Position paper on best procurement practices

Summary

Across Europe, the current procurement practices have generated a number of undesired effects, namely reduced competition and consequently medicine shortages, which in the long term also lead to originator monopolies and unwanted price increases. Developing optimal procurement practices is an opportunity to create healthy competition and guarantee patient access to medicines, by increasing the number of manufacturers in the market and thereby reducing the risk of medicine shortages.

Medicines for Europe believes that the procurement process design can be optimised by:

- Adjusting the number of procurement winners according to the market, product and country characteristics
- Preventing disproportionate penalties to encourage a sustainable supply of medicines to patients
- Guaranteeing that the procurement processes open after the entry of the first multisource medicine to ensure a competitive and predictable supply to patients
- Using selection criteria that consider other factors than price and ensure fair competition
- Using extended lead times that guarantee a predictable supply of medicines to patients

Procurement specialists should take a holistic view when designing procurement processes to safeguard that competition is guaranteed in the long run. A well-functioning system would ultimately lead to a competitive market environment that benefits patients, healthcare professionals and payers, in both the short and long-term.

The objective of this position paper is to recommend the best procurement practices, where procurement is already in place, in order to address the increased challenges for sustainable healthcare systems.

Background on procurement/tendering

The sustainability of healthcare systems is a challenge for many European governments. Multiple factors, such as a growing and ageing population, increased disease burden, the introduction and increased cost of new innovative medicines and cuts to pharmaceutical expenditure have intensely affected access to medicines in Europe[1,2,3]. In particular, the generic, biosimilar and value added medicines industry continues to be heavily

[1] The Parliament Magazine. 2015. Available at: https://www.theparliamentmagazine.eu/articles/opinion/many-patients-europe-have-limited-or-no-access-treatment
[2] Eurostat Population Statistics
[3] OECD, Fiscal Sustainability of Health Systems: Bridging Health and Finance Perspectives. 2015.

affected by cost-containment measures that do not take into account the merits of these medicines in expanding the availability of pharmaceutical treatments to a larger number of patients and in reducing overall public spending. In particular, some authorities are applying cost-containment measures such as procurement/tendering on generic and biosimilar medicines, which in the long-term can prevent competition and will not provide the expected additional efficiency for healthcare budgets that a timely access to these medicines would bring.

Experience has shown that these practices can result in the continuation of monopolies that will have little positive impact on the pharmaceutical budgets and increase the risk of medicine shortages. In some countries, the number of multisource competitors in some disease areas has already decreased to a critical level for sufficient market competition, due to unsustainable market conditions. For instance in Germany, a study that regularly analyses generic medicines competition has recently demonstrated that the number of generic medicines manufacturers has halved from the period of 2006-2009 to 2013-2014, mainly due to the tendering system in place[4]. In Italy, the rate of participation from generic medicines manufacturers at hospital level has also progressively decreased, mainly due to the current tendering practices[5]. This has also been acknowledged by WHO[6]. As shown in Figure 1, the application of short-term cost-containment measures such as centralised procurement/tendering by authorities, have been demonstrated to reduce the number of suppliers for essential life-saving medicines in both the hospital and ambulatory sectors, ultimately putting patients' health at risk by increasing the potential for shortages[7,8,9, 10,11,12,13,14,15,16,17,18,19,20,21,22,23,24].

[4] IGES analysis on generic medicines competition. 2017. Available at: http://www.progenerika.de/presse/zahl-des-monats-juni-2017/
[5] Nomisma study. The generic medicines system in Italy. Hospital spending, tenders impact and sustainability. 2016. Available at: http://www.assogenerici.it/it/download/rapporto-nomisma-2016-assogenerici.pdf
[6] WHO report. Challenges and opportunities in improving access to medicines through efficient public procurement in the WHO European Region. 2016.
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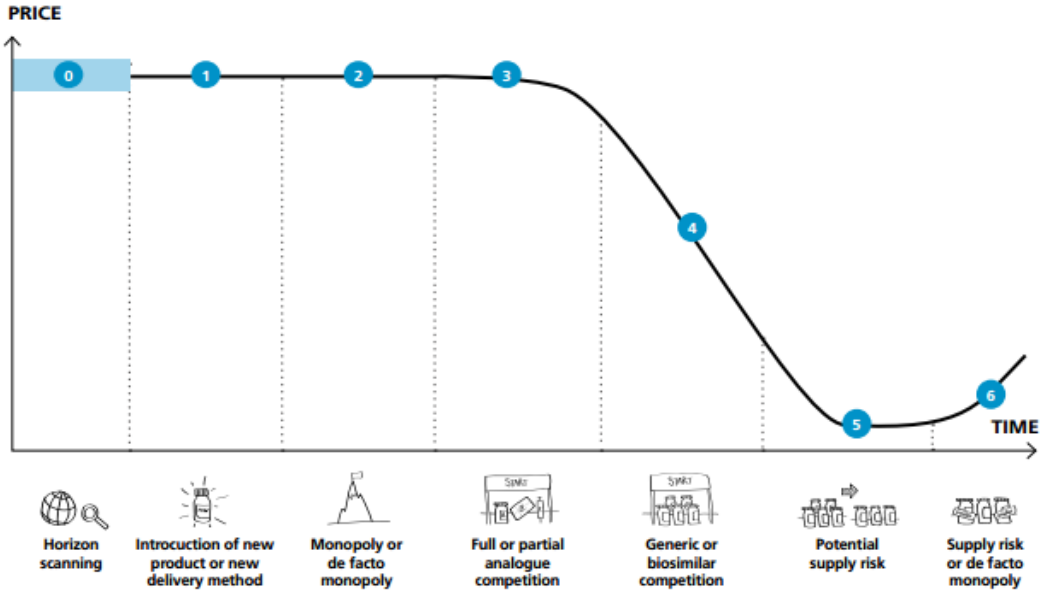
Figure 1. Pharmaceutical lifecycle stages and generalised price development for a specific disease area or condition.



Source: WHO report 2016[6].

To avoid this risk of market consolidation, which might endanger patients' health in case of medicines shortages, it is necessary to achieve a healthy market which considers long term objectives for achieving sustainability. Therefore, governments must review the long-term consequences of applying procurement/tendering mechanisms to this sector and, whenever this mechanisms are in place, develop optimal procurement practices that guarantee competition and patient access to generic, biosimilar and value added medicines.

The objective of this position paper is to recommend the best procurement practices, where procurement is already in place, in order to address the increased challenges for sustainable healthcare systems. Designing a well-performing procurement mechanism is crucial to achieve a sustainable and competitive market for medicines and should be a strategic priority for all stakeholders including healthcare policymakers, payers and providers, as well as medicines manufacturers and distributors.

Best procurement practices recommended by Medicines for Europe

Adjust the number of procurement winners according to the market, product and country characteristics

The market environment for medicines can differ considerably between different settings. To guarantee sustainable competition, an analysis of the market should be made and the number of procurement winning

manufacturers should be selected according to the different characteristics of the market. **Multi-winner tenders should be preferential**[25] to guarantee multiple manufacturers in the market and prevent medicine shortages.

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

The objective of procurement models is to avoid having a limited number of suppliers for all medicines and to consider a number of winners according to the market, product and country characteristics (preferentially multi-winner tenders[25]). This might be achieved, for instance, by dividing the market into lots for the different winners (e.g. first winner gets 50% of market, second winner 30%, etc.).

Prevent disproportionate penalties to encourage competition and a sustainable supply of medicines to patients

Penalties should be proportionate to the contract value to ensure competition in the procurement process

In most procurement contracts, there are clauses that stipulate penalties in case the manufacturer is unable to supply the awarded medicine. In some cases, the penalty for one month of inability to supply might be as high as the value of the entire business per annum. It is clear that this practice puts the manufacturers at considerable financial risk and thereby acts as a disincentive to compete in the procurement process. **Therefore, the value of penalties should be proportionate to the contract value agreed by the manufacturers in order to encourage participation in the tenders and ensure a sustainable supply.**

Before the application of penalties, there should be some flexibility to find solutions for the interruption in supply.

The inability of a manufacturer to supply may sometimes be due to reasons beyond their control (e.g. manufacturing problems with the supplier of the active pharmaceutical ingredient, regulatory related problems, hurricanes, unplanned political issues, etc.). It is also known that some medicine product characteristics might make them more vulnerable to supply disruptions than others (e.g. injectable medicines vs. standard oral tablets). Therefore, **penalties should be adjusted according to the cause of the inability to supply and the medicine product characteristics. Classifying circumstances that are beyond the control of the manufacturer and medicines that are more susceptible to supply disruptions than others in the procurement contract** would

[25] Except Belgium where the quantity of medicines tendered is low and consequently the market volume is too small to create a mature and balanced market.

better reflect the complex process of manufacturing and significantly relieve the burden of penalties. Particularly, in the case where a supplier is unable to supply the medicine due to external reasons, there should be an exit clause for the manufacturer and/or a **flexible framework that allows the manufacturer to find a solution for the supply interruption** (e.g. buying the medicine from another supplier) and avoid medicine shortages.

Accurate estimates of volume to be provided should guarantee a continuous supply

The operational business of manufacturers is complex: raw material availability, excipient availability, manufacturing time, manufacturing capacity, packaging time, availability of human resources, etc. These are amongst the many factors that have to be in place before a medicine is manufactured. Therefore, it is essential that the procurement awarding bodies provide accurate estimates of the volumes to be supplied (e.g. minimum and maximum volume caps), as manufacturers cannot increase their manufacturing capacity in a short period of time. In some cases, an unexpected peak in demand (e.g. to avert stock-out caused by the inability of another company to supply) leads to the manufacturer being unable to supply the requested volume. Therefore, **manufacturers should only be liable for volumes that were specified in the procurement contract and no penalty should be imposed in case of inability to supply unexpected volumes**.

Guarantee that the opening of a procurement process ensures a competitive and predictable supply

In some countries, all the procurement processes start in the same period of the year (e.g. January-March). In this case, a manufacturer that wins multiple procurement processes for various medicines in the same period of time can have its ability to supply these medicines compromised. Therefore, it would be recommended that **the procurement processes should be spread throughout the year to accommodate manufacturing capacity to address demand and avoid medicine shortages. Furthermore, procurement/administrative processes should open when the medicines are about to lose their patent protection/loss of exclusivity, so that competition can start immediately after the patent/exclusivity term i.e. a procurement process should not run longer than the patent term of the originator or there should be an option to invite the respective multisource manufacturers to participate in a procurement process. Finally, the procurement process/administrative procedures should be predictable, harmonised and transparent to ensure participation of multiple manufacturers and reduce the risk of medicine shortages.**

Use of selection criteria that consider other factors than price and ensure fair competition

In many procurement processes, the lowest price is the only or major factor determining the winner. Solely focusing on price does not take into consideration the rising costs associated with manufacturing these medicines (e.g. regulatory costs). In the long-run, manufacturers will have to be more selective when choosing which procurement processes they would like to participate in, leading to a concentration of suppliers (less

manufacturers' participation). Through less competition the supply of medicines is threatened, especially if there are medicines with only one player left alone in the market.

A further key issue that arises from focusing only on the lowest price is that such a system fails to take into account value components which may be beneficial for patients and the wider healthcare system. This means that the best value for money may not be achieved. The recent Public Procurement Directive (PPD), Directive 2014/24/EU, adopted by the Council of the EU on 11 February 2014, highlights that contracting authorities should base their decision on the basis of the most economically advantageous tender (MEAT). The MEAT shall use a cost-effectiveness approach taking into account criteria such as qualitative, environmental and/or social aspects (patients, healthcare professionals, etc.). This shows that focusing on the reduction of price levels does not always mean the best value for money. The Directive provides examples of criteria to possibly be considered: quality, organisation, qualification and expertise; after-sales service and technical assistance, or delivery conditions. It is important to highlight that **these criteria should not put in place any access barriers for generic, biosimilar and value added medicines.**

Procurement criteria should be designed to ensure a secure and continuous supply of medicines to patients. For this reason, the focus should not only be on the lowest price of the medicine, but a holistic view should be adopted and additional relevant criteria considered that do not undermine access to generic, biosimilar and value added medicines. These criteria should ensure the best value for money for the benefit of patients and healthcare systems.

- **Procurement criteria should consider product-specific characteristics**

Criteria within the MEAT could also consider product-specific characteristics. This is especially important for value added medicines, medicines based on known molecules that address healthcare needs and deliver relevant improvements for patients, healthcare professionals and/or payers[26]. An example of a value added medicine are pre-filled syringes (PFS), which are especially beneficial for healthcare professionals (HCPs) in a hospital setting. Medicines delivered through PFS are convenient to use for HCPs as they require a reduction of re-constitution steps when compared to glass or COC[27] vials, leading to decreased medication errors and increased safety for patients[28]. On top of this, these products are not only safer to use for HCPs as they decrease the risk of needle-stick injuries, but also more efficient for payers as they reduce wastage of the medicine[29]. The stakeholder benefits and long-term efficiency gains generated by value added medicines are one of the multiple criteria that should be considered by hospital systems when procuring medicines.

- **Procurement criteria that consider other factors than the lowest price should ensure fair competition**

While procurement systems should expand their design to focus on other criteria than the lowest price, this should be performed without raising barriers for competition. For example, if a supplier has just started manufacturing a product, it will not have a 'proven track record of supply' for the specific product, which may be

[26] Please see more info on value added medicines here.
[27] Cyclic Olefin Copolymer
[28] http://www.pharmtech.com/node/222093?rel=canonical
[29] http://www.bioprocessonline.com/doc/prefilled-syringes-the-next-big-thing-0001

included in the procurement criteria. In such cases, context-specific exceptions should be made to allow fair competition and guarantee supply of medicines to patients. Furthermore, allowing more flexibility in the acceptance criteria for specific characteristics such as different strengths[30], ensures multiple opportunities and more suppliers interested in the market.

Use of extended lead times that guarantee a predictable supply of medicines to patients

The manufacturing lead time, i.e. the time from the award of the procurement process to the start of the contract when the manufacturer is required to supply, is frequently too short to enable the production of the requested volume of medicine within the estimated time. This inability to supply the medicines in time consequently results in supply disruption that affects both healthcare professionals and patients.

Aiming to comply with the current short lead times in case of award, manufacturers often hold stock in anticipation. However, if the procurement application fails, the manufacturer is left with an excess of stock which generally has a shelf life of only 10-12 months. As a consequence, the manufacturer has to destroy his stock, which is very costly, or faces increased pressure to win the next procurement process, which might disrupt competition and lead to market dumping at unsustainable low prices (sale price or sometimes even below the level of the cost of goods).

Lead times can vary across countries. On average, the minimum lead time needed for a manufacturer to supply a generic medicine is around six months, whereas this might be even longer for biosimilar, complex generic or value added medicines due to the more sophisticated manufacturing processes. **Therefore, lead times should be adapted to the product characteristics (e.g. complexity in manufacturing, regulatory requirements and additional efforts due to serialization) as well as the requested volumes to be supplied, to guarantee a predictable supply. Furthermore, it is important to highlight that the process of extending lead times is not onerous for authorities, and this measure can significantly reduce waste and improve efficiency.**

Conclusion

Cost-containment measures such as procurement/tendering have been applied to pharmaceuticals, in particular to generic and biosimilar medicines. Experience has shown that these practices can result in the continuation of monopolies that will have little positive impact on the pharmaceutical budgets and increase the risk of medicine shortages. Most of these processes focus mainly on the lowest price and do not consider other criteria (that would not create access barriers to generic, biosimilar and value added medicines). On top of this, most procurement processes do not take into account the unique characteristics of pharmaceutical manufacturing operations (e.g. insufficient lead times, disproportionate penalties, inaccurate volumes, etc.), do not promote an adequate number of participating suppliers in tenders and do not guarantee competition as soon as patent/exclusivity ends. The combination of these factors is preventing competition by threatening the long-

[30] As long as the concerned medicines deliver the same outcomes.

term sustainability of the pharmaceutical industry as well as the supply-reliability of medicines which ultimately harm patient health.

Procurement specialists should take a holistic view when designing procurement processes to ensure that competition is guaranteed in the long run. It is therefore crucial that procurement specialists and industry have a dialogue to better understand each other's needs and requirements. A well-functioning system would ultimately lead to a competitive market environment that benefits patients, healthcare professionals and payers, both in the short- and long-term.