### Optimising Procurement of Medicinal Products: A Hands-On Workshop for Procurers and Policymakers

### 26 September 2023 – Brussels

This closed workshop focused on the public procurement of medicinal products and was specifically designed for procurers and policymakers; some 60 participants came to Brussels on 26 September 2023 to exchange experience and to network. The aim of the practical workshop was to provide support in optimising procurement policies and procedures through best practice exchanges and practical exercises.

#### Introductory notes

The meeting was opened by Sylvain Giraud, Head of Unit 'Medical products: quality, safety, innovation', European Commission, DG SANTE who spoke of the objectives set forth in **the Pharmaceutical Strategy for Europe**, including improving access to affordable medicines, tackling medicine shortages, and reducing the environmental impact of pharmaceuticals. He highlighted that **public procurement can be effective to contribute to achieve these objectives** and invited participants to bridge the gap between theory and tangible actions, through mutual learning and capacity building.

# Main findings and recommendations from the study on "Best Practices in Public Procurement of Medicines"<sup>1</sup>

Maximilian Salcher-Konrad from Gesundheit Österreich GmbH / Austrian Public Health Institute presented the main findings from the Study on Best Practices in Public Procurement of Medicines, which was commissioned by DG SANTE. Opening with the background and motivation for the study, he explained the study aims and its methodology. He then presented the different organisational forms of Public Procurement of Medicines (PPM) across the EU, highlighting the wide heterogeneity. Moving to award criteria for PPM in Europe, it was noted that price still dominates as the most important criterion, with limited use of Most Economically Advantageous Tender (MEAT). The presentation moved on to the impact of procurement practices on affordability of medicines, availability of medicines, security of supply and crisis preparedness. PPM and the environment were covered, specifically the increasing use of environmental criteria and possible trade-offs between them and price and competition. To conclude, the policy recommendations made in the study were highlighted, being to: (1) develop and communicate a PPM vision and strategy; (2) support implementation of the PPM strategy through investments; (3) monitor and adapt the strategy; (4) consider intra-country and cross-country collaboration as a key principle; (5) select PPM practices strategically, applying a product life-cycle approach; and (6) facilitate exchange of experiences among procurers. Best practices at the technical / operational level were then identified.

The floor was opened for questions and comments were made on the number of suppliers and low use of MEAT criteria. The low use of MEAT can be explained by concerns about legal challenges as well as the need to prioritise and weight criteria, which requires political steering in terms of the objectives that matter to society.

<sup>&</sup>lt;sup>1</sup> <u>https://op.europa.eu/en/publication-detail/-/publication/ca856a7f-7c37-11ed-9887-01aa75ed71a1/language-en/format-PDF/source-277530713</u>

#### <u>Best Practices in Action: country experiences leveraging procurement for security of supply,</u> <u>access, affordability, and environmental protection</u>

This session facilitated understanding of the practical aspects involved in implementing specific procurement policies, by highlighting hands-on experiences and presenting concrete country examples.

Firstly, Eirik Sverrisson from the **Norwegian Hospital Procurement Trust** spoke on using MEAT criteria with a focus on better security of supply. To open, he explained the background to the Nordic Pharmaceutical Forum, with its focus on knowledge sharing and collaboration. The lifecycle approach to procurement of pharmaceuticals was explained, with differentiated approaches depending on the lifecycle stage of medicines (innovative versus off-patent medicines). It was particularly noted that the 'two winners' approach ensures security of supply but requires sufficient market size to split the market, something that can be addressed through procuring jointly. Experience shows that the criterion on user friendliness led to small price increases, whereas criteria on sustainability and environmental aspects did not increase prices. Dialogue with industry remains key. Following the COVID-19 pandemic, active steps have been taken to secure supply, such as longer contract periods (2-3 years), storage requirements (up to 180 days) and multiple winners. When there are two winners, the market share is split in a 65%-35% ratio with each product attributed to a specific region and the cost being shared. To conclude, a practical example of MEAT criteria in use was given.

The next presentation of the session was on lessons from Denmark's integration of environmental criteria and lifecycle approach in tenders by Rasmus Syberg Hazelton from **Amgros**. The strategic use of procurement processes across the product life cycle was explained, followed by the reasoning behind integrating environmental criteria in tenders. The need for broader collaboration was highlighted, using the Nordic Pharmaceutical Forum as an example; Danish pilots with environmental criteria were presented, with criteria on packaging and transportation being established in dialogue with industry. The number of bids and prices did not change as result of using environmental criteria. However, the evaluation required much more resources and time (tenfold). To conclude, Rasmus Syberg Hazelton called for common EU environmental criteria for medicines procurement that could serve as an example to procurers.

The final presentation of the session was on collaborative procurement in the Baltics: Estonia's experiences and success stories in joint procurement initiatives, made by Eveli Bauer of the **Baltic Procurement Initiative**. The Baltic Procurement Initiative's establishment, legal base and procedure was explained. The initiative has led to improved security of supply and lower prices, eliminating price differences between participating countries. How this works in practice was then explained in detail. The first pilot projects were detailed as an example for finding an object for joint procurement. Key characteristics and results were explained per country (Latvia, Lithuania, and Estonia), followed by lessons learnt, which had led to amendments. To conclude, the key benefits of cross-border joint procurement were summarised, being: (1) aggregation of the demand: lower prices; (2) Framework Agreements: possibility to share the reserved volumes; (3) information sharing: prices, availability of the stock, market research results; (4) harmonisation of procurement plans: overview of the stock situation, effective planning -> security of supply; and (5) lending agreement: possibility to lend stock quickly and effectively (no additional bureaucracy).

Speakers then answered questions. The problems of how to **solve shortages** was raised; Norway has nationalised the procurement process to rectify supply issues, as well as storing up to six months of all critical products as part of the negotiated contracts. Estonia explained they require 3 to 6 months of stock for the jointly procured vaccines; estimations can be very specific given that the demand is rather stable. Another question was on the **data on reduction in environmental impact**; Denmark

responded that there is not yet any data as they are currently doing studies and pilots; there has been tremendous cooperation with producers helping to come up with sustainable criteria. This led to discussion on **improving the production ecosystem** and the ability of producers to take over when the competitor is in shortage of supply.

#### <u>Aligning Procurement Strategies with Supplier and End-User Needs: unveiling key challenges and</u> <u>considerations</u>

This panel discussion consisted of stakeholders that are involved in procurement processes and covered crafting procurement approaches that effectively cater to the requirements and concerns of suppliers and end-users.

Panellists were:

- > Anca Toma, Executive Director, European Patients' Forum (EPF)
- Sarada Das, Secretary General of the Standing Committee of European Doctors (CPME)
- Despoina Makridaki, Member of the Board and Scientific Committee of the European Association of Hospital Pharmacists (EAHP)
- Kristine Peers, General Counsel, European Federation of Pharmaceutical Industries Associations (EFPIA)
- > Adrian van den Hoven, Director General, Medicines for Europe

The first topic for discussion was on critical factors related to security of supply. Adrian van den Hoven spoke of the lifecycle of medicines, where security of supply is mainly a concern in the later stages when price pressure leads to consolidation of the market with a limited number of (generic medicine) suppliers as result. There is a need to encourage more investment in production to move away from consolidation. Multi-winner tenders need a certain volume for the market to be sufficiently attractive, but have proven to be effective in reducing shortage risks. He recommended looking at other criteria than price, e.g. supply chain resilience and environment and noted that some systems drive shortages, e.g. applying a maximum price ceiling based on the price of previous bids means that prices can only be reduced over time. A balance is needed between reward on the market and the risks of penalties which can be close to the commercial value of the tender. Kristine Peers commented that EFPIA published a white paper on the effectiveness of public procurement of medicines. She zoomed in on two recommendations, being 1) the need to have input of clinical experts to help design and review tenders (accurate estimates of volumes required) and appropriately group the medicines based on their therapeutic equivalence, and, 2) the importance of a balanced assessment of quantitative and qualitative criteria with the use of multi-winner framework contracts. Despoina Makridaki spoke of procurement procedures and identifying and categorising the needs. She concluded by opining that one does not know how needs will evolve and that it is not the doctors who make the needs, but the patients. Sarada Das commented on the importance of involving doctors and ensuring dialogue and transparency on how decisions are made. Regarding security of supply, one should look at past reliability of supply, consider EU production as criterion and look beyond single suppliers as we need a degree of continuity. Anca Toma commented on recurring shortages, which is a big concern for patients, for example for anti-inflammatories. She explained that there are two areas where patients should be more involved in design of tenders. Firstly, the security of supply to have options to be treated when one needs to be treated. Secondly, where therapeutic added value is a criterion and where patients can assess with clinicians and pharmacists on treatment. She concluded by citing other words that the E and A in MEAT could stand for (ethical, accessible, appropriate, etc.).

The second topic related to **environmental aspects** in the procurement process. **Adrian van den Hoven** commented that environmental aspects are a good approach but need to be evidenced. Procurers look at it from a product level whereas manufacturers consider the environment at corporate or manufacturing site level. ESG corporate-wide standards are widely applied, but this is not product-specific. A collective standard for whole industry, called the AMR-Industry Alliance standard, e.g. for antibiotics production, is now being certified and audited. Nevertheless, external certification requires a couple of years. Kristine Peers echoed this by commenting that more and more countries are implementing this, in line with the EU goals to procure goods and services in a sustainable and environment friendly manner (Green Public Procurement). The aim is to become greener in all processes, but adapting manufacturing processes takes time, so we need a phased approach. Environmental criteria also need to be meaningful and thus should be part of the holistic, balanced price-quality assessment. Anca Toma opined that using environmental considerations in procurement strategies is positive. However, some patients depend on medicines that are rather toxic where there are no alternatives, e.g. oncology or respiratory. There are trade-offs, policy-measures to streamline environmental concerns should not hamper patient access. Patients should be involved, to better understand environmental aspects and policy aspects (e.g. access). She concluded by commenting on the importance of paper leaflets, which must not turn into a greenwashing tool by switching to digital as this restricts access. Sarada Das commented from the clinicians' perspective, for example using packaging sizes to reflect standard dosage and the importance to avoid unnecessary pharmaceutical effluent. She concluded by noting the importance of developing effective procurement strategies. Despoina Makridaki commented on the role of hospital pharmacists, who have a holistic perspective. It is crucial to safeguard access of patients to therapeutic care. There are clear differences between countries in the organisation of procurement issues, there are many ways of working, which also depends on national law. Prices are still the most powerful criterion. She concluded by stating that it is possible to see good practices and gave an example from Greece. Sarada Das mentioned that medical professionals can provide insights to the procurement process, also in relation to the life cycle, such as feedback on the capacity whether or not to substitute. While procurement processes are extremely fragmented, there is value, also for smaller procurers, in reaching out to and involving medical professionals in the discussions. Anca Toma commented that patient involvement adds complexity, however it brings a nuance to make better decisions. If one uses horizon scanning, then there is a better understanding of their needs. It is optimal to involve patients in assessing and addressing shortages.

The panellists were then asked to share their key message for procurers and policymakers. Sarada Das proposed involving doctors due to their knowledge of therapeutic value. She added that procurement has the possibility to solve some problems with stable supply, e.g. safety stocks. Anca Toma cautioned that patients are seen as dragging up costs and as recipients of expenditure; it is extremely important for them not to be seen as a cost, but rather as a partner for more efficient and effective healthcare. Patients are always the first to see value of the treatment. Despoina Makridaki commented that she would like to see specific guidelines and recommendations that effectively incorporate best practices for prudent procurement. Procurers and policy makers should put patients at the centre and take responsibility regarding the prevention of shortages; She concluded by suggesting involving pharmacists in more processes. Kristine Peers commented that in a fast-changing environment, there is a need for high-level and continuous structured dialogue between the different stakeholders about trends and practices to support a more sustainable situation in countries and avoid supply disruptions. Adrian van den Hoven commented that there is a need for more EU organisation of the market. He suggested a (European) standardised approach or alignment for those criteria that will eventually be used for non-price elements. Secondly, he commented on shortages, where there is a divergence between small and medium-sized countries being willing to collaborate to solve supply issues and the five large Member States who seek to secure the supply only for their own country. The EU should intervene to restore solidarity and balance.

The moderator **Petra Wilson** concluded the session with three key words reflecting the discussion: collaboration, innovation and balance.

#### **Closed Breakout Sessions**

The afternoon saw a series of **closed breakout sessions**, enabling frank and open discussion and exchange between participants. Key messages that were shared in Plenary thereafter are reflected below.

# Session A: Ensuring Security of Supply: Optimising Procurement through Multiple Winners Awarding and Supply Criteria

In this breakout session, the focus was on addressing supply security through procurement strategies, emphasizing the use of security of supply criteria and multi-winner awards for optimal outcomes. The discussion highlighted challenges related to legal barriers and the need for flexibility when implementing **multi-winner awards**. The consolidation of API sources was recognized as a potential barrier to diversifying supply. Best practices included clarifying estimated demands, tailoring contract durations (e.g., 2-3 years) to prevent market exits, setting price ceiling and floor to limit the price range between winners, defining allocation and prioritization between regions upfront, and maintaining flexibility for adjustments (e.g. when a low number of bids). When considering **supply security criteria**, participants favoured MEAT criteria but stressed the importance of legally sound criteria to avoid appeals. Topics such as stock requirements, reliability/past shortages, and penalty effectiveness were also discussed. Further best practice exchanges were deemed beneficial to improve security of supply through procurement practices.

## Session B: Lifecycle Approach and Trade-offs: Developing a Robust Strategy for Procurement of Medicines

This breakout session emphasised the importance of developing a comprehensive strategy for the procurement of medicines, in order to have policies in place that can achieve long-term objectives. To be able to treat as much patient as possible, it was therefore reiterated that the importance of award criteria can change according to the lifecycle stage of a medicine (e.g. security of supply criteria becoming more important as prices of a medicine go down in the later stages). The importance of Horizon Scanning was highlighted, for procurers and policymakers to be aware of what is coming up; as well as the potential of having more centralised procurement, especially in smaller Member States. Several challenges were also identified, such as the willingness-to-pay for improved security of supply; the fragmentation of healthcare systems; and potential lack of compliance by prescribers to use procured medicines. Finally, and to alleviate some of those barriers, it was suggested to continue sharing success stories and knowledge.

### Session C: Environmental Criteria Integration in Tenders: Promoting Sustainable Procurement Practices

This breakout session centred on the integration of environmental criteria in tenders, highlighting the significance of sustainable procurement practices. To start, practical guidance was provided on drafting tenders that effectively address environmental concerns. Current examples where shared, such as upholding corporate ISO standards, as well as introducing transport and packaging criteria, and considering shelf life of products. Barriers included the difficulty to effectively evaluate and control certain criteria, having the necessary time and technical expertise, as well as legal implications. Potential solutions brought forward were increased supplier engagement and having common standards.

#### Session D: Collaborative Procurement: Leveraging the Power of Joining Forces

This session emphasized the benefits of collaborative procurement, aiming to provide procurers and policymakers with guidance for successful collaboration. The discussions mainly focused on cross-country procurement, with varying objectives for larger and smaller Member States. Motivations for cross-country procurement included information sharing, resource pooling, enhanced quality, and

improving accessibility, affordability, and availability to reduce costs. Starting with like-minded countries facing similar challenges and gradually addressing legal barriers, building trust, ensuring flexibility, and incorporating safety and efficacy data for new medicines were proposed steps. Participants suggested the Commission could facilitate continuous knowledge sharing, with a need to avoid duplication when implementing concrete actions such as developing guidance on overcoming legal obstacles and piloting EU-level collaborative procurement.

#### **Conclusions**

The Chair concluded the meeting by asking participants what specific forms of support or resources would be most valuable to implement the different recommendations from the study, and if there were any other areas not yet discussed that need support or discussion. The European Health Public Procurement Alliance (EHPPA) highlighted their buyer's community, a platform for 15 000 European hospitals launched in summer 2023 to exchange information and to use common force. The EU was asked to come up with **best practice guidelines on optimised procurement of medicines** and to **facilitate further discussions between different stakeholders**. The Chair ended the meeting by concluding there is an interest to **develop a community of procurers and policymakers** in the field, building on existing initiatives. Initiating this process is paramount, and the Commission can offer structural and logistical support starting from the existing NCAPR group. The Chair encouraged all interested parties to join the efforts and thanked participants for their active contributions.