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Revision of EU rules on public procurement

Strengthening EU Resilience through sector-specific procurement guidance for pharmaceuticals

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Medicines for Europe, the European Association representing generic, biosimilar and value added medicines, strongly supports the need for a revision of the Public Procurement Directive. As **7 out of 10 dispensed medicines** in the EU are generic medicines[1] and approximately 40% of medicines are being purchased via public procurement procedures[2], Directive 2014/24/EU plays a crucial role for our industry.

Moreover, in many countries, procurement accounts for almost 100% of medicines purchases through the hospital channel, making it a strategic tool to ensure security of supply, access to medicines and rational use of health budgets.

Health accounts for the largest share of public procurement spending, with approximately 30% across OECD countries, and going up to over 40% in several countries, including Belgium[3]. Moreover, due to the highly technical nature and strategic importance of medicinal products, as illustrated in the Draghi report[4], the revision of the Public Procurement Directive considers the specialised needs of the sector, and delivers dedicated guidance for procurement of these products.

Public procurement of medicines has seen some of the same trends identified in the European Commission staff working document[5] which supported the revision of these directives. Amongst the most important trends are the very limited use of Most Economically Advantageous Tender (MEAT) criteria, most procedures being single winner, as well as a lowering of the number of bidders in tenders.

These criteria represent the overall value of an offer beyond price alone also including quality, sustainability, environmental impact, delivery and service performance. In practice, the most typical MEAT criteria applied in medicines procurement consider elements such as supply chain stability, environmental impact criteria and product quality requirements.

For example, in France, data from a regional hospital group shows that for tenders covering 2024-2027 more than 50% of tenders received either one or no offers, in comparison with approximately 30% for 2017-2021.[6]

Current pricing and procurement practices, focused on lowest price only are linked to the increasing consolidation that we see in the generic sector with, for example, 8 out of 10 critical generic medicines having fewer than 3 suppliers on the market across all of Europe[7]. This consolidation leads to risks to security of supply[8], as evident from the number of shortages in the past years. When it comes to biosimilar medicines, the negative impact of existing procurement practices leads to products not being developed – only approximately 30% of molecules losing exclusivity in the next years face biosimilar competition[9].

In recognition of the shortcomings of existing procurement practices, several attempts have been

[1] IQVIA Institute. *Beneath the Surface: Unravelling the True Value of Generic Medicines*, April 2024 (link)
[2] IQVIA Institute. *Tendering Landscapes in Europe*, 2023 (link)
[3] Government at a Glance 2025 (link)
[4] https://commission.europa.eu/topics/competitiveness/draghi-report_en
[5] European Commission, *Commission Staff Working Document – Evaluation of the 2014 Public Procurement Directives*, SWD(2025)332
[6] MEDINAQ. *Appel d'offres médicaments 2024-2027*. via GEMME (France)
[7] Teva. *Generics Health Check 2025*, 2025
[8] S.Vogler et al. *Study on Best Practices in Public Procurement of Medicines*, European Commission (DG GROW)
[9] IQVIA Institute. *Assessing the Biosimilar Void*, October 2023

made to try and address these, both by procurers in different countries[10], cross-border initiatives[11] as well as by the European Commission who, in the 2023 Communication on Medicines Shortages, mentioned its intention to issue EU guidance on procurement[12]. The Communication was built on the 2022 Study on Best Practices in the Public Procurement of Medicines[13], which illustrated that one of the key challenges to improving procurement practices are the limited institutional capacity and resources of contracting authorities. This happens particularly in more fragmented and less centralised procurement, where multiple regional or local authorities conduct tenders independently.

For a more successful demand-side policy over the longer term, there must be an alignment across the EU, especially criteria that impact supply chains and manufacturing processes of companies operating globally.

We would therefore strongly support the fact that the revision of the Public Procurement Directive addresses the specificities of the pharmaceutical sector by setting out **sector-specific rules** for medicine procurement:

- ✓ **Mandatory** application of **MEAT award** criteria
- ✓ **Mandatory multi-winner tenders** for the off-patent sector, where possible.
- ✓ Price-adjustment possibilities, **volume** estimations, sufficient **lead time**, and proportionate **penalties**.
- ✓ More clarity on factors considered and a clear methodology for assessing **abnormally low bids.**

1. More support is needed to ensure the implementation of MEAT criteria

Public procurement of strategic goods across Europe remains dominated by lowest-price-only awards, despite several other criteria being mentioned within Article 67 of the existing Public Procurement Directive, such as environmental and sustainability performance, delivery conditions and supply reliability. Both the Commission's own evaluation[14], and the European Court of Auditors' Report[15], show that uptake of MEAT criteria remains low across the internal market, despite its potential to support policy objectives such as sustainability, resilience and innovation. It is observed that Member States still award a very large share of contracts based on price alone. In 2021, eight Member States awarded more than 80% of tenders based exclusively on the lowest price, and in 2023, twenty Member States still awarded more than 50% of tenders only on price[16]. Many contracting authorities continue to rely mainly on price-only award criteria, because they perceive MEAT criteria as

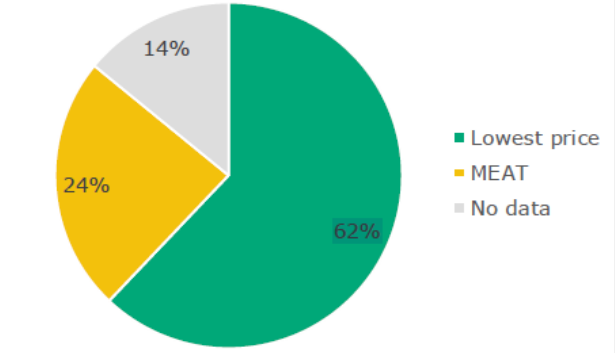
[10] Sykehusinnkjop (Norway). *Environmental Criteria in Medicines Procurement – Results 2024*
[11] Nordic Pharmaceutical Forum. *Procurement Initiatives & Results*
[12] European Commission. *Communication on Medicines Shortages in the EU*, 2023
[13] S.Vogler et al. *Study on Best Practices in Public Procurement of Medicines*, European Commission (DG GROW)
[14] European Commission, Commission Staff Working Document – Evaluation of the 2014 Public Procurement Directives, SWD(2025)332
[15] European Court of Auditors, Special Report 28/23 – EU Public Procurement: Competition and SME Participation
[16] European Court of Auditors, ibid

administratively complex, not supported by practical guidance and more exposed to litigation.

This strong downward price pressure discourages participation from smaller or mid-sized suppliers and leaves markets more exposed to disruption. Furthermore, when tenders are awarded based on the lowest price, suppliers are pushed into cycles of constant price reductions. Over time, these repeated cycles erode the economic capacity to maintain multiple production lines, thereby increasing the fragility of supply chains.

Even when MEAT criteria are formally used, the quality components often receive extremely low weighting; meaning price continues to determine the outcome in practice. This limits the Directive's ability to promote truly quality-based procurement[17].

Figure II: Award criteria in PPM in the study countries, 2008-2021



MEAT = Most Economically Advantageous Tender
Source: European Commission TED data, analysis by authors

We observe the same trends in the medicines sector, where 24% of tenders for pharmaceutical products use MEAT criteria, while 62% of tenders rely primarily on price. In certain therapeutic classes, such as antineoplastic agents, the share of price-only awards goes up to 84%. This trend shows that important quality and supply considerations are not yet included in current tendering practice[18]. In multi-supplier markets, MEAT criteria targeting reliability and secure supply chains help mitigate the effects of global shortages or disruptions. It shows that jurisdictions applying MEAT consistently experience greater continuity of supply because evaluation frameworks reward suppliers that maintain diversified production capacity involving more than one manufacturing site or region.

For European pharmaceutical markets, supply chains are international and interconnected, with a cross-European approach needed to ensure security of supply. MEAT award criteria can incorporate elements such as supply-chain security, manufacturing resilience, packaging and product quality aspects without creating disproportionate administrative burdens for buyers. These practices demonstrate that quality-based evaluation improves the functioning of markets and enhances resilience.

For wider implementation of environmental criteria in procurement, it is crucial that a pragmatic approach is taken 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

[17] European Commission, Commission Staff Working Document – Evaluation of the 2014 Public Procurement Directives, SWD(2025)332
[18] S.Vogler et al. Study on Best Practices in Public Procurement of Medicines, European Commission (DG GROW)

practice initiatives for responsible wastewater management, greenhouse gas emissions reductions and the promotion of sustainable practices across the pharmaceutical supply chain.

A series of specific criteria environmental and security of supply criteria which are suitable for the off-patent medicines industry can be found in our proposal for EU procurement guidelines, available here: https://www.medicinesforeurope.com/wp-content/uploads/2024/01/Position-paper-proposal-for-EU- procurement-guidelines-Final.pdf

In markets where competition is already limited, extensive pre-qualification criteria may unintentionally exclude reliable participants with the risk of intensifying supply risks. In such cases, MEAT award criteria offer a more proportionate instrument since they allow assessment of quality attributes and promote an open and competitive market.

The suitability of pre-qualification versus award criteria depends on market structure. In low-competition markets, a rather common situation in the field of medicines, overreliance on pre-qualification can reduce participation further and risk increasing the number of tenders with no bids. Therefore, award criteria would be more appropriate as they allow authorities to integrate environmental and security of supply considerations without reducing competition.

To avoid fragmentation and unequal administrative burdens, MEAT criteria and especially those relating to supply reliability and environmental impact should be harmonised as much as possible at EU level, supporting more effective and balanced negotiation of tender conditions between contracting authorities and suppliers. Divergent national frameworks produce inconsistent obligations for suppliers and buyers, weakening the ability to use procurement as a strategic tool.

The weighting of MEAT criteria is decisive in determining the quality elements' influence on the tender outcomes. Weightings must be proportionate, transparent, clearly communicated ex-ante and balanced to avoid reverting to lowest-price criteria as the dominant factor. Quality criteria should be designed and assessed on the basis of objective, measurable and clear parameters. Product-specific characteristics such as extended expiry dates, unit-dose packaging, storage conditions, logistics advantages or ease of handling may be reflected through predefined bonus points when they meet non-discrimination requirements and are directly relevant to the subject matter.

Recommendations

➔ Make MEAT award criteria mandatory for medicines procurement

The revised Directive should establish the MEAT award criteria as the default for all medicines procurement. Moving away from price-only awards is essential to protect continuity of supply and long-term market sustainability. MEAT criteria should be realistic, transparent and appropriate for the tender subject matter. Clear guidance from the Commission on appropriate MEAT criteria and supporting documentation would lower implementation barriers and promote consistent application across Member States. The design of MEAT criteria should be informed by a multi-stakeholder approach, involving clinical experts (to ensure medical expertise), procurement professionals (to reflect market realities), industry representatives and policymakers (to align with broader health and industrial policy objectives).

➔ Promote EU convergence of award practices

Harmonised MEAT criteria would help reduce fragmentation between Member States and drive common strategic objectives, such as security of supply and environmental sustainability. The Directive should encourage the development of standardised templates and common indicators that can strengthen competition based on value rather than lowest cost alone and allow suppliers to re-use the same documentation across multiple Member States rather than adapting it country by country.

➔ Provide EU-level guidance for transparent and proportionate quality criteria

The Directive should state that contracting authorities are expected to apply weighted and evidence-based non-price criteria, such as supply-chain resilience, reliability, and transparency or environmental conduct. Specific guidance with minimum expectations of weighting should support these criteria to ensure that quality factors are practically considered. Contracting authorities should be required to describe ex-ante how compliance with awarded MEAT criteria will be monitored and followed up during contract implementation.

2. Making multi-winner tendering the norm increases competitiveness and security of supply

The Commission's own evaluation[19] and the European Court of Auditors' Report[20] both underline a horizontal trend of decreasing participation and a rise in single-bid procedures across the internal market.

In markets where supply is concentrated among very few operators, allocating the entire demand to a single supplier increases the risk of disruption. When the tender design does not ensure the continuous presence of multiple qualified suppliers, even a minor operational issue can result in prolonged unavailability of strategic and critical medicines. For generic medicines 2/3 of shortages are associated with a low supplier country[21].

Procurement frameworks should encourage supplier participation by limiting disproportionate financial and logistical risks. For example, by providing agreements with guaranteed price indexation, and ensuring proportional allocation of purchases among multiple awarded suppliers during the same contract period.

In the medicines sector, across different EU member states many medicines reach the market exclusively through public procurement. Particularly in hospital settings, where 22 out of 30 countries rely on procurement[22], awarding single-winner tenders can create de-facto monopolies. Long

[19] European Commission, Commission Staff Working Document – Evaluation of the 2014 Public Procurement Directives, SWD(2025)332
[20] European Court of Auditors, Special Report 28/23 – EU Public Procurement: Competition and SME Participation
[21] IQVIA Institute. *Beneath the Surface: Unravelling the True Value of Generic Medicines*, April 2024 (link)
[22] Medicines for Europe, *Generics Market Review 2025*

contract duration, which is generally around 12-24 months, and extending up to 36-48 months in several countries[23], blocks the market for other suppliers, rendering it, in many cases, economically unviable to cover the costs of maintaining the product on the market. Consolidation has been increasing across all generic medicines since 2014, but it has grown 3x faster for critical generic medicines, where a higher percentage is supplied via procurement channels. In fact, we observe that for 83% of critical generic medicines, there is only 1 major supplier across Europe (>60% of the market share)[24].

This also exposes contracting authorities since they risk remaining without alternatives of additional fluctuations in demand. The remaining suppliers cannot compensate for any unforeseen disruption since they may have reduced or discontinued production after losing tenders. Re-starting production for these products is often a lengthy process due to regulatory and technical constraints, which can delay patient access. Awarding a single-winner tender can therefore undermine supply reliability, as there may be no alternative source capable of meeting demand if the winner is unable to deliver.

Evidence from the medicines sector[25] shows that single-winner tendering often contributes to excessive concentration of supply and increases exposure to shortages. The study indicates that tender designs awarding 100% of the volume to a single supplier, especially in markets characterised by lowest-price-only awards, contribute to excessive concentration of supply and heighten exposure to supply disruption.

Highly consolidated markets, such as the pediatric antibiotics market, illustrate how awarding 100% of volumes to one supplier can delay patient access when production cannot scale rapidly to meet unexpected exogenous patterns. When it comes to biologics markets, similar issues arise since, while multi-winner tenders are legally possible in most Member States, they are not implemented in practice, and even when they are, volume distribution is often not applied. Manufacturing of biological medicines, including biosimilar medicines, involves longer lead-times, particularly linked to long planning, often up to two years in advance, complex production processes, regulatory approvals and supply chain constraints, which limit the ability to rapidly increase the output. Single-winner tendering in biologics, including biosimilar medicines procurement, therefore creates disincentives for non-awarded suppliers to remain active (ready to supply) and weakens the overall reliability of the supply chain.

These dynamics also contribute to the "biosimilar void," where limited market access opportunities and insufficient demand predictability reduce companies' ability and willingness to invest in the development of new biosimilar medicines candidates or trigger re-evaluation of existing portfolios maintenance. More favourable and sustainable procurement conditions, including predictable volumes and multi-supplier frameworks, are therefore essential to support continued investment and long-term competition in biosimilar markets.

Multi-supplier tendering, where no single company carries the full burden of supply, has proven to guarantee delivery consistency even if one supplier faces temporary disruption, since it reduces

[23] Medicines for Europe, *ibid*
[24] Teva. *Generics Health Check 2025*, 2025
[25] European Commission, *Commission Staff Working Document – Evaluation of the 2014 Public Procurement Directives*, SWD(2025)332

dependency on any single entity. Moreover, contracting authorities benefit from greater flexibility to respond to changing demand patterns due to predictable supply cycles enabled by multi-winner tendering.[26]

Multi-winner tendering, combined with proportionate allocation mechanisms and guaranteed volumes, offers a flexible instrument for contracting authorities to safeguard supply stability. However, this is also dependent on the reliability of the awarded suppliers, therefore multi-winner approaches need to be complemented by the inclusion of supplier reliability as part of award criteria. This can be demonstrated e.g. through references to previous deliveries demonstrating their reliability. Diversity of suppliers and avoidance of over-concentration are strategic components of any resilient procurement system. In terms of market competition, multi-winner tenders make participation more attractive to smaller and medium-sized manufacturers, and they improve the quality of long-term competition.

In Norway, national procurement for medicines is organised around regional segments (approximately 65 % and 35 % of total volumes) and applies shared tendering between multiple suppliers across those segments, which has been reported to enhance parallel supply options rather than a single national winner[27]. In Denmark, procurement authorities (through Amgros framework agreements) often conclude non-exclusive multiple supplier agreements, with primary and secondary supplier roles, such that second suppliers function as fallback in case the primary supplier faces stockouts or failures[28].

However, not all ways of implementing multi-winner frameworks are equal in practice. For example, in Italy, although the national law requires multi-winner framework agreements for off-patent biological medicines[29], in practice, hospital purchasing groups place orders with just one of the suppliers, negating the positive effects of the multi-winner framework.

In Greece, the scenario is different since the three lowest bidders are awarded fixed shares of around 50%, 30%, 20% of the tender volume, so as to ensure that different suppliers are active in parallel. Also, in the UK, NHS hospital procurement relies on framework agreements and centralised procurement at regional level, which can be then split into slots. This means that different suppliers are awarded different lots within the same procedure instead of relying completely on a single national winner[30]. Similarly, Denmark and Norway have centralised procurement models with strong implementation capacity and clear governance structures[31]. Both systems are based on dedicated national procurement bodies which enable consistent tender execution and effective follow-up during contract implementation[32] [33].

[26] European Commission, Commission Staff Working Document – Evaluation of the 2014 Public Procurement Directives, SWD(2025)332
[27] European Commission, *Biosimilar practices and tendering in Norway*, 2024
[28] Amgros, Framework Agreement Template, 2023
[29] S.Vogler et al. *Study on Best Practices in Public Procurement of Medicines*, European Commission (DG GROW
[30] Medicines for Europe, *Biosimilar medicines Market Review 2025*.
[31] S.Vogler et al, *ivi*
[32] European Commission, *Biosimilar practices and tendering in Norway*, 2024
[33] Amgros, *About Amgros – Central procurement for Danish hospitals* (link)

Recommendations

➔ Make multi-winner tenders the norm for off-patent medicines

The Directive should explicitly favour multi-winner tenders for off-patent medicines to increase security of supply and prevent excessive concentration. The norm should shift towards models that distribute volume and responsibility across multiple qualified suppliers, while single-winner tenders should be considered an exception for specific circumstances, and contracting authorities should be required to justify any single-winner decision based on objective and transparent criteria.

➔ Ensure that multi-winner tenders deliver real volume allocation

Although current EU rules already allow multi-winner frameworks, their implementation is often ineffective with multiple winners appointed but without enforceable distribution of volumes. The Directives should clarify that, where multi-winner models are used, predictable and proportionate allocation mechanisms such as minimum guaranteed volume shares, quotas or lots are expected.

3. Increase demand predictability with appropriate lead times and volume estimates

Procurement planning is an area with much room for improvement across Member States and sectors[34]. There are ongoing challenges concerning late publication of tenders, short deadlines for submission and inaccurate or outdated volume estimates[35] and unforeseeable lead times. This unpredictability leads to lower participation and avoidable supply pressures, as it has been proven that markets with predictable tender calendars and clear volume forecasting have higher supplier participation and more stable market conditions[36].

For medicines, lead time between contract award and first delivery is extremely short **(less than 60 days[37])** in most countries, which comes in direct contrast with timelines for medicine manufacturing for which processes are often complex with many different stakeholders and interdependences[38]. The total lead time, from starting materials to final product is estimated to be **1 – 1.5 years,** according to an internal consultation of Medicines for Europe's manufacturing and supply chain committee.

Aiming to comply with the current short lead times in the case of being awarded the tender, manufacturers need to hold stock in anticipation. However, if the manufacturer does not win the tender, they are left with an excess of stock. Consequently, the manufacturer must often destroy its

[34] European Commission, *Commission Staff Working Document – Evaluation of the 2014 Public Procurement Directives*, SWD(2025)332
[35] S.Vogler et al. *Study on Best Practices in Public Procurement of Medicines*, European Commission (DG GROW)
[36] S. Vogler et al., *ibid*
[37] Medicines for Europe, *Generics Market Review 2025*.
[38] According to data from a member company, there are more than 350 components required to be produced/purchased from supplier/local manufactures/build in-house until the medicine arrives to local warehouse

stock (as no alternative use of the products exists), which is very costly and has negative 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 is 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[39] as well as under WTO rules).

On average, the minimum lead time needed for a manufacturer to supply a generic medicine is around six months. This might be even longer for biosimilar, complex generic or value-added medicines due to complex manufacturing processes[40]**.** Therefore, lead times should be adapted to the product characteristics as well as the requested volumes to be delivered (e.g. complexity in manufacturing, regulatory requirements and additional efforts due to serialisation). It must be considered that even the simplest molecules are subject to demanding supply planning requirements, with a minimum lead time of at least six months, to guarantee a predictable supply. For example, in Norway lead times for tenders have now been increased to 6-9 months, which is much more appropriate for adequate supply planning and manufacturing timelines. This approach should be distinguished from procurement following loss of exclusivity, where timely tendering and immediate market access are essential to ensure immediate supply once competition becomes available.

Accurate volume estimates and indicative timings are essential to ensure predictability of supply; however, they are only in place in a minority of cases. In several settings, tender preparation is not systematically informed by horizon scanning and robust forecasting of post-expiry market dynamics, which can lead to misalignment between procurement timing/volumes and manufacturing planning.[41]

Recommendations

➔ Require binding and proportionate minimum volumes

The Directive should clarify that contracting authorities are expected to provide minimum binding commitments together with realistic indicative volumes based on historical data or forecasting. To maintain dedicated production lines and allocate capacity efficiently, manufacturers need to have predictable volumes over the duration of the contract.

Introduce a minimum lead time of 6 months to first supply. The Directive should also establish a minimum 6-month period, applicable to medicines with simple manufacturing processes between contract award and the first delivery. For medicines with higher manufacturing or regulatory complexity, longer lead times should be envisaged. This interval reflects all the types of cycles (regulatory, manufacturing, logistical) in the medicines supply chain and functions as an important

[39] 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

[40] Medicines for Europe. *Proposal for EU Procurement Guidelines*, 2024

[41] S.Vogler et al. Study on Best Practices in Public Procurement of Medicines, European Commission (DG GROW)

safeguard for manufacturers against the risk of shortages when switching suppliers.

4. Address disproportionate burdens which threaten the financial viability of suppliers

Many contracting authorities avoid including review clauses due to the perceived complexity of Article 72 Procurement Directive and uncertainty about what constitutes a permissible modification. Therefore, long-term contracts often remain rigid even in the face of major market changes, such as rising energy costs[42].

In medicine markets, tender durations are long (usually between 12-24 months, but sometimes up to 48 months)[43] and contract clauses sometimes allow further extensions[44].

This is compounded by the fact that, in most cases, medicines prices are very strictly regulated, and while they are revised on a regular basis (every 6-12 months on average), most of the time these can only go down[45] (82% of cases according to data from our members). This can be a significant barrier, as often these regulated prices act as ceiling prices in tenders. In several countries, if during the tender period the regulated price drops below the one awarded in the tender contract suppliers are forced to reduce their price further[46]. In some markets, such as Bulgaria, re-entry into the market is only possible at the last awarded tender price, even where that price level was set many years earlier, effectively preventing later market entry or re-entry. However, similar adjustments are not allowed even in duly justified cases (e.g. producer costs for antibiotics have increased by 32% over the last 4 years, while prices have decreased by 10%[47]).

This contributes to insecurity of supply, with contracts without review clauses having contributed to temporary market withdrawals, and additional pressure on supply continuity[48]. Where appropriate, limited contract extensions by mutual agreement could provide additional flexibility to manage unforeseen market developments. Longer contract durations, including periods exceeding 12 months, an enhance predictability for manufacturing planning and supply continuity, provided that appropriate price revision mechanisms are foreseen.

Another factor is the use of disproportionate or rigid penalty schemes in procurement contracts. In the medicines market, certain penalty systems are excessively punitive relative to the value of the products concerned or the nature of the disruption, and do not distinguish between avoidable supplier failures and genuine external shocks such as dramatic demand increases. 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

[42] European Commission, *Commission Staff Working Document – Evaluation of the 2014 Public Procurement Directives*, SWD(2025)332
[43] Medicines for Europe, *Generics Market Review 2025*
[44] Medicines for Europe, *Biosimilar medicines Market Review 2025*
[45] Medicines for Europe. Generics Market Review 2025 – Key Findings.
[46] Medicines for Europe, *Generics Market Review 2025*
[47] https://www.viatrispolicy.eu/en/about/securing-access-improving-lives
[48] S.Vogler et al. *Study on Best Practices in Public Procurement of Medicines*, European Commission (DG GROW)

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 and 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.

Procurement systems using proportionate penalty frameworks that differentiate on the events' nature tend to achieve better supply performance. In these systems, penalties work as an incentive to maintain high service levels rather than as a deterrent that pushes suppliers out of the market[49].

Recommendations

➔ Enable price-adjustment mechanisms in multi-year contracts

The revised Directive should recognise that rigid and long-term contracts can become economically unstainable and drive suppliers out of the market. Tender pricing should be structured to reflect volume-based efficiencies, as larger and more predictable volumes enable economies of scale and allow suppliers to offer sustainable discounts. Tenders should include legally binding and transparent price adjustment mechanisms that consider inflation and evolving market conditions. Contracting authorities should be expected to include transparent and objective price-adjustment tools (e.g. inflation indexes, cost-based formulas) for contracts with long duration or contract extensions, where such extensions are agreed by mutual consent, which can be used in duly justified cases, and applied at clearly defined and predictable moments. These mechanisms should be coupled with consistent application of the rules on abnormally low tenders, to prevent strategic underbidding in the initial phase of the contract and subsequent price increases without renewed competition.

➔ Ensure fair and predictable penalties

Penalties should be proportionate to the executed portion of the contract volume and capped as a percentage of the remaining contract value and calculated based on net contractual prices rather than list prices. Penalty frameworks should consider the cause of the supply failure (e.g. force majeure or external shocks) and, where relevant, the complexity of production. They should only apply to failure to supply without undermining the supplier's ability to re-enter future tenders.

5. Establish a clear methodology for investigating abnormally low tenders

The Commission's evaluation highlights a challenge in the application of Article 69 Public Procurement Directive on abnormally low tenders across the internal market. Contracting authorities in many Member States struggle to detect and evaluate abnormally low tenders, often due to the absence of

[49] S.Vogler et al. *ibid*

clear benchmarks and a lack of clarity on which cost elements should be considered. This results in a high frequency of acceptance of abnormally low tenders without adequate assessment, also because contracting authorities avoid questioning such bids due to procedural risks[50].

The evidence shows that the Public Procurement Directive legal framework leaves significant room for divergent national practices. Many authorities focus on price-only comparisons without assessing the economic plausibility of offers and some others use informal or non-transparent thresholds without the needed harmonisation across Member States. This fragmentation can produce different outcomes for similar cases depending on the Member State or the individual contracting authority.

This Commission's evaluation notes the assessment of abnormally low tenders as one of the most challenging components of procurement practice due to limited guidance and insufficient capacity among public buyers. These issues are not limited to medicines. The current abnormally low tender regime does not provide contracting authorities with the necessary tools or expertise to identify offers that may threaten continuity of supply and the long-term viability of competition. Therefore, contracting authorities rarely request justification due to uncertainty about which factors can be examined.

For the off-patent medicines sector, this risk can become even greater since the market is based on structurally low prices, and competition is highly concentrated.

In pharmaceutical procurement, abnormally low tenders often arise in tenders where price is the dominant award criterion. In such cases, offers may be below the realistic cost of producing or supplying the product[51].

For example, in Germany, the contracts between health insurance companies and generic drug manufacturers require the companies to offer extremely aggressive discounts. The amount of these discounts is confidential and therefore almost never made public, however a data breach showed that AOK was offered a discount of more than 99% of the list price for several bids, leading to a cost of half a cent per tablet[52] in one case. These types of discounts are clearly unsustainable.

Recommendations

➔ Clarify the criteria for identifying abnormally low tenders

The Directive should enable more consistent scrutiny of low bids in strategic sectors such as medicines. Specific guidance should clarify the economic and supply-risk indicators that should trigger an investigation of abnormally low tenders in medicines procurement. Indicative factors may include offers priced below verifiable production cost benchmarks, such as API input costs, or bids that are not economically sustainable considering supply obligations and market conditions.

[50] European Commission, *Commission Staff Working Document – Evaluation of the 2014 Public Procurement Directives*, SWD(2025)332
[51] S.Vogler et al. *Study on Best Practices in Public Procurement of Medicines*, European Commission (DG GROW)
[52] https://www.progenerika.de/news/datenpanne-bei-der-dak-offenbart-ruinoese-rabatte/

➔ Strengthen the assessment obligations once abnormally low tenders are detected

The Directive should require contracting authorities to formally request justification from bidders and to exclude a bid where supply reliability cannot be guaranteed or when there is a high-risk of failure to deliver, particularly in cases where tenders are awarded to opportunistic suppliers. Where an abnormally low bid is nevertheless accepted, the contracting authority should be required to document and make public the justification.

6. Technical recommendations on the application of "Made in Europe" criteria

The consolidation of supply and manufacturing that we see currently in the off-patent pharmaceutical space is a direct result of procurement and pricing policies that do not factor in the security of medicines supply. Procurement reforms (mandatory security of supply criteria, MEAT criteria, multi-winner approaches, etc.), must reward security of supply, strategic autonomy and diversification. These broader reforms should apply to all medicines and localisation (Made in Europe) criteria, if implemented by Member States, should be applied alongside them, ensuring a coherent approach to enhancing supply security, autonomy, or diversification.

The technical design of localisation ("Made in Europe") measures will impact their effects in the market. The EU's cooperation with key trading partners is fundamental to strengthening supply chain security and reinforcing Europe's role in international pharmaceutical trade. The EU should continue to champion open trade and multilateral cooperation by promoting resilient, diversified and secure supply chains, including through new and existing trade agreements.

It is therefore critical that the design of these measures supports resilient supply chains while remaining compatible with open and competitive markets.

This includes ensuring the application of EU localisation criteria to part of the tender and maintaining multi-winner approaches for both the part in which EU localisation criteria has been applied, as well as for the one open to all manufacturers (both EU and non-EU), where feasible. This can support EU production while also ensuring supply diversification and safeguarding competition. Furthermore, in the absence of sufficient bidder interest, provisions should allow participation in tenders to be open to all interested parties, thereby ensuring the continuity of medicine supply.

Secondly, a clear and pragmatic definition is needed for what would be assessed as "Made in Europe", particularly as pharmaceuticals have complex production processes and global supply chains spanning across multiple jurisdictions. Just as a brief illustration of that, for each product there is an average of more than 350 components required to be produced/purchased from suppliers/ manufactured/built in-house until the medicine arrives at the to local warehouse, according to one of our members.

In our opinion such a definition should consider the various essential stages involved in the production process, including the chemical synthesis or biological production of active substances, the preparation and use of key intermediates and other critical raw materials, formulation and

compounding development, technology and manufacturing process development, bulk production of the drug product and primary packaging.

These different components and stages may all independently contribute to ensuring strategic autonomy, security of supply and require complex and costly manufacturing processes, therefore they should be considered in their own right.

Furthermore, to ensure security of supply and considering that EEA countries, UK and Switzerland are heavily integrated in EU supply chains, they should be considered jointly with EU countries, when making these assessments.

Finally, given the very nature of pharmaceutical supply chains, appropriate technical expertise is needed, therefore marketing authorisation holders should be involved in the further discussions on the implementation of these criteria at both EU and national level.

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.

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