ASCERTAIN'S ACCESS-BASED PRICING MODEL

WHAT PROBLEM IS IT TRYING TO SOLVE?

Many new medicines are launched at very high prices, which can make them difficult to afford and can lead to **unequal patient access between countries**.

The goal of this new **access-based pricing model** is to support price setting discussions between pharmaceutical companies and public health authorities or health insurers by considering the needs of all major stakeholders:

Patients
need affordable access to new treatments

Health systems
need prices they can sustain

Pharmaceutical companies
need returns to drive continued innovation and future medicine access

HOW DOES THE MODEL WORK?

The proposed price is built on four main components:

Research & Development Costs | **Value-based Reward** | **Operational Costs** | **Operational Profit**

ⓘ The price calculated by the model is intended as an additional starting point for price negotiations between healthcare payers (e.g., insurance companies) or national authorities on one side and pharmaceutical companies on the other but will not necessarily be the final selling price.

EXAMPLE SCENARIO

A hypothetical example of a new tablet treatment for a rare condition:

- **A chemical substance**, administered as **2 tablets of 250 mg each**, once every day
- For a small (rare) indication: yearly incidence (new patients) **7/100,000**
- Approved only **for this indication**
- The R&D benefited from **substantial public support**
- **Two alternative treatments** are expected to come to the market in the next 10 years
- The treatment duration is **1 year**
- **The treatment fulfils an unmet medical need**, and provides important societal benefits
- **The medicine provides a major added benefit** to the patient over the standard of care according to the clinical trials, but the quality of evidence of the trials is low

Full treatment total cost:
€41,238

Day cost:
€113



All these figures are per patient:

R&D:
(including reward for investors)
€8,211

Value-based reward:
€5,953

Operational costs:
(production and others)
€20,923

Operational profit:
€6,151

Visit access2meds.eu to find resources, insights and updates tailored to help you understand how ASCERTAIN is working to make life-saving treatments more accessible for everyone. To find more about the policy tool please visit: toolbox.access2meds.eu

Funded by the European Union

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the European Health and Digital Executive Agency (HaDEA). Neither the European Union nor the granting authority can be held responsible for them. Grant Agreement 101094938.

WHAT IS ASCERTAIN'S ACCESS-BASED PRICING MODEL?

WHAT PROBLEM IS IT TRYING TO SOLVE?

Many new medicines are launched at very high prices, which can make them difficult to afford and can lead to unequal patient access between countries. At the same time, pharmaceutical companies need incentives to continue investing in the development of the needed innovative treatments.

The goal of this new pricing model is to help price setting discussions between pharmaceutical companies and public health authorities or health insurers by creating an **"access-based pricing model"** that considers the needs of all major stakeholders:

- Patients need affordable access to new treatments
- Health systems need prices they can sustain
- Pharmaceutical companies need a return on their investment and incentives to continue to innovate and provide access to future medicines.

These needs may come at odds with one another as some stakeholders will have different priorities.

Many tools used today to set the price focus solely on paying for the additional value of the medicine for the patient. They present challenges:

- When the price of a new medicine is set based on the price of an older treatment for the same disease, and if that price is increased because of the new medicine's added value, each new treatment tends to cost more than the last. As a result, medicine prices gradually increase over time
- It is difficult to get to an agreement between stakeholders on what constitutes value
- The evidence that is derived from clinical trials does not always allow to assess the value with enough certainty

Other existing models mainly focus on covering costs. They have disadvantages too, due to:

- The lack of transparency on real costs incurred by the companies and on real prices paid
- The lack of incentive for doing efficient research and development (R&D for short)

Rather than looking only at what a medicine costs to make, or only at the value it provides, the ASCERTAIN model tries to address the access challenges by combining both perspectives.

HOW DOES THE MODEL WORK?

The model proposes a new way to calculate the price of a new medicine. The proposed price is built on four main components:

1. Research and Development (R&D) costs

- This is the cost of discovering, testing and bringing a new medicine to market. The model also includes the cost of failed development projects that will not reach the market
- A return on investment to shareholders and investors who funded the research can also be granted in the model
- These costs can be reduced if there has been considerable public funding to finance the R&D of the medicine and a return is given to the public for its investments
- These R&D costs are distributed evenly among the number of patients that are expected to get treated with the new medicine in Europe over a ten-year period. This number of patients is calculated based on how many people have or get the disease, whether they can get treated, and whether alternative treatments will come to the market during the ten-year period.

2. Value-based reward

- The value-based reward is a bonus given on the estimated R&D costs per patient
- This additional reward is linked to the medicine's added benefits for the patient over the usual treatment
- This reward can be decreased if the studies on the product are of poor quality and don't show convincing evidence of the medicine's added benefit
- It can also be increased if the medicine addresses unmet medical needs for a severe disease
- Additional rewards may be given for broader societal benefits of the medicine.

3. Operational costs

- These costs include manufacturing, sales and administration costs.
- The production costs consider what kind of active ingredient is used, how it is administered (e.g., as a tablet, or via a vial), the dosage, and how long the treatment goes on for. Logistics-related costs are also accounted for.

4. Operational profit

- A reasonable profit margin is given to make sure that the business can keep running.

WHAT MAKES IT DIFFERENT?

A few notable features:

- It includes **both costs** and **value**.
- It uses several elements in a flexible way to reflect the user's preferences. Some parameters must be used (such as covering the R&D expenses and rewarding the therapeutic value for the patient), while others are optional (such as reducing the reward

for public return). A value for most elements is proposed and sometimes fixed, but it can be adjusted for many.

- The price calculated by the model is intended as an additional **starting point for price negotiations between healthcare payers (e.g., insurance companies) or national authorities on one side and pharmaceutical companies on the other** but will not necessarily be the final selling price. Other current tools will still be used in the negotiations.

Example

A hypothetical example of a new tablet treatment for a rare condition:

· the new medicine is a chemical substance, administered as 2 tablets of 250 mg each, once every day

· It is for a small (rare) indication: yearly incidence (new patients) 7/100,000

· it is approved only for this indication

· the R&D benefited from substantial public support

· two alternative treatments are expected to come to the market in the next 10 years

· the medicine provides a major added benefit to the patient over the standard of care according to the clinical trials, but the quality of evidence of the trials is low

· the treatment fulfils an unmet medical need, and provides important societal benefits

· the treatment duration is one year

By using the model, which operates with publicly available knowledge about costs, estimated component of the price per patient will be:

R&D costs per patient (including reward for investors): € 8,211

Value-based reward: € 5,953

Operational costs (production and others): € 20,923

Operational profit: € 6,151

Based on these estimated costs and rewards, a proposed price for the new treatment will then be:

Total price (full treatment): €41,238

Total price (day): € 113

KEY TAKEAWAY FOR A NON-SPECIALIST

This tool tries to answer the question:

"What would be a fair price for a new medicine if we considered development costs, manufacturing costs, patient benefits, and reasonable profits, while also trying to maximise patient access?"

Such a model could help governments, healthcare payers, and pharmaceutical companies have more transparent and balanced pricing negotiations.

For more information on ASCERTAIN please visit: https://www.access2meds.eu/