

Questions and Answers on Procurement in pilot study for new reimbursement model

Which antibiotic products should be procured?

The antibiotic products that we intend to procure should have activity against pathogens that we (the Public Health Agency of Sweden) together with independent experts have identified as high priority resistance types and considered to be a current or potential high-level medical risk in Sweden. These are in line with the WHO-defined critical priority pathogens.¹ Furthermore, the antibiotic products should have received market approval (MA) by the European Commission during the past six years, or have a probable expected MA shortly (latest year 1 of the contract), have a low sales volume in Sweden the previous year (in this case 2019), and not be associated with serious side effects. All of these principles follow the model we developed in a previous government assignment.

Timeline for procurement?

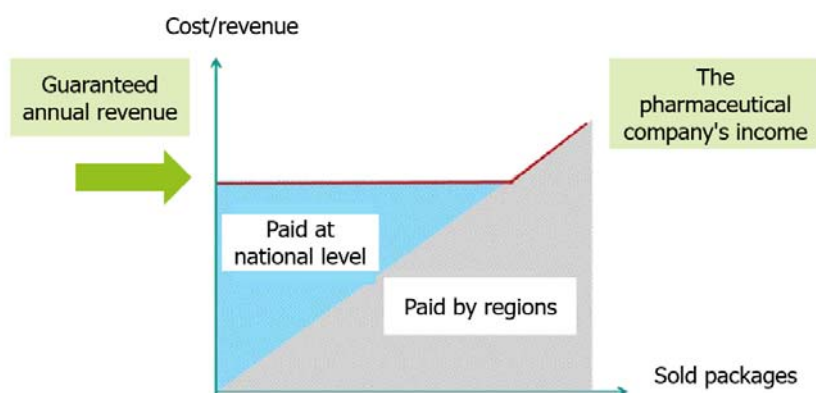
The announcement of the procurement is scheduled for the end of the first quarter of 2020. The procurement will be announced in the Swedish Visma TendSign system ([link](#)).

Principles of the model to be tested in the pilot study

This procurement is part of a government assignment and is based on the alternative reimbursement model we presented in a previous assignment.² In short, the model entails a national contract to ensure good accessibility in Sweden against a lowest guaranteed income.

The principles of the reimbursement model can be described as ensuring that the pharmaceutical companies that enter into contracts and fulfill the requirements for availability according to the contract are guaranteed a certain annual minimum income from the national level (the state and/or regions jointly). Regions continue to buy and pay as usual for the products included in a national contract during this pilot study. If the actual income from regions to these companies turns out to be lower than the guaranteed income for a given year, the difference will be paid from the national level at the end of the year. If, on the other hand, revenue from actual sales exceeds the guaranteed level for a given year, the company anyhow receives 10% of the value of the guaranteed annual compensation, for fulfilling the availability requirements, see Figure 1.

Figure 1. Schematic illustration of the reimbursement model with guaranteed compensation.



¹ https://www.who.int/medicines/publications/WHO-PPL-Short_Summary_25Feb-ET_NM_WHO.pdf

² <https://www.folkhalsomyndigheten.se/publicerat-material/publikationsarkiv/t/tillganglighet-till-antibiotika/>

What does good availability mean?

Good availability means access to specific antibiotic products within a defined contract period (defined security stock and delivery time frame), based on a clinical need. For this, there is no requirement for a large physical warehouse in Sweden.

The scope of the contract?

All products (substances) that meet the compulsory requirements in the procurement can enter into a contract for guaranteed revenue against fulfilled requirements regarding, among other things availability.

The starting point for the level of guaranteed annual compensation is to ensure availability from a medical need. The medical need is based on the current state of resistance and a possible national need during the contract years. Principles for the calculated scope has previously been reported in the former published report¹.

The level of the lowest guaranteed annual revenue is calculated as follows: *“price per package (estimated average price)” * “number of packages (based on medical need)” * “1.5 (150 percent to cover additional administrative overhead and logistical costs)”*.