

Proposal – Economic model for new antibiotics

Background

There is insufficient development of new antibiotics to meet the growing resistance problem. There are several reasons for this. The scientific challenge is great and the current business model does not provide sufficient incentives for pharmaceutical companies to develop new substances to finished products. The general business model for medicines is that revenue increases as the drug is used. In the case of antibiotics, the opposite is desired. New antibiotics should be used only when absolutely necessary, to reduce the risk of resistance.

Sweden has in comparison with other countries less problems with resistant bacteria and thus less need to use new antibiotics. There is nevertheless necessary to have new antibiotics available in Sweden for the few cases when they are needed.

There is thus a great need to develop and test new economic models that provide adequate incentives for pharmaceutical companies to develop new substances to finished products and also to provide them on the Swedish market. LIF has – together with member companies AstraZeneca, MSD, Astellas and GSK – developed the following proposal for such a model.

Two-part proposal

The proposed model is not primarily intended to increase the incentive for basic research. There are many global and EU initiatives which focus on that. The model focuses mainly on increasing the incentive to develop scientific breakthroughs into finished medicinal products that will be available for the health care system. If the model is successful, it will in the long run also help to increase incentives for basic research.

Sweden has since 2002 a value-based pricing of medicines, and the starting point has been that the proposal should be value-based. Another aspiration has been to find an insurance-like model that provides security for both society and the pharmaceutical companies. It has therefore been natural to design the proposal in terms of a premium based model.

The proposal described below is intended to stimulate further discussion and development. In order to reach a final form the proposal need to be reviewed by Swedish authorities and Swedish health care. LIF also sees a need to test the proposal in practice to see if it is possible to find the levels of remuneration in different situations that are acceptable to both society and companies.

The value of additional treatment options

Traditional cost-benefit analysis of drugs can be described as measuring and analyzing the *value of replacing an existing tool in the tool box with a new one*. Such analysis is largely based on the properties of the new drug and the health economic model is adapted to the unique situation. The models can be said to measure the *value of a new alternative antibiotic*. For various reasons, such analysis is not always optimal to measure the full value of new antibiotics.

Therefore LIF along with the company PAREXEL developed a health economic model which instead measures the *value of adding a new tool in the toolbox*. This model can be said to measure the *value of a world with a new antibiotic* as compared to a world without such a new antibiotic. The model focuses more on epidemiological measures linked to a specific infection than the characteristics of the particular drug. It is therefore natural that the model is evaluated by authorities that have the best knowledge about various infections. It also means that the model is more generic and can be used for the evaluation of different drugs for the same infection. LIF is also of the opinion that the model may be used in other countries with similar health systems as Sweden.

The *value of a world with a new antibiotic* that the health economic analysis results in is supposed to underpin the premium that is proposed as the basis of the economic model. The premium may be lower than the appraised value, but not higher. The antibiotic value model thus includes dynamics where the final premium is determined in a negotiation.

Premium-based remuneration

The economic model suggested by LIF is a premium-based remuneration. It has features in common with the procurement of pandemic vaccines. The model consists of three parts; a premium, a unit cost and a fixed ceiling for the total cost.

As described above, the proposed **premium** is to be value-based. LIF suggests that the state pays the premium in order to - together with other countries - contribute to an increased incentive to ensure the development of pharmaceutical products. The premium is also meant to secure access to the product in Sweden.

Financing of actual medication use is, however, the responsibility of the county council-driven health care system. LIF therefore suggest that the premium is to be combined with a **unit cost** paid by the county councils when the antibiotic is used. There may be reasons to have a higher unit cost for low usage to support a restrictive use. In the event of outbreaks of resistance and the need for increased use, there may be reason to lower the unit cost. The relationship between the premium and the unit cost should be determined in each individual case by negotiation between society and the company.

For the model to work as an actual insurance, society will also need a **fixed ceiling for the total cost**. This means that the premium paid by the state also offers insurance cover in the form of a predictable maximum cost in a situation where the need to use a new antibiotic increases dramatically. The insurance shall also include that the company is committed to deliver the increased amount of medication needed.

Financing

LIF suggests that the state premium should be financed by an "antibiotic charge". The price of commonly prescribed antibiotics would be increased by a limited amount, without changing the current compensation to companies and pharmacies. The price increase would accrue to the state, and today's antibiotics users will thus help to pay for continued access to effective antibiotics.

Continued development

In addition to the need to review the proposed model as well as the need for live tests in Swedish health care to reach the final design, there is also a need to address practical issues surrounding the distribution to health care and ensuring a good adherence to the strict treatment guidelines that society needs to develop.

In addition, there is a necessity to document and assess that the model really contributes to that the pharmaceutical companies experiences an increased incentive, to that health care do get greater access to antibiotics and to that Sweden develops a more appropriate use of antibiotics.

Inspiration for international development

That Sweden as a small country are considering a new economic model for new antibiotics obviously has no direct global effect, but someone has to start. It is LIF's hope that the proposed model could inspire other countries to begin similar processes. The health economic model can probably be used by others to determine the value of a new antibiotic in each country. The elements of the economic model probably need to be adapted to various countries' health systems and how they finance medicines. In this way, the incentive to develop the scientific breakthroughs into finished drugs can gradually be strengthened.