Folkhälsomyndigheten
PUBLIC HEALTH AGENCY OF SWEDEN

Questions and answers – Agreements signed for a pilot study of a new reimbursement model

What was required to enter into an agreement and thereby participate in the pilot study?

The agreement is a service contract regarding the availability and supply of antibiotic products. It includes partly specified requirements, for example regarding activity and safety that the antibiotic must fulfill, as well as specified commitments that the company must fulfill.

All antibiotic products (substances) that meet the set requirements and where the supplier meets the set requirements for requested services were accepted to enter into an agreement.

What were the requirements for the product?

The antibiotic product would meet defined requirements for special medical

value and have or risk having a lack of availability on the Swedish market. The annual sales value of the product (substance) must not have exceeded SEK 4 million during the previous year (2019).

The antibiotic must have an antibacterial spectrum with demonstrated good activity against multiresistant Enterobacteriales, including strains producing carbapenemases, and / or against carbapenem-resistant Pseudomonas aeruginosa and / or carbapenem-resistant Acinetobacter baumanii. Thus, it must be approved for treatment at WHO's critical priority pathogens, 2017, at least for two of the following indications:

-complicated intra-abdominal infection

-complicated urinary tract infection including acute pyelonephritis

-hospital acquired pneumonia

and/or

-infections caused by aerobic gram-negative organisms in patients with limited treatment options.

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Furthermore, the product must have a bactericidal effect, i.e. killing effect leading to bacterial cell death at therapeutic concentrations and having a good safety profile, similar to that of existing beta-lactam antibiotics.

What were the requirements for the companies?

The company / supplier must have experience in delivering services to the Swedish or European market. The supplier must show that it has the professional capacity required to deliver the object of the contract and perform requested services regarding warehousing, delivery capacity and reporting.

Stock

The warehouse must be located in Sweden. The supplier must ensure that the inventory's size of the current product per quarter corresponds to the previous quarter's sales twice; however, the inventory must correspond to at least two weeks of treatment at each emergency hospital in Sweden. The authority does not guarantee a certain sales volume. The real need may be less or greater than the estimate. The supplier has three months from the start of the contract to build up the stock volume, unless otherwise agreed. Compensation for availability will be paid only when the supplier can demonstrate that the stock meets the said volumes.

Delivery

Regions / hospitals shall order the product according to regular routines.

To ensure availability, distribution of the agreed product must take place no later than the next day from order (weekdays) if the order is made no later than 4 pm (similar to Ordinance 2009: 659 on trade in medicines) to the hospitals.

Reports

The Supplier must submit documentation once the warehouse is established, distribution channels are in place and that the Supplier is ready to fulfill its obligations in accordance with the agreement. The supplier must also report quarterly, including sales and deliveries of the antibiotic product with a specification of the time for receiving the orders and delivery time.

Were there any tenders that did not meet the requirements and if so why?

No, all tenders received were judged to meet the set requirements.

How does the payment to the companies work?

The size of the compensation is directly linked to the sale of the product (substance) according to the formula:

Compensation availability inventory = 4,000,000 - the annual sales

Required products must be invoiced to the region / healthcare principal who ordered the product.

If sales exceed SEK 4,000,000 / year during the agreement period, however, the company is guaranteed 10% of the maximum amount that is SEK 400,000 / year as long as the commitments made in the agreement are fulfilled.

How is the pilot study financed?

The pilot study is funded by Vinnova and the Swedish Public Health Agency.

How long do the agreements apply or does the pilot study last?

The planned agreement period for the assignment is from 2020-07-15 to 2022-07-15, with the possibility of extension for up to 24 months. Extension can take place on one or more occasions. The pilot study will run until end of 2022. The project will be reported annually to the Government Offices.

Can new applications be received at a later date?

No, not for this pilot study. The final report, including an evaluation of the pilot study, may form the basis for a possible government decision on the continuation.

Are there similar initiatives in other countries?

There is nothing completely similar to the Swedish initiative, aiming to ensure accessibility through a guaranteed annual minimum compensation based on potential need. The United Kingdom has recently communicated a new value-based payment model that aims to provide incentives for research and development of new antibiotics to ensure the availability of antibiotics to UK patients. Two products will be selected in December 2020 in this test study, one recently approved and one that is in the final phase prior to approval. These will then be assessed during 2021 with regard to the medical value, and the level of

reimbursement will then be determined. The agreements are planned to take effect from April 2022.

How will the pilot study be evaluated?

The Swedish Public Health Agency intends to conduct follow-up research regarding the pilot study within this government assignment, continuously during the project period. This is to get relevant information close in time (avoid recall bias) and to hopefully instill ideas for improvement during ongoing study. The following sub-projects are planned:

Subproject 1. "Availability before and after implementation of new compensation model"

Aim: To investigate whether the pilot model has improved the availability in Swedish healthcare for the antibiotic included in the pilot study and whether it has affected sales of similar drugs.

Subproject 2. "Economic consequences of the pilot model"

Aim: To describe the costs of our financing model and possible impact on sales of alternative competing products, from different perspectives.

Subproject 3. "The procurement process"

Aim: To evaluate the procurement procedure regarding, among other things, the definition of which antibiotics are to be procured, the advantages and disadvantages of the selected procurement model compared with alternative models, and the experiences from the pilot project regarding collaboration between different authorities and SKR.

Subproject 4. The interest of the pharmaceutical companies / LIF

Aim: To gather information on how the pharmaceutical companies concerned perceive the pilot study and the model as such, during the period 2019-2022.

The Supplier shall be helpful in the Purchaser's follow - up research and shall assist in producing the necessary information / data regarding, for example, prices, stock values and deliveries "before agreement".

Problems with out-of-stock situations of antibiotics often apply to older drugs with high demand in healthcare. Can a similar approach be relevant for other categories of antibiotics?

Not at the moment. The pilot study intends to focus on drugs active against WHO's proposed critical pathogens. If the outcome of the study is assessed as positive, it is part of the Swedish Public Health Agency's task to consider and make a recommendation as to whether the model can also be applied to other antibiotics or drugs.