner, due to the lack of manufacturing capacity to address unexpected demand. Additionally, the remaining manufacturers might have decided to withdraw the production of the concerned medicines due to not being awarded in the procurement process. This might lead to a delay in patient access to medicines, as re-starting a manufacturing process can be lengthy. If there are only a few players on the market for a given medicine, awarding a single-winner tender might endanger the supply reliability as there will be limited opportunities to source the product with another supplier.

The objective of procurement models is to avoid having a limited number of suppliers for all medicines in the short and medium to long term, and to consider awarding several winners according to the market, product and country characteristics (preferentially multi-winner tenders). This might be achieved, for instance, by dividing the market into lots for the different winners (e.g. the first winner gets 50% of the market, the second winner 30%, etc.).

2. Increase demand predictability

Medicines manufacturing takes time as the process is often complex, involves many different stakeholders and interdependences. Raw materials must be ordered and delivered, as well as excipients, packaging, active pharmaceutical ingredients (materials, API) produced and ready, manufacturing lines reserved, packed, and shipped to the final warehouses. These are just some of the steps of the process that take many months[13] or years complete.

The manufacturing lead time, which is the time from the start of the manufacturing process to beginning supply, must be aligned with the procurement timings, i.e. from award of the supply to date. Usually, the delivery time is too short to enable the production of the requested volume of medicine within the estimated time. This misalignment of procurement and manufacturing times can result in supply disruption.
Aiming to comply with the current short lead times in the case of being awarded the tender, manufacturers often hold stock in anticipation. However, if the manufacturer does not win the tender, the manufacturer is left with an excess of stock. Consequently, the manufacturer must often destroy its stock (as alternative use of the products does not exist), which is very costly and has environmental implications. The result is additional pressure to win the next procurement process at a very low price, which might disrupt competition and lead to market dumping at unsustainably low prices (sale price or sometimes even below the level of the cost of goods which would be considered an abnormally low bid – a practice that is forbidden under the EU Procurement Directive according to the Commission Guidance on 3rd country bidders[14]). **On average, the minimum lead time needed for a manufacturer to supply a generic medicine is around six months**, whereas this might be even longer for biosimilar, complex generic or value added medicines due to complex manufacturing processes. Therefore, lead times should be adapted to the product characteristics (e.g. complexity in manufacturing, regulatory requirements and additional efforts due to serialisation) as well as the requested volumes to be delivered, to guarantee a predictable supply. **It is essential that the procurement awarding bodies provide accurate estimates of the volumes to be supplied** (e.g. minimum and maximum volume caps) **and indicative**

[13] Total lead time, from starting materials to final product is estimated to 1 – 1.5 years, according to internal consultation of the Medicines for Europe's manufacturing and supply chain committee.
[14] According to the guidance, procurers are obliged to investigate such cases and remedy any potential abuses. This would apply to any bidder, EU or non-EU based. "*Where a public buyer receives an offer that it suspects to be abnormally low, it is under a legal obligation to request an explanation of the price offered from the economic operator concerned;*" P.14 "*If you have established that the offer is abnormally low because it does not comply with the legal obligations under Article 18 (2) of Directive 2014/24 it has to be rejected;*"P.17 C(2019) 5494 - Guidance on the participation of third country bidders and goods in the EU procurement market

timing of supply as manufacturers cannot increase their manufacturing capacity in a short period of time without disrupting the supply of other medicines.

Additionally, it is important to establish regular meetings between awarded suppliers and procurers, for example on a quarterly basis, to monitor progress, performance and ensure adherence to the tender protocol.

3. Prevent disproportionate penalties for suppliers

In most procurement contracts, there are clauses stipulating penalties if the manufacturer is unable to supply the awarded medicine. In some cases, the penalty for one month of inability to supply can be as high as the value of the entire business per annum and in other cases, the penalty is disproportionately strict as far as removing a supplier from future tender bids. This practice puts the manufacturers at considerable financial risk and thereby acts as a disincentive to compete in the procurement process and can explain why there are fewer bidders in low value & low volume medicine tenders, even though the medicine may be medically important. **Therefore, the amplitude of penalties should be proportionate to the contract value and terms agreed by the manufacturers to encourage participation in the tenders and ensure a reliable supply.** We recommend that the penalties should be capped to a % value of a tender, and adapted over time to capture the price adjustments, taking into account the % of the executed contract and other factors.

In some cases, an unexpected peak in demand (e.g. to avert stock-out caused by the inability of another company to supply) leads to the manufacturer being unable to supply the requested volume. Therefore, **manufacturers should only be liable for volumes that were specified in the procurement contract and no penalty should be imposed in the case of inability to supply unexpected volumes**.

4. Introduce the possibility to adjust pricing, in duly justified cases

The possibility of adjusting pricing becomes relevant when tenders are prolonged or when dealing with multiannual tenders for several reasons.

Firstly, during a prolonged period, the economic landscape can experience fluctuations that can significantly impact the cost of production and distribution (e.g. inflation rates cause an increase in the prices of raw materials, workforce, and transportation). The ability to adjust pricing allows suppliers to account for these changes and ensures that they can maintain a reliable supply of medicines. Ultimately, this flexibility promotes a more sustainable and resilient procurement system, ensuring that patients have access to the required medications even in the face of prolonged tender processes. When the possibility of reviewing pricing exists, special attention should be given to ensure that the process is accessible and not overly bureaucratic, requiring fit-for-purpose administration and evidence.

5. Introduce Most Economically Advantageous Tender (MEAT) criteria

The suitability of pre-qualification criteria or award criteria depends on the level of expected competition in different segments of the procurement process. Pre-qualification criteria ensure that bidders comply with quality requirements. In the procurement of medicines, it is important to critically evaluate the consequences over time of applying pre-qualification criteria, to ensure a steady supply and avoid shortages. If the competition is already low, such criteria can lead to further limited participation in the tender processes putting future access at risk. To mitigate that risk, award criteria can be used to align individual tenders with broader policy objectives. Award criteria allow for a more detailed assessment of bids and have a smaller impact on competition compared to pre-qualification criteria.

To prevent fragmentation, undue administrative burden and avoid limited positive impact of the introduced award criteria in medicines procurement, it is crucial to harmonise criteria across Europe, especially relating to global manufacturing processes.

Reflection on the appropriate *weight* apportioned to different MEAT criteria is an important factor to the overall success of achieving intended political objectives. **It is crucial to assign appropriate weights to criteria beyond price, which need to be clearly communicated in the tender documentation** and ensure that it is balanced to avoid a disproportionate focus on lowest-price tenders. Assigning preliminary weight/importance to each criterion based on its significance, and alignment and engagement with relevant stakeholders will be key in achieving the set objectives.

We propose that procurers focus on:

⇒ **Environmental award criteria**, to align with the policy objectives of promoting more environmentally and socially sustainable development and reward manufacturers applying such practices

⇒ **Security of supply award criteria**, to give appropriate weight to mitigation of supply-chain risks and ensure long-term supply chain resilience.

⇒ Include **desirable product-specific characteristics** as bonus criteria in tenders that are not discriminatory and ensure fair competition.

Green procurement MEAT criteria for generic medicines

With the *European Green Deal* as one of the key priorities for the European Commission, Europe is on the path to a green transition, with the ultimate goal of reaching climate neutrality by 2050. The politics should support the transformation of the EU into a fair and prosperous society with a modern and competitive economy[15].

Sharing the commitment to advance more sustainable operations while safeguarding reliable access to medicine, manufacturers continuously invest in their production facilities and along their supply chains. There are several examples across the off patent pharmaceutical sector, including participation in launching the industry wide AMR Industry Alliance's Common Antibiotic Manufacturing Standards and the Responsible Effluent Management Principles, as well as shifting towards renewable or low-carbon energy across manufacturing and R&D sites[16].

Yet, to truly meet the objective of becoming climate neutral by 2050, and making sure the generic medicines sector is future-proof, further action is needed.

Green Public Procurement can play an important part in incentivising and rewarding sustainable practices while safeguarding reliable supply. However, to date, recognition of these efforts has been inconsistent and not always aligned with measurable targets proposed by industry standards. The European Commission has developed tools to facilitate the inclusion of environmental requirements in public tender documents[17] albeit with no specific resources for pharmaceuticals available.

[15] https://www.consilium.europa.eu/en/policies/green-deal/

[16] Examples include more sustainable antibiotic production in Austria [16], sustainable R&D facilities built in Greece [16] and others (https://www.politico.eu/article/belgium-leads-charge-eu-commission-medicine-pharma-reshoring-plans/)

[17] EU GPP criteria

For wider implementation of environmental criteria in procurement, we propose a pragmatic approach and straightforward logic that rewards manufacturers investing in reducing their environmental footprint in a way that does not generate unnecessary administrative burden and costs. We recognise that procurers might not always have the expertise and/or resources to evaluate the environmental sustainability of pharmaceutical manufacturing, therefore we propose to focus on the established industry standards and established platforms for publicly available standardised information.
Overall, we propose the inclusion of objective and measurable environmental award criteria in tenders that reward adherence to applicable industry standards as well as other self-regulated industry best practice initiatives for responsible wastewater management, greenhouse gas emissions reductions and the promotion of sustainable practices across the pharmaceutical supply chain.

We also recommend that the environmental criteria should recognise that fundamental changes leading to ultimately achieving net zero, will take time and substantial effort. For this reason, we propose that procurers reward strategies put in place, and publicly announced commitments, that showcase the ambition to make near term Greenhouse Gas (GHG) reductions on the path towards net zero and reduce the environmental footprint beyond GHG.

Antimicrobial resistance

In the specific case of antibiotics, the industry has made significant efforts to limit the development of antimicrobial resistance and is committed to continuing to invest in practices protecting the continued effectiveness of antibiotics as well as their availability to healthcare professionals' and patients. The AMR Industry Alliance [18] has created a manufacturing standard, which provides clear guidance to manufacturers in the global antibiotic supply chain to ensure that their antibiotics are made responsibly, helping to minimise the risk of AMR in the environment.

As such, the Standard requires that the manufacturer of an antibiotic must have an effective environmental management system and that the antibiotic's Predicted No-Effect Concentrations (PNEC), or the level at which a substance will not have an adverse effect on its environment, are met. To provide further guidance and quality assurance, a certification scheme has been developed recently, that enables antibiotic manufacturers to

[18] https://www.amrindustryalliance.org/antibiotic-manufacturing-standard/

demonstrate, through independent third-party evaluation, that the requirements of the Standard have been satisfied.[19]

Proposal for MEAT criteria relating to **environmental conduct that can be included in** tenders:

Topic	Question
Climate disclosure: general	**1) Does your company publicly disclose climate data?**
	1a) Does your company have an external rating related to environmental sustainability?
Climate: Green House Gases	**2) Does your company have a target to reduce GHG emissions for Scope 1 and 2? (y/n)**
	2a) Basic reward: The company has a publicly available climate target for scope 1, 2 (GHG –reduction)
	2b) Premium level 1: The company has committed to Science Based Targets initiative (SBTi) targets (which can be substantiated via the SBTi website)
	2c) Premium level 2: The company's targets are validated and approved by SBTi (which can be substantiated via the SBTi website)
Waste management	**3) Does your company have a waste reduction/recycling commitment?**
	3a) if yes: Is the commitment publicly available?
	3b) if not: Is the company willing to share its commitment?
Water management	**4) Does your company have a commitment to responsible water management?**
	4a) if yes: Is your commitment publicly available?
	4b) if not: Is the company willing to share its commitment?
AMR-Industry Alliance (*antibiotics specific)	**5) Is your company a member of the AMR IA and/or does it adhere to the AMR Industry Alliance principles?**
	5a) Does your company comply with the AMR Industry Alliance's Common Antibiotic Manufacturing Standards and working towards achieving PNEC target values?

19 https://www.europeanpharmaceuticalreview.com/article/183716/amr-certification-recognising-responsibly-in-antibiotic-manufacture/

Environmental Certifications	**6) Does your affected production-site hold or plan an ISO14001 certification (or equivalent e.g. ISO14001, ISO50001, EMAS)?**
Corporate Social Responsibility/Supplier sustainability evaluation	**7) Is your company considering CSR / sustainability criteria in the supplier evaluation and engagement?**

Security of supply MEAT criteria for generic medicines

Procurement of generic medicines has seldomly considered the reliability of supply as a criterion to include in tendering and has worked under the assumption that all marketing authorisation holders have an undifferentiated supply chain and therefore, opted not to reward manufacturers that have demonstrably good practices that offer additional supply robustness.
A recent U.S. Food and Drug Administration (FDA) study[20] recommends the promotion of more sustainable supply contracts, including considerations for supply chain maturity to be rewarded in contractual agreements. In Europe, a similar approach could be considered for the benefit of patients. We recommend basing it on the following criteria:

1. Supply chain reliability

The first criterion we propose is highlighting **the importance for a supplier to have a locally established team that can interact with the procurer** in case of a surge in demand or other supply-related questions. Having a locally established team ensures effective and efficient communication between the supplier and the procurer. A locally established team can respond quickly to any urgent requests or emergencies, ensuring a smooth flow of information. They can swiftly mobilise resources, arrange alternative solutions, and provide immediate assistance. They can help resolve problems, managing increased requirements, and avoiding disruption in the supply chain. A locally established team would have a better understanding of the local market dynamics, regulations, and cultural nuances. This helps in providing accurate advice and solutions to the procurer, ensuring compliance with local

[20] U.S. Food and Drug Administration (2019) - Drug Shortages: Root Causes and Potential Solutions

laws and practices. Regular interactions and face-to-face meetings can foster trust, collaboration, and a sense of partnership, leading to a long-term business association.

The second criterion touches on suppliers' professionalism, reliability, and commitment to fulfilling their obligations to supply. The core industry's mission is to supply medicines to the market, but there may be external factors such as natural disasters, wars, or pandemics that can cause disruption beyond their control. Therefore, the second criterion we propose is **not having experienced any 'uncommunicated' shortages** (*as in non-notified* shortages *that lead to real disruption)* in the past year.

Example: Certificate of Good Performance

In Greece, manufacturers have the option to include a "*Certificate of Good Performance*" in their bid for tenders. The bidders would request purchase bodies (hospitals in Greece and abroad) to provide a signed document attesting that they fulfilled their obligation to supply. This signed document is included in the bid application. While this is not a mandatory requirement, it serves as a reliability proof for companies to demonstrate their past successful supply records. This helps showcase their reliability and capability to supply.

2. Supply chain resilience

To minimise possible supply chain disruption, manufacturers can implement internal processes to increase manufacturing resilience. Suppliers may employ various strategies and practices to mitigate supply risks depending on their specific circumstances, tailored based on their unique context and challenges. By aligning their mitigation strategies with their specific circumstances, suppliers can effectively reduce supply risks and maintain a resilient supply chain.

Therefore, rather than basing the evaluation of the bids on one specific criterion, we recommend evaluating the proposed mitigation strategy by the supplier on an individual basis.

Different possible policies could include (but are not limited to): A global inventory of finished products or dual sourcing of critical raw material/API or inventory policy for key starting materials/API.

The other criterion that could have weight in procurement is the **suppliers' ability and flexibility to accommodate unplanned demand**. For this to be possible, certain regulatory flexibilities need to be in place, such as the possibility to market alternative packaging or strength in the impacted portfolio. Sometimes, it would also be beneficial to offer alternative therapy (in the case of a global shortage), if available in the company portfolio.

3. Supply chain transparency

It is important to understand the global and extensive nature of the pharmaceutical supply chain. Manufacturing issues can occur irrespective of the manufacturing locations and are far more influenced by the maturity of the supply chain. Furthermore, global and diversified supply chains enable flexibility, and can help offset risks and build resiliency. No country can manufacture all the medicines they need. As such, the geographical location of individual manufacturing facilities is not a predictive rate of supply reliability or resilience. Nevertheless, an understanding of the supply chain and its geography can help procurers to mitigate potential shortages. Therefore, we recommend, where necessary, that the manufacturer discloses, case by case, depending on the most applicable: the final warehouse from where the product will be distributed or packaging site or final dosage manufacturing site or active pharmaceutical ingredient manufacturing site. Due to business sensitivity, this information should be exclusively available to the procurers involved in the procurement process under a non-disclosure agreement or other appropriate confidentiality rules.

Proposal for MEAT criteria relating to the **security of supply that can be included in** tenders:

Supply chain reliability	The supplier has a locally established team[1] that can interact with the procurer in case of a surge in demand or other supply-related questions.
	The supplier did not experience any 'uncommunicated' shortages in the past year.

[1]Such as Customer Service & Key Account Manager

Supply chain resilience	The supplier can demonstrate supply chain resilience, with a specific mitigation policy in place. Different possible policies include (but are not limited to): global inventory of finished products or dual sourcing of critical raw material/API or inventory policy for key starting materials/API.
	The supplier has the capacity to mitigate OOS by reallocation of stock from other EU countries, possibly by offering alternative packaging or strength in the portfolio, or alternative therapy available in the company portfolio[2].
Supply chain transparency	The marketing authorisation holder to disclose, where requested by procurers to help mitigate potential shortages, the site for the product tendered (possibilities include, case by case, depending on the most applicable): the final warehouse from where the product will be distributed /packaging site / final dosage manufacturing site/active pharmaceutical ingredient manufacturing site (exclusively to the procurers involved in the procurement process under a non-disclosure agreement). This information will remain confidential from other stakeholders.

MEAT criteria: Product-specific characteristics

Depending on the products and their expected use, product-specific characteristics can also be considered and awarded bonus points. These criteria must be developed

[2] Requires regulatory flexibilities, namely in terms of packaging and labelling.

transparently and impartially to prevent any potential discrimination and ensure fair competition. Characteristics such as expiry date, packaging formats (e.g. unit dose), logistical advantages (storage conditions), ease of handling, and need for reconstitution, among others, could be considered and should be given appropriate weight.

We recommend including product-specific characteristics as bonus criteria in tenders that are not discriminatory and ensure fair competition.

As this is highly dependent on the product and the organisation of the healthcare system itself, it would be challenging to list all the possible characteristics in this paper. Consequently, we recommend a transparent procedure to discuss with potential bidders the possibilities for product characteristics to give all bidders a fair opportunity to compete and to deliver the best value to healthcare systems. When designing product-specific criteria, we highly recommend procurers consult stakeholders, particularly healthcare professionals and patients to make sure that the product characteristics are of actual value to them.

Medicines for Europe

Medicines for Europe (formerly EGA) represents the generic, biosimilar and value added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines for Europe, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members employ 160,000 people at over 350 manufacturing and R&D sites in Europe and invest up to 17% of their turnover in medical innovation.