

Joint Nordic Procurement – 2028

FGL, the Swedish Association for Generic Medicines and Biosimilars, welcomes the opportunity to comment on the proposed joint Nordic procurement.

FGL's starting point is that regional procurement is preferable to national procurement. We oppose a general move towards centralised Nordic procurement. Centralisation risks excluding smaller and newly established suppliers and reducing the number of companies remaining in the market. If a single supplier serves several countries, a supply failure also becomes harder to manage. Local tenders by the Swedish regional authorities allow more suppliers to remain active and provide alternative sources of supply.

FGL recognizes the objective of making the combined Nordic market more attractive to suppliers and thereby improving long-term availability. However, a larger aggregated procurement does not in itself guarantee stronger security of supply. If centralization results in fewer awarded suppliers, lower commercial viability for alternative suppliers or increased dependence on one supply chain across several countries, the effect may instead be greater market concentration and increased vulnerability.

For each product, the procurement authorities should therefore assess not only the number of bids received, but also the likely impact on supplier diversity and continued market participation throughout the contract period and after the contract has ended.

There may, however, be exceptions. Joint Nordic procurement can be appropriate for products with small volumes, particularly critical medicines where demand in individual countries is insufficient to attract suppliers or maintain availability. The purpose should be to make continued supply commercially viable. Joint procurement should not replace functioning competition or be used to extend the lowest price in one country across the Nordic region.

FGL therefore broadly shares Farma Norge's view that joint procurement should focus on selected products with small volumes and vulnerable supply. For such procurement, we propose the following conditions:

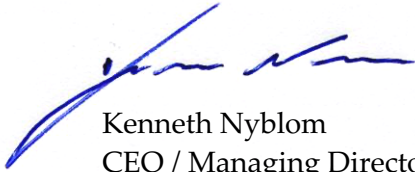
1. Suppliers should be able to submit tenders for one country or several countries without having to supply the entire Nordic market. The tender structure should allow several suppliers to be awarded contracts where volumes permit. The number of suppliers, the allocation of volumes and the rules for purchases from each supplier must be clear before bids are submitted. Awarding a framework agreement without a realistic prospect of sales does not provide a basis for maintaining supply.
2. Common basic requirements, standard documents and a shared digital tender portal should reduce administration. Company documentation should be submitted once and updated when necessary. Information already held by medicines authorities should not be requested again. These improvements should also support regional procurement.
3. Timetables should be published early, with at least seven months between award and supply start, and equivalent notice for extensions. Forecasts should specify country, strength and pack size. Purchasers should commit to buying at least 80% of the estimated volume, with exceptions for circumstances beyond either party's control. Contracts should allow competition to start when patents expire.
4. All participating countries should include a specific price adjustment clause covering the revised Urban Waste Water Treatment Directive (UWWTD), building on the wording used by Sykehusinnkjøp. The clause must expressly allow costs arising from the directive to be invoked even though the directive was known before the deadline for final tenders.

FGL's position is that the purchaser should bear the financial risk of these additional costs. Documented increases in the actual cost of supplying the contracted products resulting from implementation of the UWWTD should be compensated through corresponding price adjustments. The entitlement, documentation requirements and timing of adjustments must be set out in advance and apply throughout the contract, including extensions. Suppliers cannot reasonably be expected to include an unknown future cost in a fixed tender price.

5. Penalties and compensation for supply failures must be proportionate and subject to clearly defined limits. The Norwegian provisions limiting compensation provide a useful starting point. FGL wants the Nordic contracts to include both a maximum liability for an individual failure and an overall financial ceiling for the contract period. The ceiling should cover the combined effect of contractual penalties, damages and additional costs of replacement purchases. Suppliers must be able to assess their maximum financial exposure before submitting a bid. Suppliers that have fulfilled reasonable commitments should not face penalties for shortages caused by covering another region's needs or complying with mandatory allocation decisions.
6. Contracts should provide for annual price adjustments linked to a specified consumer price index. Tender and payment currencies must be stated in advance, together with a transparent mechanism for handling significant exchange rate changes. A supplier should not have to carry the full currency risk throughout a multi-year contract. The interaction between inflation adjustments, currency adjustments and compensation for UWWTD costs must also be clear.
7. FGL supports taking price, sustainability and security of supply into account when evaluating tenders. Security of supply should carry substantial weight. Criteria must be transparent, proportionate and possible to demonstrate without excessive administration. Requirements should be assessed against their effect on supplier participation, particularly for the small-volume products that joint procurement is intended to support.
8. Regulatory and practical requirements must be clarified before the tender is launched. This includes marketing authorisations, packaging, labelling, language requirements and distribution arrangements in each participating country. The procurement authorities should coordinate with the relevant medicines authorities so that differences between countries do not create avoidable barriers to participation.
9. Suppliers and the national generic and biosimilar associations should be involved before the product selection, award criteria and contractual conditions are finalised. Draft documents should be made available for consultation while changes can still be made. This dialogue should establish whether joint procurement would improve availability for each selected

product and whether the proposed obligations are commercially and operationally feasible.

Best regards,



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