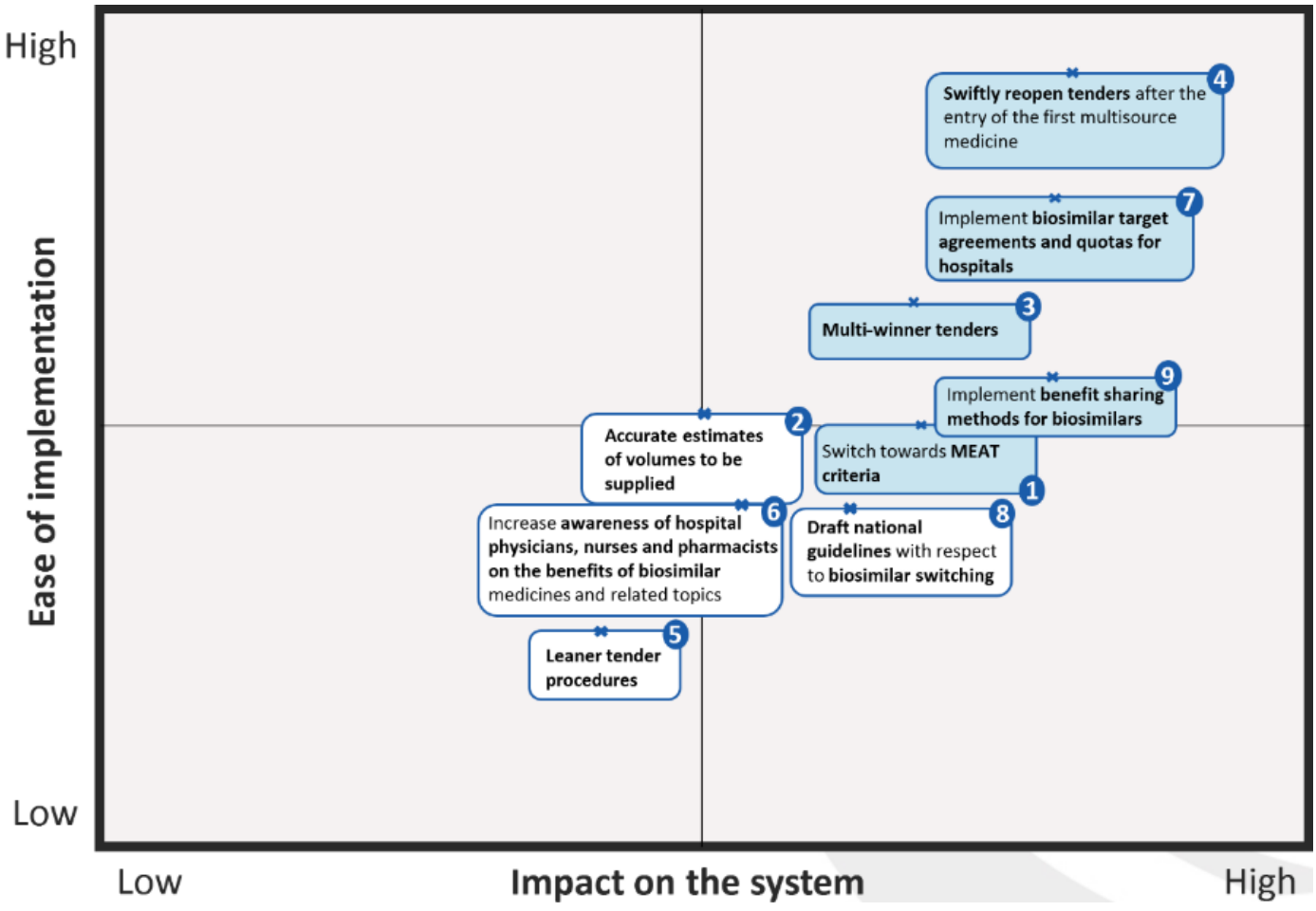
Overarching recommendations for improved access to generic and biosimilar medicines in the hospital setting

This section describes nine key ingredients for a hospital pharmaceutical environment that optimally fosters utilization of generic and biosimilar medicines. Please note that some of the studied countries may already have one or multiple of the key ingredients listed below present in their hospital pharmaceutical market. In addition, some countries require additional country-specific ingredients to optimally foster utilization of generic and biosimilar medicines. Country-specific recommendations for increased utilization of generic and biosimilar medicines in the hospital setting can be found in Appendix B of the study. The figure below shows these nine key ingredients prioritized according to ease of implementation and impact on the system.

9 key ingredients for increased utilization of generic and biosimilar medicines in the hospital setting and prioritisation of these ingredients according to ease of implementation and impact on the hospital system.



1-9 For more information, on each key ingredient, please consult the recommendations in the section below
1-5 ingredients related to improvement of procurement practices
MEAT – Most Economic Advantageous Tender

Nine key ingredients for increased utilization of generic and biosimilar medicines in the hospital setting

A key ingredient for increased utilization of generic and biosimilar medicines in the hospital setting is **a procurement/purchasing system that stimulates competition**. Competition forms a cornerstone for sustainable market dynamics and creates an opportunity for hospitals to achieve efficiency gains which can be invested in other aspects of hospital care. Many hospital systems choose to conduct procurement/ purchasing mechanisms using tendering systems, which can be an efficient mechanism when conducted appropriately. Stimulation of long-term competition can be sustainably achieved by finding the fair spot between risk and reward in the procurement/purchasing system.

In order to stimulate a long-term sustainable competition, we recommend:

1 **Switch from the frequently employed lowest bid procedure towards a most economically advantageous (MEAT) procedure**, which takes other qualitative elements into account that add value to bids, such as a proven track record of supply reliability on company level. A shift to more 'economically advantageous' procedures may stimulate competition as it creates more opportunities and interest from manufacturers to compete sustainably on more parameters than just price. Actions that ensure the active participation of the manufacturers in the hospital market will stimulate competition and consequently originate efficiency gains that can be invested and benefit the hospital system as a whole. It is important to closely monitor the effects of such additional award-criteria, to ensure that this is well balanced and does not prevent competition, such as in Belgium, where additional award-criteria seem to favour the originator manufacturers (see chapter 4.1.4).

2 **Set accurate volume estimates to guarantee a continuous supply.** This ingredient raises the interest of manufacturers to compete, as it enables medicine manufacturers to accurately weigh the effect of economies of scale in their bids. The settlement of accurate volumes to be supplied, helps manufacturers to better forecast demand creating predictability and attractiveness to bid which not only stimulates competition and benefits the healthcare system but also reduces the chance of medicine shortages.

3 **Award tenders to multiple winners[1].** Single-winner tenders lead to a risk of reduced competition, as only one manufacturer is active in the market and other manufacturers might choose to discontinue their production. This might lead to a reduced number of manufacturers participating in the next round of tenders, reducing competition. In addition, single-winner tenders might contribute to medicine shortages. In the case of a supply issue of the sole tender winner, other manufacturers might not be able to cope with the sudden demand as they might have significantly reduced or even entirely discontinued their production. Hence, multi-winner tenders with predictability of volumes for each winner not only increase supply reliability that is essential to prevent medicine shortages but also sustain healthier levels of competition in the tendering system, which both benefit the healthcare

[1] Except situations/countries where the quantity of medicines tendered is too low and consequently the market volume is too small to create a mature and balanced market.

system as a whole (please see positive examples in Italy and UK chapters, respectively).

4 **Swiftly reopen tender procedures after the entry of the first multisource medicine.** Reopening tender procedures directly after the entry of the first multisource medicine fosters competition. This enables timely patient access to cost-effective treatments i.e. generics and biosimilars. Timely enhanced competition in tender procedures promotes a better allocation of economic resources which benefits the healthcare system as a whole[2].

5 **Make the tendering procedure leaner.** The tendering systems in most studied countries are administrative, disharmonious and labour intensive, which may discourage medicine manufacturers from participating in tenders. A concerted effort to make tendering operational procedures harmonious and simpler by requiring submission of essential information for the tender and by fully digitizing the procedure reduces the required effort, and therefore also sunk costs, of medicine manufacturers to participate in hospital tenders. A leaner tendering incentivizes the participation of multiple manufacturers in the tenders, which stimulates competition in the procedure and benefits the healthcare system as a whole.

Next to the key ingredients 1-5, which biosimilar medicines share with generic medicines, we have identified **four biosimilar-specific key ingredients** for increased utilization in the hospital setting. These four biosimilar-specific key ingredients focus on improving market access of biosimilar medicines by increasing awareness of hospital physicians, nurses and pharmacists, implementing biosimilar target agreements and quotas and by drafting guidelines on treatment switching. In order to increase access of biosimilar medicines in the hospital market and to stimulate competition, we recommend:

6 **Create guidelines and/or information campaigns to increase awareness of patients and healthcare professionals (including hospital physicians, nurses and pharmacists) regarding the efficacy, quality and safety of biosimilar medicines as well as other important topics such as biosimilar medicines introduction in the clinical practice and physician-led switching.** A general lack of awareness/education on biosimilar medicines still contributes to some resistance among healthcare professionals including hospital physicians, nurses and pharmacists. In order to improve the clinical use of biosimilar medicines by healthcare professionals, and therefore to increase patient access to biologic medicines, it is important for hospitals and other trusted stakeholders to create information campaigns and educational settings to disseminate information on the benefits of biosimilar medicines and relevant biosimilar-related topics such as physician-led switching. In addition, it might be useful to disseminate information about the importance of biosimilar medicines in cost-efficient quality care improvement in the hospital setting not only to healthcare professionals but also to controllers and managers which issue the tenders and often have an incentive to limit pharmaceutical spending (e.g. hospitals, regional health agencies or central procurement agencies). For instance in UK, the update of NICE guidelines after biosimilar filgrastim launch in

[2] Important to take into consideration a balanced re-opening of tenders for biosimilar medicines. Frequent re-opens associated with short duration would be challenging given the extended manufacturing lead time and consequent less predictability.

2008[3] reflected the improved cost-effectiveness of biosimilar filgrastim vs. alternative treatments. As a result, G-CSF prescribing restrictions were relaxed and usage also recommended for primary prophylaxis of neutropenia versus secondary prophylaxis only. Consequently, this guideline update stimulated an increased use of biosimilar filgrastim and enabled a greater number of patients to access these treatments at an earlier stage of the therapeutic cycle.

7 **Create incentives for biosimilar use that take into consideration the long-term sustainability of the sector such as the implementation of target agreements and quotas for biosimilar medicine use.** Setting concrete milestones for the use of biosimilar medicines with target agreements for physicians and quotas for hospitals, is acknowledged to stimulate competition, to increase patient access to biologics and to supply physicians with more treatment options. Targets must be accompanied by robust tracking to ensure accurate awareness of progress towards milestones. Regarding target agreements for physicians, there is a concrete example in Germany in the region of Westfalen-Lippe where these target agreements are applied and the physician association plays a major supporting role to physicians by organising information campaigns and by providing reporting to physicians about the progress of the management of the switch.

8 **Draft national and or local hospital guidelines with respect to treatment changes & medicines exchange.** By drafting national/hospital guidelines on treatment switching, hospital stakeholders are informed on the safe and positive experience of physician-led switching and on the process of exchanging therapeutic alternative medicines (switching from a group of patients already undergoing treatment with an originator biological medicine to a biosimilar). Ample evidence supports the safety of switching to biosimilar medicines and can be incorporated in hospital guidelines and communication to physicians and patients[4,5].

9 **Implement benefit sharing methods.** Benefit sharing models and schemes should be encouraged so that cost-effectiveness gains resulting from the increased use of biosimilar medicines are re-invested into healthcare for the benefit of patients and all the relevant hospital stakeholders. For instance, in the University Hospital Southampton NHS Foundation Trust in the UK , there is an example of a benefit sharing model, where a managed physician-led switching program of biosimilar infliximab for all inflammatory bowel disease patients is available. This switching to biosimilar medicines allowed more patients to be treated and created the opportunity for re-investment in improvements of patients' care, e.g. hiring more nurses to provide targeted support/better care to the patients.

[3] Simon-Kucher & Partners, IMS Health, MIDAS, IMS Consulting Group, Nov 2015
[4] Kurki P, van Aerts L, Wolff-Holz E, Giezen T, Skibeli V, Weise M.
Interchangeability of Biosimilars: A European Perspective. BioDrugs. 2017 Apr; 31(2):83-91.
[5] Ebbers HC, Muenzberg M, Schellekens H. The safety of switching between therapeutic proteins. Expert Opin Biol Ther. 2012 Nov;12(11):1473-85.