



Strengthening access to off-patent antibiotics

Antibiotic shortages can threaten responsible antibiotic treatment. Sweden is a small market and we use older narrow-spectrum antibiotics more frequently compared to other countries thanks to our relatively favorable resistance situation. In order for pharmaceutical companies to continue to provide important antibiotic products on the Swedish market, the government considered that the financial incentives for certain drugs need to be reviewed. Three authorities jointly propose different measures to strengthen access to a wide range of older off-patent antibiotics in Sweden.

Unlike many other medicines, older antibiotic products commonly have an important place in treatment. The use of off-patent antibiotics often means appropriate and cost-effective alternatives to novel drugs and constitutes an important part of the Swedish strategy against the development of antibiotic resistance. These drugs should therefore neither be phased out nor replaced by new products, as this would limit the treatment options in the future.

In recent years, severe shortages of antibiotic products have increasingly attracted attention. This especially applies to formulations for children. In addition, several clinically valuable antibiotics have completely disappeared from the market. While important, novel antibiotics are mainly used to treat seriously ill patients.

Government assignment to strengthen access to older antibiotics

In September 2021, the Public Health Agency of Sweden, The Dental and Pharmaceutical Benefits Agency and the Medical Product Agency were commissioned by the government to survey the market and identify measures to strengthen access to older antibiotics. The objective was that the healthcare system should continue to have access to a wide range of effective older antibiotics.

There are two different types of availability problems – one being temporary shortage situations when existing medicines are not available for a period of time, and the other being when important drugs are not nationally marketed. The measures to reduce the two problems are somewhat different. For the first problem, measures that give companies financial incentives to stock medicines are a possibility, while for the second, it is largely about making it profitable to keep, or introduce, a product on the market. The fundamental challenge is to combine the healthcare system's need for a wide range of antibiotics and a restrictive use, with the pharmaceutical companies' demands for profitability.

Mapping the antibiotic market

The market for antibiotics has declined sharply in recent decades. The decrease is mainly explained by a lower use in outpatient care where average prices have remained unchanged, while sales in inpatient care have been relatively stable with slightly increased average prices in recent years. Several product groups have lower sales today compared to ten years ago. A low sales value is an important indicator that a product risks leaving the market.

The authorities stated that there is a need to review the financial incentives in order to strengthen access to valuable older antibiotics on the Swedish market.

Shortages of medicines

Health care does not always have access to the recommended first-line alternative for antibiotic treatment, which can lead to worse outcomes and more side effects. In addition, there is a risk of increased development of resistance. Antibiotic shortages are worrying because there are often few or no equivalent treatment options. Of the shortage notifications for antibiotics (ATC code J01) that were reported to the Medical Product Agency in 2021, 26 percent were not considered interchangeable. Alternative solutions in case of shortages take time from

healthcare professionals, pharmacies, caregivers and patients. In addition, the start of the treatment is delayed. The consequence may be that an antibiotic with a broader spectrum has to be used, which entails an increased risk antibiotic resistance.

Clinical evaluation of off-patent antibiotics

In order to identify which antibiotic products are particularly valuable for health care, the Public Health Agency of Sweden, in collaboration with an external reference group, has carried out a clinical evaluation and prioritization of antibiotic products considered to be at risk for a lack of access in Sweden. Products evaluated by the reference group either had a total sales value of less than 3 million SEK in 2021, had repeated long shortages in the last five years, or were often prescribed on a named-patient basis if not marketed in Sweden. Antibiotics that were large products in Europe but not marketed in Sweden were also evaluated. Parallel imports were excluded.

The products were then classified into categories A, B and C, where the A category are considered the most valuable. These products would have significant clinical consequences if not available. The majority of products in category A (22/32) were not interchangeable.

A total of 128 antibiotic products were assessed, of which 108 were marketed in Sweden December 2021. The evaluation showed, for example, that paediatric formulations were given high priority.

Suggestions for measures

Measures to reduce the number of temporary shortages are focused on increased stock-piling through the procurement of availability. Measures aimed at making the market more attractive include improved regulatory advice and fee reductions. Adjustments to the pricing within the pharmaceutical benefits could be a possible remedy for both problems.

The Public Health Agency of Sweden, the Dental and Pharmaceutical Benefits Agency and the Medical Product Agency propose a model for increased stock-piling, changes in pricing, regulatory measures, advice and communication efforts. The following measures were proposed when reporting the assignment to the government, November 11, 2022:

- The Public Health Agency of Sweden proposes an in-depth investigation and pilot testing of a new reimbursement model where pharmaceutical companies receive a fixed annual compensation for

providing a defined buffer stock of certain identified antibiotic products

- The price ceiling must be able to be raised above the current level
- It should, under certain conditions, be possible to make exceptions when deciding on price and subsidy
- The Dental and Pharmaceutical Benefits Agency intends to compile and clarify information aimed at pharmaceutical companies about price increases on the agency's website
- The annual fee for having antibiotic products registered in Sweden should be removed
- The possibility of common packaging in the Nordic countries should be investigated further.
- The Medical Product Agency intends to start up an expanded consultancy for pharmaceutical companies and to systematically look for antibiotics at risk of being deregistered.

Explanations of words and concepts

- Off-patent or old antibiotics –antibiotics where market exclusivity has expired and where generic products may be present
- Generic drug – drug that contains the same active substance, in the same preparation form and with the same strength as the reference product
- Shortage situation – occurs when a pharmaceutical company cannot deliver a medicine for a period of time
- Substitution group - is a group of medicines that, according to the Medical Product Agency are mutually interchangeable
- Price ceilings in substitution groups – the highest accepted price.