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ON THE EFFECTIVENESS OF PUBLIC PROCUREMENT OF MEDICINES IN THE EU

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TABLE OF CONTENTS

INTRODUCTION P. 3

RECOMMENDATIONS ON SUBSTANTIVE GUIDANCE P. 4

KEY TRENDS IDENTIFIED IN THE EFPIA SURVEY P. 5

1. Lack of clinical staff involvement leads to inadequate design of tender procedures and negative spillover effects P. 5

1.1. Inaccurate estimation of the necessary quantities of medicines leads to duplication P. 5

1.2. Inappropriate grouping of medicines through unjustified product expansion without a proper assessment of the products' therapeutic equivalence unduly limits prescribers' choice P. 5

2. Duplication and lack of adherence to contract duration increase costs and impact supply P. 7

3. Use of imbalanced/divergent award criteria increases complexity and costs P. 8

4. Increased recourse to 'price only' awards threatens supply sustainability that is further compounded when combined with 'winner takes all' awards P. 9

5. Transparency of awards should not threaten price confidentiality P. 11

6. Imbalanced contractual terms, insufficient tender lead time between award of contract and expected deliveries with no concomitant offtake obligations P. 12

7. Complex cross-border joint procurement procedures compounds the challenges identified P. 14

CALL FOR THE ADOPTION OF BEST PRACTICE GUIDANCE FOR EFFECTIVE PROCUREMENT P. 15

ANNEX 1: OVERVIEW OF THE EU PUBLIC PROCUREMENT FRAMEWORK P. 16

ANNEX 2: OVERVIEW OF KEY SURVEY FINDINGS P. 17

INTRODUCTION

Recourse to the public procurement of medicines has increased in recent years as payers across the EU struggle to balance constrained healthcare budgets and increasing demand. Yet the practical application of the procurement rules varies widely across EU Member States in ways that are not always aligned, effective, or compliant with the spirit or the letter of the core provisions of Directive 2014/24/EU.[1]

The Commission's recent Report on implementation and best practices of national procurement policies in the Internal Market ("Implementation Report"), the first official reporting exercise on the implementation of the Directive, concludes that there is much room for improvement.[2] It calls for better quantitative reporting on procurement at national level, and for more stringent implementation of strategic procurement considerations to support an inclusive recovery and socio-economic resilience.

Many of the Implementation Report's key findings are validated by market feedback from a recent EFPIA survey on national tendering practices across the EU and the UK.[3] The survey highlights seven of the most evident anomalies that are harming competition and potentially harming patients (as illustrated in the chart at Annex 2).

In addition, the COVID-19 pandemic has generated renewed interest in cross-border joint procurement in the healthcare sector. Complex cross-border procedures come with increased challenges that exacerbate the negative trends identified. They should be limited to emergency situations that pose serious threats to health and structured so as to avoid duplication and stockpiling at national level.

This White Paper is a sector-specific contribution to the broader debate on the efficacy of the EU procurement rules in the context of the EU's resilience and growth goals. Against this background, EFPIA calls for the Commission to elaborate and promote best practice guidance on the basis of Article 168 TFEU[4] to ensure that procurement procedures, including joint procurement, deliver high quality medicines for patients in the right quantities, and at the right time.

It is hoped that the promulgation of best practice guidance will not only improve formal public procurement procedures, but also influence informal tendering processes that are increasingly employed outside the confines of Directive 2014/24/EU.[5]

Providing suppliers with sufficient predictability across the design and implementation of tender processes is important both in the short-term to enable accurate forecasting of demand volumes, but also in the longer term to foster the necessary investments in manufacturing and innovation.

1 Directive 2014/24/EU (here) of the European Parliament and of the Council in respect of the thresholds for public supply, service and works contracts, and design contests (as amended, latest consolidated version). An overview of the EU Public Procurement Framework is provided in Annex 1 below for additional context for non-specialist readers. Public procurement mainly concerns hospital medicines and vaccines. Whilst the findings in this Paper are generally relevant to vaccine procurement, there are some specificities that may warrant a more tailored approach. For more details, see Vaccines Europe's Position Paper on Joint Procurement of Vaccines in Europe (here) and its Position Paper on Recommendations to improve tendering practices of vaccines in EU Member States (here)

2 "Implementation Report", COM(2021) 245 final (here), 20 May 2021.

3 The survey was carried out between November 2020 and January 2021 with the support of Baker McKenzie to ensure the protection of confidentiality. 13 member companies as well as EFPIA member associations in 18 countries responded to the survey.

4 In ensuring a high level of human health protection, Article 168(2) empowers the Commission to assist Member States coordinate their policies including through "…initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation."

5 Some countries, Germany and the Netherlands in particular, employ tenders in the retail market, mainly in the off-patent market segment. Some actors in the retail market, such as sick funds, are not subject to EU procurement rules. Even where they do qualify as 'contracting authorities', the contracts they award are not 'public contracts' within the meaning of the Directive (they may not involve procurement as such, but are rather aimed at identifying a preferred product). These entities run some form of competition for contracts that do not meet the standards of EU public procurement. While the law may not require formal EU procurement procedures in these situations, it would nonetheless be appropriate for these actors to follow general best practice tender principles, ensuring transparency and equal treatment in line with accepted EU procurement standards.

RECOMMENDATIONS ON SUBSTANTIVE GUIDANCE

1. Member States and contracting authorities should be encouraged to formally provide for **increased input from clinical experts** in designing and reviewing tender procedures. That will improve security of supply, lead to greater efficiencies, and ensure the availability of a sufficiently broad choice of alternative medicines.

2. Tenders should **group only those contract products that are fully interchangeable** and of therapeutic equivalence, thereby preserving the autonomy of the physician to choose the most appropriate treatment option and allowing continuation of treatment on which the patient is stable.

3. Contracting authorities should take adequate **measures to avoid, and at the very least mitigate, the impact of tender duplication**. Greater involvement of clinical experts and likely bidders at the design stage of the tender can reduce the risks of inaccurate volume forecasts, or delays due to unclear tender requirements, which are the main causes for duplicative procedures. Where duplication cannot be avoided, steps should be taken to minimise disruption, for example, by allowing for existing terms to be amended rather than automatically cancelled.

4. Tenders should **reward quality and promote innovation** by ensuring that awards are **based on the best price-quality ratio**, including an appropriate mix and weighting of qualitative selection and award criteria (such as the quality of the products, the services infrastructure associated with the product, including environmental objectives and supply chain security, among others).

5. **Increased transparency** about how criteria are determined, how awards are determined, and whether successful tenderers were actually awarded the anticipated volumes would build confidence and improve short and long-term supply sustainability.

6. Tender procedures should **avoid 'price-only' and 'winner takes all' awards** and any combination of both.

7. Procurement processes should **guarantee supply volumes and fair competition by using effective multi-awardee framework contracts** that encourage the long-term presence of numerous suppliers on the market.

8. Member States and contracting authorities should **respect the confidentiality of pricing** throughout the procurement process and at different levels (national, regional, local) to ensure long-term sustainability in accordance with Article 21 of the Directive.

9. **Avoid imbalanced contractual terms** that unduly penalise suppliers or impose heavy costs on them **without concomitant offtake obligations**, to ensure sustainable competitive markets. Contract terms must be respected: arbitrary early terminations for short-term cost savings undermine trust and supply sustainability.

10. The aggregation of demand and stockpiling requirements are particularly onerous in cross-border joint procurement. Lessons learnt from the pandemic should be reflected in guidance to **avoid compounding supply constraints in periods of high demand**.

KEY TRENDS IDENTIFIED IN THE EFPIA SURVEY

1 Lack of clinical staff involvement leads to inadequate design of tender procedures and negative spillover effects

The Commission's May 2021 Implementation Report identifies the difficulties contracting authorities face in formulating proper and meaningful quality criteria, as well as the lack of adequate prior market research that results in unrealistic or outdated specifications.

In the context of pharmaceutical tenders, not only is the patient voice absent from procurement decisions, but the lack of involvement of experienced clinical staff at the stage of the preparation of the tender has also been identified as a significant problem.[6]

This absence is felt throughout the process at the stages of: market scanning/consultation; assessing therapeutic equivalence of different medicines; mapping clinical needs (therapeutic but also volumes required); and the translation of these various factors into clear, relevant and objective tender specifications and award criteria.

This major flaw has the potential to impact not only prescribers' clinical choice and patient access to the best medicines, but also producers' ability and incentives to participate in tenders. These negative spillover effects are often a result of inaccurate estimates of the volumes required and the inappropriate grouping of medicines in tender procedures, as discussed below.

1.1. Inaccurate estimation of the necessary quantities of medicines leads to duplication

On numerous occasions, tenders organised without prior consultation of hospital pharmacists have led to inaccurate volume estimates that fall far below the actual needs of the local hospitals. This pushes local hospitals to organise separate short-term tenders, putting at risk patient access to medicines and causing unnecessary duplication of time and resources at supplier level. In relation to some regional tenders in Italy, suppliers have had to respond to multiple tenders for the same product in a short period of time (2 to 3 times in one year alone).

1.2. Inappropriate grouping of medicines through unjustified product expansion without a proper assessment of the products' therapeutic equivalence unduly limits prescribers' choice

Grouping of medicines should not lead to tendering across an entire therapeutic area because this unduly limits prescribers' choice of treatment in the best interests of their patients. Treatment decisions should be the result of an informed discussion between patient and prescriber based on the safety and efficacy of the medicine and the value that it offers.

6 The Expert Panel on Effective Ways of Investing in Health (EXPH) in its Opinion on Public procurement in healthcare systems, 28 April 2021 (Recommendations 1.3 and 3), emphasizes the need to involve healthcare experts, including patients, to achieve more effective and quality-based procurement of medicines.

CASE STUDY: NATIONAL HEALTH SERVICE ENGLAND (NHSE) GROUPING OF DIRECT ORAL ANTICOAGULANTS (DOAC) INFLUENCING PRESCRIBERS' CHOICE

In 2020, NHSE launched a tender for the supply of DOACs for the period May to December 2020 in order to switch 200,000 patients from warfarin to DOACs. The tender grouped all DOACs which were on-patent and selected only two of them.

Accompanying guidance encouraged clinicians to prescribe the product with the lowest acquisition cost where more than one product was available for the indication, thereby prioritising cost over the physician's freedom to choose the most suitable therapeutic option for individual patients.

In Italy, there are examples of tenders based on ATC4 in at least two therapeutic categories: epoietins and G-CSF (Granulocyte colony-stimulating factor). Several tenders were based on the therapeutic class equivalence, but only one API (an originator or biosimilar) was ultimately awarded the tender based on the lowest-price criterion. Despite numerous appeals, this approach is now well-established.

A number of other questionable practices have also been observed in Norway and Sweden in particular, including:

- **Indication tendering:** different innovative medicines are grouped together in the same tender (Norway, Sweden),[7]
- **Tender groups:** different innovative medicines with an approved indication plus one product with a non-approved label are grouped together (Norway, Sweden),
- **Compounding/vial splitting:** the basis for the tender makes mention of splitting the products (Norway).

Any grouping of biologics and biosimilars must entail a thorough assessment of the products' therapeutic equivalence and allow for competition between 'like for like' products. In some cases, different on-patent molecules with equivalent indications have been included in the same tender process as referenced products and their biosimilars. In any specific tender, lots should only include the referenced medicinal product and the referencing biosimilar.[8]

Widening the group to include a non-referenced product,[9] and/or products with different dosing schedules and/or routes of administration, may lead to competition between non-equivalent products, negatively impacting therapeutic efficacy and individual patient outcomes.

AN EXAMPLE OF GOOD PRACTICE: SPAIN - GROUPING OF BIOLOGICS/BIOSIMILARS OR MEDICINE/GENERIC AT ATC 5 LEVEL ONLY

Lots in public procurement processes are based on the API (ATC 5) which means that the reference groups for each lot only include the referenced branded biologic and its corresponding biosimilar(s) with the same administration mechanism. The same approach applies for chemically synthesised medicines, grouping the original medicine and its generics.

Recent examples include procurement for infliximab, where other TNF-inhibitor biologics were not included in the lot, and the procurement for atorvastatin which excluded other statins such as pitavastatin or simvastatin. This approach has the merit of preserving a range of treatment options available to patients.

Similarly, the Italian law requiring multi-awardee framework contracts for the procurement of off-patent biologics provides that, where the referenced branded biologic and its corresponding biosimilar(s) are based on the same API (ATC 5), and have the same dosage and route of administration, they must be grouped in the same lot. Whilst Italian law also allows for direct competition between chemically synthesised medicines based on different APIs, their inclusion in the same lot is subject to the Italian Medicine Agency's prior assessment of the products' therapeutic equivalence - another example of good practice.

7 In tenders in the Nordics and in Hungary, several different molecules (infliximab, adalimumab and etanercept) have been included in the same tender where the cheapest product wins the contract and only one molecule is subsequently available. Their indications are not identical and the products do not have the same positioning in therapeutic guidelines, severely limiting treatment choice. The same phenomenon has been observed in relation to tenders involving patented products Vectibix (panitumumab) and Erbitux (cetuximab) that treat colorectal cancer. Their precise indications vary as do their administration profiles which have a direct impact on patient convenience, adherence and cost of administration.

8 This refers to the original patented product in relation to which exclusivity has expired and the product has been categorised as referenced for the purposes of biosimilar products granted regulatory approval, demonstrating similarity to the referenced product in terms of quality characteristics, biological activity, safety and efficacy.

9 This refers to the original product which has not been categorised as referenced, or which may have been referenced but the referencing biosimilar has not been launched; or to a different molecule with equivalent indications that is still subject to market exclusivity.

2 Duplication and lack of adherence to contract duration increase costs and impact supply

There has been an increase in unnecessarily duplicative tendering processes with direct individual negotiations taking place at the level of local/regional hospitals or sick funds following an initial national tender process. The added bureaucracy is inefficient, creates uncertainty, and puts further strain on margins that may lead to suppliers pulling out of the market.

There are numerous drivers of this phenomenon. For example, prolonged delays in regional tendering processes, that can run into years in the case of biosimilar tenders (in Spain for instance), means that rather than waiting for the outcome, hospitals open individual negotiations with suppliers. Once the regional tender eventually does open, the hospitals continue with their chosen supplier, regardless of who is ultimately awarded the tender.

CASE STUDY:
THE EFFECTS OF TENDER PROCEDURES LAUNCHED FOR SAME PRODUCT AND SAME PERIOD BY A REGIONAL HEALTH AUTHORITY AND LOCAL HOSPITALS IN ITALY

A regional authority organised a multi-lot tender in December 2020 for several products. Each lot was awarded to a single supplier based on the lowest price offered. Compounded by a 4-5 month delay between the call for tender and the actual award, and exacerbated by a failure to adequately estimate volumes needed, several local hospitals issued simultaneous tenders for some of the same products covering the same contract period. Duplication at the levels of supply and demand, and related implementation problems due to divergent contractual terms, necessitated inefficient stockpiling by suppliers.

This issue has been especially acute in the context of the June 2020 ICU-medicines joint procurement where significant delays pushed Member States to organise their own procurement procedures on top of the EU-led joint procurement. Learning from that experience, further work is required to ensure that future complex cross-border tenders are more efficient and effective.

3 Use of imbalanced/divergent award criteria increases complexity and costs

The Commission's Implementation Report (cited above), identifies the following patterns in the limited data made available to it:

- use of shortest possible deadlines for submitting tenders or requests to participate, and short deadlines for contract execution;
- imposing too many selection criteria or not imposing any at all.

EFPIA's survey validates these general findings that have the potential to cause significant problems which, in the pharmaceutical sector, have implications for patients' health outcomes. In addition, although contracting authorities increasingly include non-price qualitative criteria (innovation, security of supply safeguards, etc.), the 'lowest price' criterion is still widespread contrary to the preferred best price-quality ratio. The scoring of the award criteria should avoid mechanistic outcomes that do not allow a holistic price-quality assessment.

It is problematic when increased recourse to technical requirements (such as hospital data aggregation demands going beyond serialization requirements allowing for tracking and identification of medicines in the supply chain), and environmental requirements (such as recent announcements in Norway[10] and Denmark[11]) are used merely as a selection criteria and have no impact on the qualitative assessment of the tender.

The increased focus on environmental requirements in tender specifications is in line with the EU's goals to procure goods and services in a sustainable and environment-friendly manner (Green Public Procurement, GPP). The Commission's May 2021 Implementing Report recognises the challenges Member States encounter in the implementation of GPP (including the lack of any legal obligation to use GPP, the lack of data on the economic benefits and effectiveness of applying GPP, the lack of specific knowledge and skills at contracting authorities). Beyond these general issues, it is imperative to ensure that environmental criteria in the context of pharmaceutical tenders neither impede patients' access to innovative drugs nor restrict choice for prescribers. Nor should they disproportionally further compound the administrative complexity of procurement.

In Finland and Sweden, hospitals are requesting 2D matrix codes beyond EMA requirements, including GTIN, lot and expiry data for primary packages, for closed-loop medication administration ("CLMA"), machine reading of medical administration, and increased traceability. Currently, there is no generally binding guidance on these sorts of requirements (although the Pharmaceuticals Information Center has worked together with some of the customers and other Nordic contracting authorities).

The burgeoning of many types of technical requirements, sometimes at the level of a single hospital purchasing group, leads to market fragmentation and increases costs across the system. It points to a broader need for increased transparency about how criteria are determined, how awards are determined, and whether successful tenderers are actually awarded the anticipated volumes.

10 See announcement on new environmental policy in Norway at Sykehusinnkjøp med revidert miljøpolicy - Sykehusinnkjøp (sykehusinnkjop.no).
11 See announcement on new environmental policy in Denmark at https://amgros.dk/en/knowledge-and-analyses/articles/sustainability-to-be-a-criterion-for-medicines-tenders/.

4 Increased recourse to 'price only' awards threatens supply sustainability that is further compounded when combined with 'winner takes all' awards

One of the patterns recognised in the Commission's May 2021 Implementation Report is the "…preference by contracting authorities to use lowest price as an award criterion, seen as simpler and more objective; best price-quality ratio is used in limited cases, due to fears of risks in compliance audits". These phenomena featured strongly in the results of the EFPIA survey.

Increased recourse to 'price only' awards:
As recognised in the Report for the European Parliament on the shortage of medicines, single-winner, 'price only' tenders cause severe price erosions, reduce the number of suppliers on the market, and often result in short lead times and penalties being imposed on companies, which further exacerbates the risk of shortages.[12]

In a recent example, a number of Italian regional authorities teamed up on bevacizumab tenders resulting in very large single winner contracts. The tenders in most regions were won by the same bidder and multiple shortages were subsequently experienced over 12-18 months.

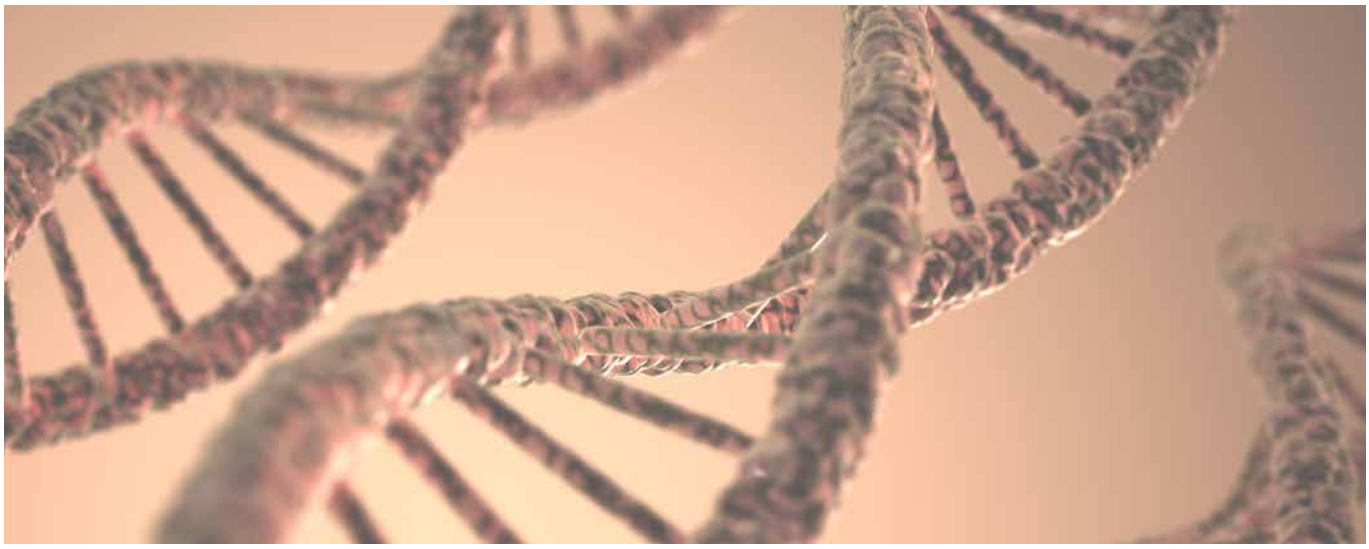
The prevalence of the 'lowest price criterion' can take different forms such as 'price only' tenders, tenders with insufficient weight being attached to criteria other than price, or tenders using qualitative criteria or a scoring methodology that do not enable differentiation between tenders with the result that awards are based on the lowest price despite the apparent use of qualitative criteria.[13]

CASE STUDY:
QUALITATIVE CRITERIA OR A SCORING METHODOLOGY THAT DO NOT ALLOW SUFFICIENT DIFFERENTIATION BETWEEN TENDERS LEAD TO A 'PRICE ONLY' AWARD

A framework contract for biologics and biosimilars by the regional health authority of Valencia, Spain included pre-qualification quality criteria making up 80 of the total points and 20 awarded to price.

35 out of the 80 qualitative points related to criteria which are mandatory legal requirements (barcode, identification and packaging requirements) or de facto standards. All bidders meeting the qualitative threshold were awarded the framework contract, but 100% of orders were directed to the lowest price bidder unless that bidder is out of stock or there is proven clinical need for continued treatment with another product.

Due to the design of the tender and the use of qualitative criteria that do not allow for sufficient differentiation between bidders, the lowest price offer was awarded the contract.



12 Opinion (here) of the Committee on Industry, Research and Energy, para. 10 as included in the Report on shortage of medicines - how to address and emerging problem (2020/2071 (INI)).
13 The economically most advantageous tend (MEAT) is the only award criteria mentioned in the Directive. The Commission recognises that a smart setting of MEAT award criteria, rewarding both quality and price, is important for innovation (see its Guidance (here) on Innovation Procurement of 18 June 2021 (C(2021) 4320 final). But the rules provide that public buyers can decide to use only the price criterion if allowed by national legislation (Article 67(2)). When they do use quality criteria, public buyers enjoy a wide margin of freedom in formulating them and weighing them.

These de facto 'price only' tenders can result in stock out situations and generally give rise to security of supply concerns in the short term.[14] They also have long-term implications resulting from insufficient rewards for innovative products or services,[15] if suppliers chose not to market a product due to the commercial unattractiveness of the opportunity,[16] or as a result of supply concentration.[17]

These effects can be further compounded by concentration at the demand level in the case of cross-border joint procurement, national level tenders, or in other instances where just a few purchasing organisations represent a high proportion of total demand. There have been examples of Italian regions clustering together, and the introduction of national tenders in Spain, both of which have led to high volatility/uncertainty in planning and supply security.

Winner Takes All Awards:
In France, an historic "winner takes all" approach has led to shortages and product withdrawals from the market. In some drug classes, there is now only one alternative available. In order to maintain competition and avoid shortages, France has course corrected and now partly implements a 'two winners' approach in national tenders. Recent examples include trastuzumab tenders with two purchasers accounting for 50% of the total market in France.

The negative effects on long term competition are exacerbated when a 'price-only' tender is combined with a 'winner takes all' approach, especially when combined with mandatory substitution for ongoing treatments. The issues are particularly acute where the tender concerns small volumes/batches, low priced, and/or hard to make medicines, particularly when only a few suppliers are active.

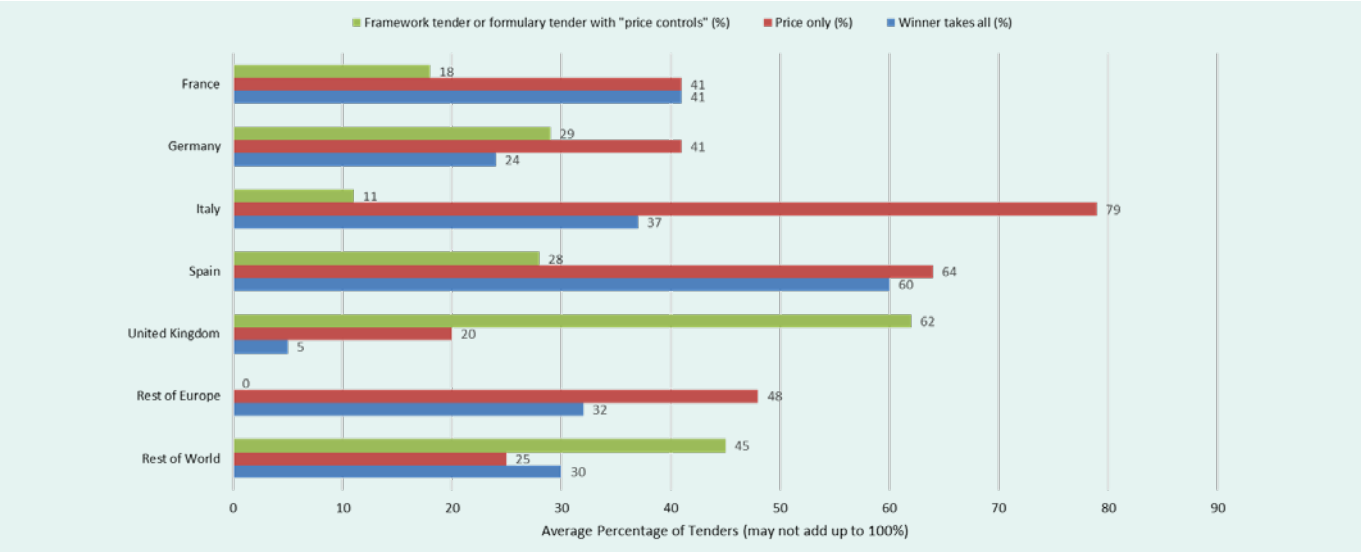
To avoid these harmful effects, tender procedures should allow for effective multi-awardee framework contracts and, at a minimum, allow for the possibility for other suppliers to step in and support in the event of supply disruptions.

AN EXAMPLE OF GOOD PRACTICE:
ITALY - THE LAW REQUIRES MULTI-AWARDEE FRAMEWORK CONTRACTS FOR THE PROCUREMENT OF OFF-PATENT BIOLOGICS

The requirement for framework contracts involving more than one supplier applies not only where the originator and its corresponding biosimilar(s) are already available at the time of the launch of the procurement procedure, but also in of the event that loss of patent exclusivity by the branded biologic occurs during the period of validity of the relevant supply contract with new biosimilar(s) being placed on the market.

This has led to a reduced number of procurement procedures, reduced transaction costs, and reduced risks of shortages.

A picture of the prevalence of the phenomenon is provided in the EFPIA survey graph below:



14 According to some reports, approximately 83% of generic drug shortages in the EU today relate to products with daily prices of less than €0.10. To increase security of supply and improve the EU's manufacturing footprint, incentives are required. Attributing more weight to a wider spectrum of ESG criteria and raising the relative weightings given to supply reliability criteria would be one such incentive.
15 The negative impact on innovation and promotion of local supply (including by SMEs) of the use of "price only" tenders has also been recognised by the Expert Panel on Effective Ways of Investing in Health (EXPH) in their Opinion on Public procurement in healthcare systems, 28 April 2021, page 41-42.
16 The 2019 Drug Shortages report (Drug Shortages: Root Causes and Potential Solutions, US Food and Drugs Administration, 2020, page 38) indicates that prior to a shortage, on average three companies per pharmaceutical product were not marketing products for which they had obtained authorisations.
17 The Rapport Biot prepared for the French Prime Minister (Rapport au premier ministre: Mission strategique visant à reduire les penuries de médicaments essentiels, Jacques Biot, 2020) notes that increased pressure on prices and reduced margins leads to an increased concentration of production of certain APIs, sometimes to the level of only one producer remaining active. For example, the production of the API for statins is so highly concentrated that contamination at one production site led to drug shortages for over six months as no alternative was available.

5 Transparency of awards should not threaten price confidentiality

Procuring entities and Member States should respect pricing confidentiality by not disclosing prices outside the group of tender participants. Within the group of tender participants, they should provide reasons for their award decisions, and a description of the characteristics and relative advantages of the winning bidder, including information about the price evaluation criterion without necessarily revealing the actual price.

Discounts from national reference pricing that are negotiated locally, regionally, or nationally through tender procedures are increasingly under threat of (or are) being disclosed beyond the companies participating in the tender without respecting contractual price confidentiality obligations and in breach of Article 21 Directive 2014/24/EU. [18]

One manufacturer has decided not to launch the generic of a particular product in Italy because the publicly available prices in relation to the first two regional tenders showed that it was uneconomical to launch.

In contrast, the Norwegian Ministry of Health provides an example of good practice by refusing to disclose unit prices of winning and losing bids or the price difference between the two in response to freedom of information requests. Price confidentiality is an established legal principle embedded in the Public Administration Act (§13.2).

The inability to safeguard price data as agreed calls into question the exchange of any confidential data. Respect of confidentiality of tender prices, discounts and managed entry agreements (MEA) is essential for ensuring the appropriate healthcare in any market. Breaches of confidentiality may dissuade companies from entering their best price bid, or from participating in subsequent tenders, or even from launching a new product in that market with the risk of reduced competition in the long run, jeopardising wider patient access to adequate and affordable healthcare.

18 In September 2018, the Czech Health Minister called for hospitals to publish the details of the discounts offered by manufacturers following which the Czech Association of Innovative Pharmaceutical Industry (AIFP) signed a memorandum agreeing that discounts would be disclosed to the Ministry of Health and relevant contracting authorities but not to the wider public.

6 Imbalanced contractual terms, insufficient tender lead time between award of contract and expected deliveries with no concomitant offtake obligations

The Commission's May 2021 Implementing Report identifies a number of issues that cause legal uncertainty in tender procedures, including political pressure to deliver a particular result, reduced time for proper planning due to pressure to get results quickly, and the use of shortest possible deadlines for submitting tenders and for contract execution.

There are a number of additional problematic phenomenon that create uncertainty and risk for successful tenderers in the pharmaceutical sector in particular.

Where a new contract enters into effect immediately as the result of a tender, this can result in the previous contractor having to destroy idle stock that it has earmarked in order to satisfy supply of security requirements under its contract. Conversely, on the award of a new tender, authorities can require deliveries of significant volumes of certain products (especially vaccines) on too short notice without due regard to the time needed to scale-up production of the specific product in question.

The practice of buyers terminating long-term contracts before the expected contract expiry in order to re-tender to secure lower prices even if just for a few short months is unhelpful. In France, for instance, hospitals may terminate contracts in a broad range of circumstances including on the loss of patent exclusivity, on the occurrence of generic/biosimilar entries, or in out of stock situations. This can have significant supply planning implications. More importantly, it undermines trust and may ultimately lead to quality suppliers declining to participate in subsequent tenders.

Sanctions for not meeting supply obligations under contract range from financial penalties to exclusion from participation in subsequent tenders. Coupled with increased recourse to security of supply obligations (such as stockpiling requirements), often with no concomitant offtake obligations on the part of the contracting authorities, this creates a level of insecurity that risks disincentivising participation in subsequent tenders for the same medicine, ultimately reducing competition.

CASE STUDY: INCREASING USE OF EVER MORE RESTRICTIVE STOCKPILING REQUIREMENTS

Tender: A 2021 hospital tender for different medicines in Norway required participating suppliers to keep a 30 or a 90 day stock of the medicines in the Nordic region depending on the medicine concerned.

Result: The geographic stock location clause made it economically unattractive and extremely difficult for any supplier based outside the Nordic region to participate in the tender, thus limiting competition and potentially leading to higher prices or insufficient supply of medicines. Only after intervention of the Norwegian Pharmaceutical Industry Association was the requirement modified.

Despite European case law holding that all the conditions and details of the award procedure must be formulated in a clear, precise and unambiguous manner in the contract notice or contractual documentation,[19] that is frequently not the case, particularly in relation to volume requirements.

For instance:

- In Finland and Sweden, the buyer is usually not guaranteed any specified volume.
- In Spain, bidders are given no volume guarantees but each needs to commit to supply the whole volume. In case the successful bidder proves unable to do so, other unsuccessful bidders can be required to step in and supply at the price level of their initial (unsuccessful) bid.
- In Italy, tender volumes required might be significantly higher than total demand and entail a long-term commitment. Bidders are often required to provide performance bonds for amounts which are disproportionate to the volumes actually purchased, or they are required to maintain large stocks of products to avoid the risk of breach of public supply contracts. Because they generally do not know what they are actually committing to, this may result in fewer bids due to the unnecessary financial burdens, risks and uncertainty. The situation is compounded by the fact that the breach of a public supply contract in Italy might result in not only the call of the performance bond (which is normally the 10% of the contract value but can be higher) but also the communication of the breach to the National Anti-Corruption Authority

19 See, for instance, Case C-25/14, UNIS et al, judgment of 17 December 2015, and Case C-216/17, AGCM, judgment of 19 December 2018.

(the Italian regulatory Authority for the public procurements sector) for registration in the Casellario Informatico, which is a sort of black list of economic operators that may be excluded from future public tenders.

The recent judgment of the European Court of Justice in Case 23/20[20] is helpful in specifying that, in line with fundamental principles of EU law, contract notices must indicate the estimated quantity and/or value as well as the maximum quantity/value of the products to be supplied in the context of a framework agreement. Once this limit is reached, the supplier ceases to be bound. There is a need for more detailed Commission guidance that builds on these general principles to solve other pressing real world problems.

For example, the use of framework contracts that only indicate a maximum volume with corresponding supply obligations for all selected bidders, but without any minimum or guaranteed offtake obligations, can lead to some suppliers having to maintain stock that is not purchased by the contracting authority.

A variation on this is multiple winner contracts that operate in a cascade, where only the first winner has a guarantee of supplying volume, and the second winner would only be called upon if the first winner is unable to supply, and so on. This may have a negative effect on the price being offered or on the number of companies participating in the tender given the uncertainties involved for production and security of supply planning.

In the event of supply disruptions (for whatever reasons), contracting authorities should provide for the possibility for other suppliers to bridge any gaps on fair terms.

An example of good practice in this area includes NHS England procurement of adalimumab, where multiple winners are guaranteed different volumes depending on their position in the tender (the first winner getting a greater share). This ensures a competitive market but also a sustainable one with multiple suppliers staying active on the market. The potential negative impact on competition is exacerbated in case of cross-border joint procurement, where the aggregation of demand and stockpiling requirements may lead to suppliers not being able to participate.

20 Case C-23/20, Simonsen & Weel, judgment of 17 June 2021.

7 Complex cross-border joint procurement procedures compounds the challenges identified

Complex cross-border joint procurement procedures come with increased challenges, exacerbating the negative trends identified above. [21]

Decision 1082/2013/EU[22] is currently the legal basis for voluntary joint procurement of medical countermeasures for serious cross-border threats to health, a notion that is construed broadly to refer to situations that are life-threatening or "otherwise serious hazard to health" (Article 3(g)).

It is crucial that joint procurement arrangements in this context involve close coordination with the industry and are structured so as to avoid undue market distortions or concentration of demand, which could further reduce competition and jeopardise the ability to respond to Member States' needs.

Commission guidance should extend to the joint procurement of medical countermeasures in light of lessons learned from the June 2020 joint tender for ICU at the height of the Covid-19 pandemic.[23] In this context, it is important for government and policy makers both at EU and national level to work closely with the industry to:

- ensure the rapid development, production, supply and distribution of high-quality medicines in response to any serious cross-border threat to health,
- ensure that borders are kept open and no artificial market supply disruptions are enacted,
- avoid disruptions that duplicative layers of joint and subsequent national procurement efforts entail, and
- ensure that the rights of non-participating Member States are respected.

21 The Expert Panel on Effective Ways of Investing in Health (EXPH) in their Opinion (here) on Public procurement in healthcare systems, 28 April 2021, recognises the additional complexities raised by joint procurement and the possible resulting negative consequences.

22 Decision No 1082/1013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC, O.J. 2013 L 293/1 that will be repealed upon the adoption and entry into force of the Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision N°1082/2013/EU, European Commission, COM(2020) 727 final, 11 November 2020.

23 'Call for tenders (here) SANTE/2020/C3/29 for the supply of medicinal products used for intensive care patients subject to the novel coronavirus (COVID-19) disease'.

CALL FOR THE ADOPTION OF BEST PRACTICE GUIDANCE FOR EFFECTIVE PROCUREMENT

The procurement of healthcare goods and services should respect fundamental procurement principles guaranteeing an open, transparent, objective, non-discriminatory award procedure leading to the selection of the most economically advantageous offer based on the best price-quality ratio.

To ensure that procurement practices are effective and sustainable, contributing to wider patient access and increased security of supply, EFPIA invites the European Commission to adopt guidance for the procurement of medicines.[24] Those guidelines should strongly advocate for Member States to provide for: (i) increased input from clinical experts in tender preparation; (ii) a balanced assessment of qualitative and quantitative award criteria leading to effective multi-awardee framework contracts; and (iii) respect of pricing confidentiality following a transparent and predictable tender process.

EFPIA urges the Commission and Member States to: (i) limit EU-led cross-border joint procurement to situations of serious threats to health; (ii) avoid unnecessary duplication of tender procedures or stockpiling requirements by participating Member States; and (iii) respect the voluntary nature of such processes.

Therefore, and in order to address shortcomings in national and cross-border joint procurement processes that negatively impact the sustainable supply of medicinal products to national markets as identified above, EFPIA calls on national competent authorities to embrace the above-mentioned best practice principles and invites:

1. The European Commission to adopt, on the basis of Article 168 TFEU, best practice guidance in dialogue with Member States in order to improve the working of procurement processes to better meet societal expectations and patient needs;

2. The EU Member States (including national/regional competent authorities) to establish a platform to hold an annual structured discussion involving key stakeholders with a view to progressively improving national procurement processes in compliance with the best practice guidance;

3. The European Commission to closely monitor the implementation of joint procurement of healthcare products under EU Decision 1082/2013/EU on serious cross-border threats to health (currently under repeal) in terms of scope, process, and participation.

24 This call is in line with the July 2020 Motion for a European Parliament Resolution on the shortage of medicines - how to address an emerging problem, paras. 28-29. https://www.europarl.europa.eu/doceo/document/A-9-2020-0142_EN.html

ANNEX 1: OVERVIEW OF THE EU PUBLIC PROCUREMENT FRAMEWORK

1. Public procurement or tendering is the process by which public authorities, such as government departments, local authorities or public hospitals, purchase work, goods or services from suppliers. The European Union has adopted directives that regulate the use of tenders for public sector procurements in general, and for healthcare purchasing in Europe specifically.

2. All procurement by national, regional or local public authorities in the EU, including for healthcare goods and services, must respect certain fundamental EU law principles and, in particular on: free movement of goods and services and freedom of establishment; equal treatment and non-discrimination on the grounds of nationality; and transparency and proportionality.

3. For procurement procedures exceeding the threshold of EUR 139,000 (central government entities) or EUR 214,000 (regional or local public authorities), the EU Public Procurement Directive applies (Directive 2014/24/EU). The Directive lays down detailed rules that Member states are required to transpose into national legislation bearing in mind any European Commission non-binding guidance, and the case law of the EU Courts.

4. The public procurement rules are designed to contribute to sustainable economic growth and achieve value for money. In principle, both objectives are aligned, but a short term emphasis on value for money may be harmful for longer-term sustainability and may negatively impact innovation incentives. For that reason, Article 67(1) of the Directive 2014/24/EU sets out the general rule that contracts should be awarded based on the most economically advantageous tender ("MEAT"). What is most economically advantageous can be assessed on price or on cost using a cost-effectiveness approach. It may include the best price-quality ratio to be assessed on the basis of qualitative, environmental or social criteria for example. The Directive allows Member States to prevent or limit the circumstances in which awards can be granted on the basis of price or cost only, which indicates that the best price-quality ratio should be the preferred approach (Article 67(2)).

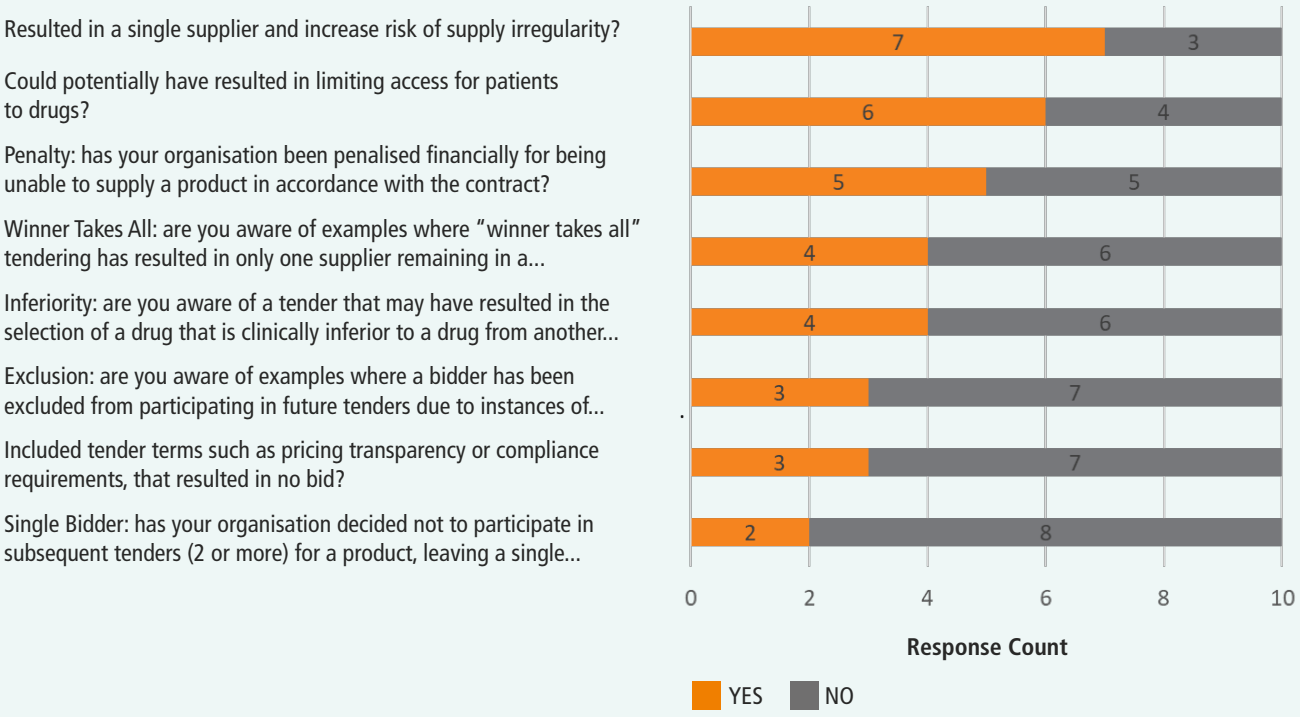
5. Cross-border joint procurement for healthcare products is currently possible under both Directive 2014/24/EU as well as under EU Decision 1082/2013/EU on serious cross-border threats to health. Directive 2014/24/EU includes among its objectives facilitating cooperation between contracting authorities and enhancing the benefits of the internal market by encouraging more cross-border procurement amongst the Member States (Recital 73, Article 39).

6. Decision 1082/2013/EU aims at improving cooperation between the EU and the Member States, including by joint procurement by the EU institutions with the Member States. Decision 1082/2013/EU was the legal basis for the adoption of the Joint Procurement Agreement for medical countermeasures (JPA) on 10 April 2014, which is a voluntary mechanism enabling participating EU countries and the EU institutions to make joint purchases to counter different categories of cross-border health threats, including vaccines, antivirals and other treatments. Decision 1082/2013/EU served as the legal basis for a number of joint procurement procedures in response to the COVID-19 health crisis (masks, gloves and protective equipment), and for the supply of medicinal products used for intensive care patients.

7. Decision 1082/2013/EU is currently being repealed and will be replaced by the November 2020 proposal for a Regulation on serious cross-border threats to health that aims to strengthen preparedness in response planning, including improved data reporting and strengthened EU intervention, including in procurement. The text is currently in inter-institutional negotiations between the Commission, the European Parliament and the European Council.

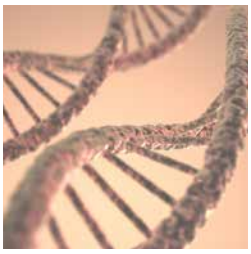
ANNEX 2: OVERVIEW OF KEY SURVEY FINDINGS

Are you aware of tenders that:



efpia

European Federation of Pharmaceutical Industries and Associations



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