Adopted by EAHP's General Assembly in June 2024

EAHP Position Paper on Procurement

This paper sets out the position of the European Association of Hospital Pharmacists regarding the procurement of medicines and medical devices. The immediate concern of any hospital pharmacist is to ensure that every patient within the hospital receives the necessary treatment -getting the appropriate medical device and the right amount of the right medicine, of the right quality, at the right time- at the best possible price.

Procurement of medicinal products (e.g. medicines and medical devices) is the indispensable requirement of ensuring an efficient supply of these items in hospitals. For this reason, hospital pharmacists have a direct stake in the effective functioning of this supply chain. Procurement of medicinal products should consider not only the volume and price, but also incorporate policy, risk mitigation, sustainability, and safety management as well as operational choices for the hospital and the larger health ecosystem.

The European Statements of Hospital Pharmacy express within their objectives in Section 2.1 that "Hospital pharmacists should be involved in the complex process of procurement of medicines and medical devices"[i].

- Hospital pharmacists (HPs) due to their knowledge and skills are specialists in the field of all medicinal products' procurement. **Hospital pharmacists should be part of the leading team in all phases of the procurement processes and practices** to ensure the continuity of supply of medicinal products that are safe, of best quality, efficient and cost-effective. The responsible use of healthcare products is directly linked to the availability, safety, quality, and efficacy of medicines in the hospital.
- Public procurement of medicinal products should be carried out by **multidisciplinary approach** involving hospital pharmacists and other healthcare professionals working in the hospitals.
- **EAHP strongly recommends the participation of hospital pharmacists in relevant Health Technology Assessment (HTA) bodies to improve methodology and share their experiences to improve patient access.**
- EAHP urges for the implementation of medicines and medical devices **procurement models not solely based on a single winner takes all concept,** to minimise the impact of shortages on patients.
- **EAHP advocates for the use of hospital pharmacists' knowledge in promoting the appropriate selection, procurement, logistics and use of biosimilar medicines and Advanced therapy medicinal products (ATMPs), and in providing education about them to both patients and other health care professionals, which could lead to support national healthcare efforts to reduce shortages.**
- **Environmental Sustainability criteria** should be implemented in the procurement of medicinal products[ii].

1. Hospital Pharmacists as a key stakeholder to optimise the public procurement of medicinal products.

a) Medicines and Medical Devices Procurement

An overarching European framework based on the EU public procurement legislation ensures transparency, equal treatment, and non-discrimination throughout the Union. The procurement rules were simplified in 2014 with the adoption of Directive 2014/24/EU.

The direct purchase of medicines by hospitals is a public contract subject to the EU Procurement Directive. Therefore, if the cumulative value of the medicines purchased by a hospital exceeds the threshold for the application of the Procurement Directive, the hospital must fully comply with the Procurement Directive when procuring these medicines. Pharmaceutical tendering is a complex process involving different stakeholders. The Directive transposition into national legislations led to diverse solutions in the different European countries. Thus, the tendering can be public or private and it can be done at a local, regional, national, or European level.

In addition, these processes are guided by publications of other international actors such as the World Health Organisation (WHO) and the Organisation for Economic Co-operation Development (OECD).

Procurement processes should be part of the hospital quality system with regular evaluation, and actions should be taken to improve the outcomes at therapeutic, patient safety and efficiency level. A prudent tendering procedure has the potential to achieve substantial savings and ensure a secure supply chain. This however is dependent on the purchasing power of the procuring entity and the market diversity for the products involved[iii].

Tendering options to improve patient safety (e.g. primary package barcoding or avoiding soundalike/lookalike), efficiency (e.g. aggregated barcoding for compliance with the Falsified Medicines Directive), environmental aspects, quality-based factor and innovative characteristics should be incorporated in the procurement process as Most Economically Advantageous Tender (MEAT) criteria, to determine the economically best solution among those offered, not only based on the lowest price.

b) The role of the hospital pharmacist in procurement

At local level, the hospital pharmacists' role is relevant for two distinct actions, namely purchasing through strategic purchasing relationships (by means of collaboration, formulary production, and negotiation) and purchasing by individual hospitals (by means of formulary production and negotiation). Local procurement at hospital level with strategic partners reduces the scale, yet it offers more flexibility in adjusting the medicines to local medical practice. The perspective of the hospital pharmacists in the entire procurement process, starting with the decisions of the drug and therapeutic committee about medicines policy and use within the hospital (therapeutic protocols), will help with the identification of high-risk medicines and medical devices, link procurement with patients' need, and ensure that appropriate procedures are implemented in procurement to reduce vulnerability in the supply chain.

At national and regional level, health authorities are increasingly opting to centralise and consolidate procurement procedures for healthcare products to achieve economies of scale. Central procurement in pharmaceutical purchasing and distribution should be minimised. In fact, in the last decade, a correlation between concentration and supply chain vulnerability is emerging[iv]. Concentration can lead to an excessive negotiating power of intermediaries and augment the pressure on hospitals for pursuing the lowest price, which can result in unsustainable manufacturing expenses for producers, and increase potential disruptions[v]. Moreover, central procurement bodies sometimes make choices

that are disconnected from the practical needs, resulting in additional workloads for healthcare professionals and a deterioration in the quality and safety of the healthcare products selected. This trend is evident where hospital pharmacists are not involved in the processes. In addition, healthcare systems need IT interoperability that is adapted to the practices of professionals working in hospitals. The occurrence of numerous technical problems puts the supply process at risk, resulting in limitation of patient access to the needed treatment.

At the European level, recent examples such as the joint procurement of COVID vaccines by the European Commission suggest that European procurement will become more common. The European regulation on HTA also represents a first step in this direction. EAHP agrees that cooperation in procurement is essential to avoid the scenario of decisions being made in one Member State creating shortages in other Member States. More coordination on pricing and procurement needs to be implemented as this could contribute to more equal and timely access to medicines, including for Member States with lower purchasing power. Such an approach could also help in defining adequate supply in relation to critical medicines.

The involvement of hospital pharmacists in procurement committees makes careful consideration of every possible aspect, including cost/benefit, quality, product-specific characteristics (e.g. pre-filled syringes), patient safety (e.g. through reduced lookalike/sound-alike), adequate quantity and reliability factors for the participating companies such as transport and distribution procedures. Hospital pharmacists should be considered as leading advisory experts in central price negotiations run by the European Commission, by national governments or by field parties within the regulatory framework. This could either be achieved through the involvement of the appropriate hospital pharmacists' associations (European, national, or regional) and/or by directly hiring specialised hospital pharmacists.

Hospital pharmacists, having a clear understanding of patients' needs, broaden the criteria that are the decisive factors for a tender procedure, so they are pivotal in the procurement process, serving as hub of information available to other healthcare professionals, economic decision-makers and end-users.

2. Medicines and Medical Devices Shortages

Optimising and enhancing more coordinated and advanced procurement procedures and rules can help tackle the shortages problem. Member states should publish and regularly update information on actual shortages of medicinal products*, including the date when the shortage occurred, expected duration, the reasons and mitigation measures*, on a publicly available website *or database interoperable with the European Shortages Monitoring Platform ('ESMP')*[vi]. Relevant elements must be communicated to the procurement committees so that all necessary measures can be taken on time.

Producers do not always have the manufacturing capacity to meet the potential need, and vulnerability to the supply chain is added if alternative suppliers drop out of the market due to loss of tender. Impact assessment tools and continuous monitoring when conducting tendering should include considerations such as medicine supply chain vulnerability and sustainability, along with existing shortages contingency plans provided by the producers and wholesalers.

Most value is obtained in medicines and medical devices that are available from multiple sources or for which there are various comparable products. EAHP urges for implementation of medicines and medical devices procurement models not solely based on a winner-takes-all concept.[vii] [viii] [ix]

3. Procurement and Sustainability

EAHP is convinced that sustainable procurement models are beneficial for the environment, but also for the economic, social and health dimensions. Environmental sustainability criteria should be implemented in procurement of medicines and medical devices. The EU public procurement legislation provides a legal framework that can be used to prioritise the procurement of medicinal products with a lower environmental impact. Sustainability needs to be harmonised as much as possible between different European countries to avoid the risk of conflicting or piecemeal standards at the EU level. In parallel, it is necessary for pharmaceutical companies to implement policies that encourage transparency among their suppliers to better understand the impact of APIs in the environment. Finally, procurers must ensure throughout the process that sustainable procurement criteria do not create a competitive barrier disadvantaging smaller companies; the focus of healthcare procurers should be on facilitating the transition of all pharmaceutical companies to a model that prioritises the sustainability of their medicinal products[x].

4. ATMPs

Outcomes-based (or pay-for-performance) arrangements offer instruments that can mitigate financial risk, avoid the unnecessary use of medicinal products in non-eligible patients, and generate further evidence. In some countries, rebates, discounts, price caps and price-volume arrangements are used[xi].

It is necessary to allow sharing information across healthcare sectors and between different departments of the health system and analyse the parameters of the agreement with alignment between stakeholders. Hospital Pharmacists should be involved in access to advanced therapy medicinal products (ATMPs) reimbursement. ATMPs varies between EU countries due to regulatory differences, commercial decisions by marketing authorisation holders and inconsistent assessment processes and criteria applied by payers. Most of the ATMPs are marketed based on early data with insufficient evidence to support the claim of cost-effectiveness in the reimbursement process. negotiations. Hospitals pharmacists have the knowledge and skills to identify the information needed to assess outcome variables using the electronic health digital records, with the clinical team.

5. Procurement of biosimilars

The recent study on best practices in public procurement published by the European Commission in 2022[xii] showed that the uptake and procurement policies for biosimilars varied greatly within Europe and that policies to encourage uptake of biosimilars in hospital settings are yet to be implemented in several countries.

EAHP advocates for the use of hospital pharmacists' knowledge in promoting the appropriate selection, procurement, logistics and use of biosimilar medicines, and in providing education about them to both patients and other health care professionals, which could lead to support national healthcare efforts to reduce shortages. The Joint EMA-HMA statement on interchangeability of biosimilar medicines[xiii], released in September 2022 and updated in 2023, supports that approved biosimilars in EU have demonstrated comparable efficacy, safety and immunogenicity compared to their reference products, and nothing further is required to support interchangeability at prescriber level. The decision can be made directly by the expert hospital pharmacist, to ensure patient safety and save valuable resources.

6. Procurement and HTA

Regarding Health Technology Assessment (HTA) issues, hospital pharmacists have the ethical duty to ensure that patients are provided with access to the most appropriate treatment, and especially to those essential for improving their health. EAHP participated in all stages of EUnetHTA and AdHopHTA

and is currently a regular member of EU-HTA Stakeholder Network since May 2023. HTA Stakeholder Network has the important mission to design and prepare the implementation of the new HTA Regulation, that defines how common methodology and approach for Joint Scientific Consultations (JSC) and Joint Clinical Assessments (JCA) will substitute national legislations and assessment criteria currently adopted by national HTA bodies.

National consultations will still be possible (by use of the common criteria) and JCA will be used in national decision making. On a national/regional level, hospital pharmacists usually participate (in most countries) in relevant national committees, sharing their knowledge and expertise, helping to adapt HTA procedures from centres of excellence, and conduct further research to improve methodology of comparisons. The development, validation and use of pan-European datasets will make possible sharing of best evidence and common methodological standards, in a transparent way.

EAHP strongly recommends the participation of hospital pharmacists in HTA bodies to share their experience to improve methodology and patients' access.

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[i] European Statements of Hospital Pharmacy, Section 2: Selection, Procurement and Distribution, https://statements.eahp.eu/sites/default/files/Commented%20version%20of%20the%20European%20Statements%20.pdf

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

[iii] To be noted that not all medicines or medical devices in all countries can be procured under tender (e.g. no bids, cheap prices, shortages).

[iv] As resulting from the study conducted for the White Paper of U.S Department of Health and Human Services "*Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States".* https://aspe.hhs.gov/sites/default/files/documents/3a9df8acf50e7fda2e443f025d51d038/HHS-White-Paper-Preventing-Shortages-Supply-Chain-Vulnerabilities.pdf

[v] Ibid., White Paper of U.S Department of Health and Human Services "*Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States".* https://aspe.hhs.gov/sites/default/files/documents/3a9df8acf50e7fda2e443f025d51d038/HHS-White-Paper-Preventing-Shortages-Supply-Chain-Vulnerabilities.pdf

[vi] https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/european-shortages-monitoring-platform

[vii] Kanavos, P., Seeley, L., & Vandoros, S. (2009). Tender systems for outpatient pharmaceuticals in the European Union: Evidence from the Netherlands, Germany and Belgium. *LSE Health London School of Economics*. https://www.politico.eu/wp-content/uploads/2019/02/Tender-systems-for-outpatient-pharmaceuticals-in-the-EU.pdf

[viii] Frank, R. H., & Cook, P. J. (2013). Winner-Take-All Markets. Studies in Microeconomics, 1(2), 131-154. https://doi.org/10.1177/2321022213501254

[ix] Zhang, Yi, Splitting Award or Winner Takes All?: Evidence from China's National Drug Procurement Auction (October 28, 2023). http://dx.doi.org/10.2139/ssrn.4615937

[x] Among the examples that may serve as an inspiration, there is the model developed by the Nordic Pharmaceutical Forum including a list of Environmental Requirements. International cooperation is one of the key elements, together with the establishment of a market dialogue, a zero-emission plan, and a regular follow-up and evaluation activity.

[xi] Rejon-Parrilla JC, Espin J, Garner S, Kniazkov S, Epstein D. Pricing and reimbursement mechanisms for advanced therapy medicinal products in 20 countries. Front Pharmacol. 2023 Nov 28;14:1199500. doi: 10.3389/fphar.2023.1199500.

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

[xiii] European Medicines Agency and Heads of Medicines Agencies (HMA) Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU, 2023 https://www.ema.europa.eu/en/documents/public-statement/statement-scientific-rationale-supporting-interchangeability-biosimilar-medicines-eu_en.pdf