Balancing Patient Access Improvement, Innovation Incentives, and Health System Sustainability:

The ASCERTAIN Project and its Access-Based Pricing Model

NVTAG Symposium April 2026

Nicolas Xander

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 HaDEA. Neither the European Union nor the granting authority can be held responsible for them. Grant 101094938

Part I: The ASCERTAIN Project

Challenges in access to new medicines

- **Financial sustainability of health systems:** As healthcare expenditure increases, affordability of newly approved medicines presents a rising challenge. How to ensure timely patient access at affordable price while providing adequate R&D incentives?
- **Substantial differences in access to IHTs and patient outcomes exist across EU countries:** Lower-income countries face delays in accessing medicines; list prices in first launch countries are often higher than real prices paid after negotiated deals. How to address disparities to achieve the principle of "equal access to health care" in EU member states?

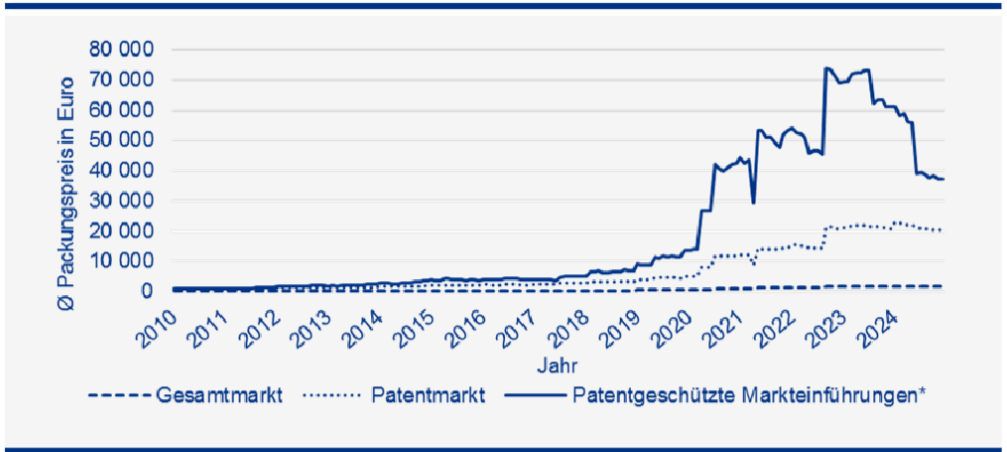


Abbildung 1-8: Durchschnittliche Packungspreise für den Gesamtmarkt, den Patentmarkt und patentgeschützte Markteinführungen im Zeitverlauf

* Es liegen die Markteinführungen der jeweils letzten 36 Monate zugrunde.

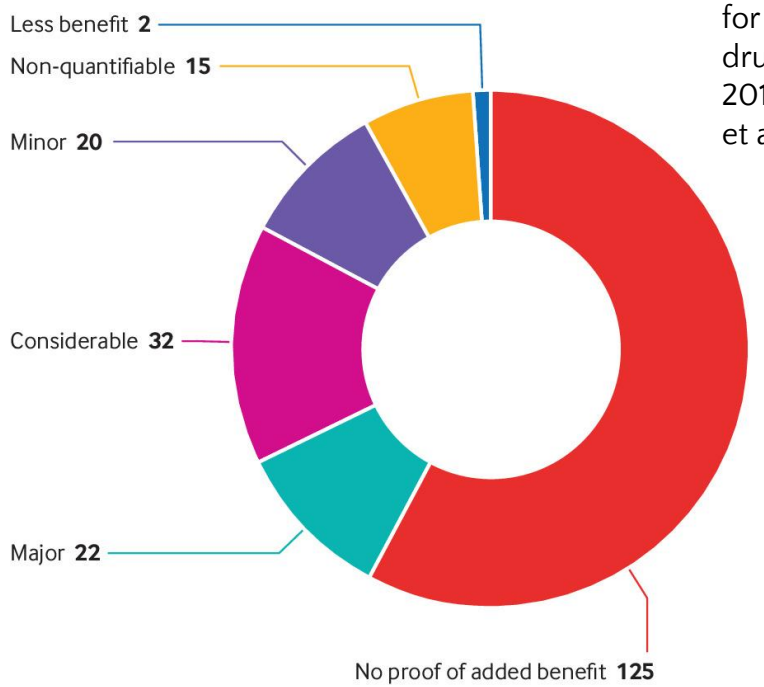
Quelle: Grafisch angepasste Darstellung auf Grundlage von Daten, die dem SVR durch das Wissenschaftliche Institut der AOK (WIdO) zur Verfügung gestellt wurden.

Average price per pack in Germany in Euros, 2010–2024 (Sachverständigenrat 2025). Solid line shows average price of products entering the market in the last 36 months.

Sources for figure:
Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen und in der Pflege (2025). DOI: 10.4126/FRL01-006510673

Challenges in access to new medicines

- **Increased uncertainty about the effectiveness and cost-effectiveness of IHTs:** medicines are increasingly approved by the EMA without phase III RCT data. How to ensure efficient use of public resources?



Added benefit ratings for newly marketed drugs in Germany, 2011–2017 (Wieseler et al., 2019)

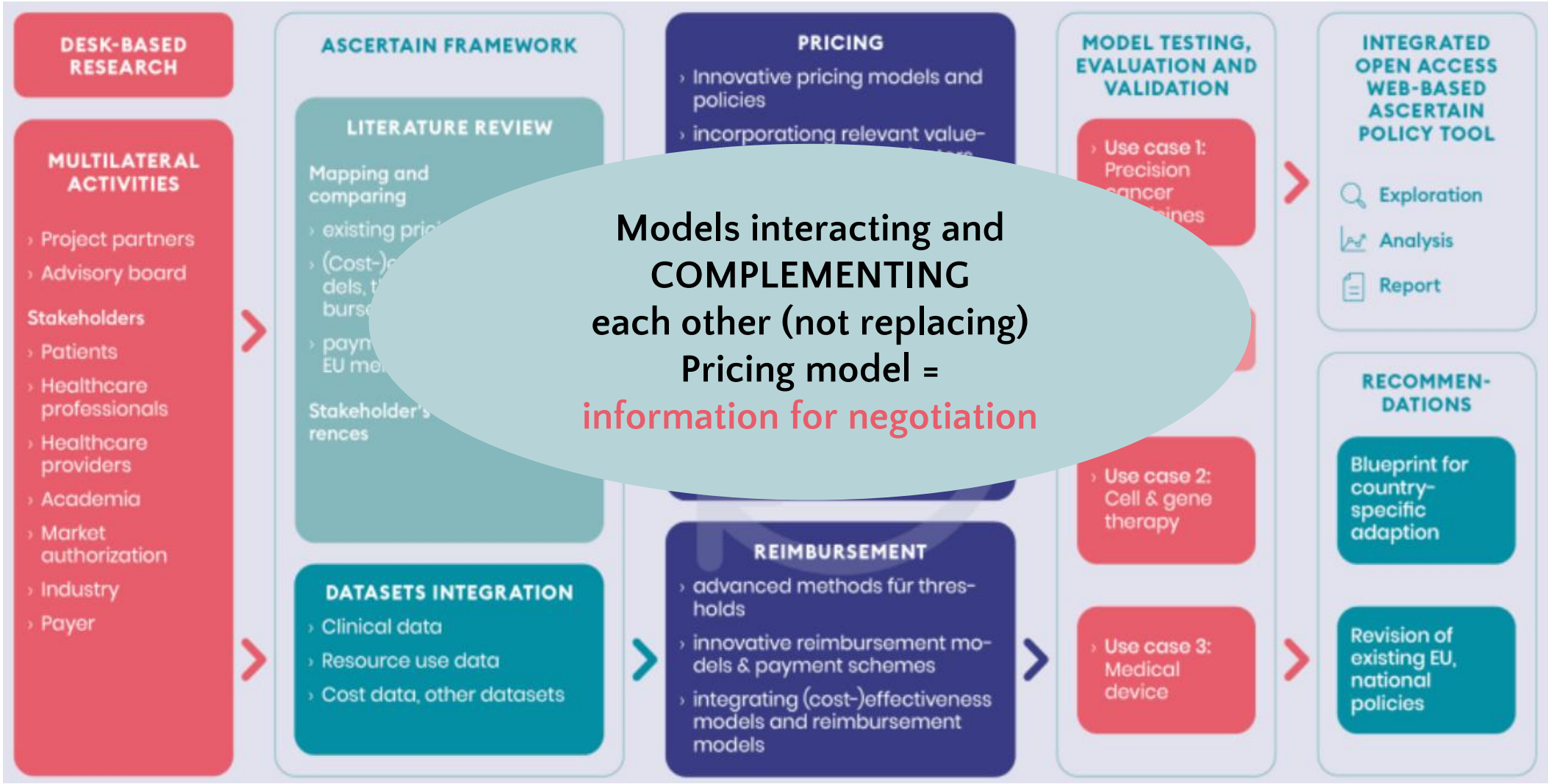
Sources for figure:
Wieseler B, McGauran N, Kaiser T. New drugs: where did we go wrong and what can we do better? BMJ 2019; 366 :l4340 doi:10.1136/bmj.l4340

Objective of ASCERTAIN: Transforming Access to Innovative Health Technologies

- Create and develop a cloud-based **publicly accessible ASCERTAIN policy support tool for decision-makers** to improve access to innovative health technologies (IHTs), including medicines.
- **Develop new models/concepts for pricing, (cost-)effectiveness, and reimbursement.** These should include data related to the **environmental impact** of health technologies' entire life cycle. This includes, e.g., drug/product discovery, production, supply chain and logistics, packaging and how products are disposed of at the end of product life.
- **Test new models with three use cases** (UCs):
  - Precision cancer medicine (PCM)
  - Cell and gene therapy
  - Medical devices (class IIb and III) or in vitro diagnostic (IVD) class D

ASCERTAIN

The ASCERTAIN cycle



Part II:
The ASCERTAIN Pricing Model

Mentimeter

Go to

www.menti.com

Enter the code

1775 2508

Or use QR code

ASCERTAIN

Why do we need a new pricing model?

Cost-based pricing

- **anchors price to costs** for the manufacturer and **risks taken** in bringing a new product to market
- costs feature in return and profit considerations

BUT:

- Opposed by some stakeholders due to (a) transparency concerns and (b) concerns regarding lack of incentive for efficient R&D

Value-based pricing

- Widely considered beneficial and efficient approach to pricing

BUT:

- does not address **affordability issue** given ever-increasing cost of standard care
- lack of agreement on **what constitutes value**
- often **uncertainty in clinical evidence**

ASCERTAIN = "Access-based" pricing combining both value and cost elements

A price that ensures patients can access new and beneficial treatments

ASCERTAIN

Informing the ASCERTAIN pricing model

Scoping review on price determinants and pricing policies

- Lack of stakeholder-elicited views on what factors are important to determine price for medicinal products (MPs)

Stakeholder elicitation: semi-structured interviews

- What elements/factors do stakeholders consider important for setting a price of a new MP?

➢ **Longlist of price determinants**

Targeted literature reviews on price determinants

- (How) can price determinants be operationalised quantitatively?

➢ **Shortlist of price determinants, operationalisation in model**

Stakeholder survey & additional expert interviews

- Operationalisation of determinants
- Incorporation of different value-based determinants

Reference: Xander, N.S.H., Belleman, T., Salcher-Konrad, M. *et al.* Price determinants and pricing policies concerning potentially innovative health technologies: a scoping review. *Eur J Health Econ* (2025). https://doi.org/10.1007/s10198-025-01834-y

ASCERTAIN

Function of the ASCERTAIN pricing model

What does the model do?

- Calculation of an **access-based price for newly authorised medicinal products**
  - Additional use case: calculation of access-based price for already reimbursed products
- Reconciliation of stakeholder interests
- **Inform** price negotiations and healthcare decision-making procedures

What does the model **NOT** do?

- Replace existing pricing policies
- Estimate (cost-)effectiveness of an MP
- (Direct) incorporation of opportunity costs
- Calculation of price for **medical devices**

Relevance for ZIN/MoHWS?

Pricing model does not test clinical or cost-effectiveness, or employ cost-effectiveness outcomes re. care under HIA/LTCA

Direct viability for (isolated) use in NL doubtful

BUT: Access-based price can be used e.g. in scenario analysis of a cost-effectiveness analysis, potentially informing reimbursement negotiations

Relevance in connection with Early HTA?

REM | Goal of early HTA: Inform development process and/or research

Pricing model in its current form works best for products with:

- marketing authorisation by EMA (re. product information)
- ideally: clinical value assessment (JCA) and subsequent appraisal (national level)

Use for Early HTA products: theoretically possible, but high level of uncertainty

Mentimeter – Question 2

Outline of ASCERTAIN pricing model

Access-based price per treatment

R&D costs	Value reward	Cost of production & sales	Operational profit

- Access-based price as additional transparent **starting point for negotiations**
- For new products **under patent**
- Dynamic price: Price per (first) **indication** – to be recalculated as new evidence emerges
- **European price** – possibility to adjust for each country
- **Compulsory and optional price determinants** to allow adjustment of the model according to user‘s context
- **Default values** with ranges to populate the model; optional **user-specified values**

ASCERTAIN

Access-based ASCERTAIN pricing model

Cost elements

- R&D[1]
- Production
- Sales and general administration[2]
- Operational profit
- Return on R&D (cost of capital)
- Return on public investment

1. Including cost of failure
2. Including medical information

Value elements

- Added therapeutic value
- Quality of clinical evidence
- High unmet medical need
- Societal value[3]

3. Such as productivity gains, impact on informal carers, environmental impact, equity and ethics

Value elements anchored (multiplying factor) in **cost elements**

Access-based ASCERTAIN pricing model

Cost elements

- R&D[1]
- Production
- Sales and general administration[2]
- Operational profit
- Return on R&D (cost of capital)

Value elements

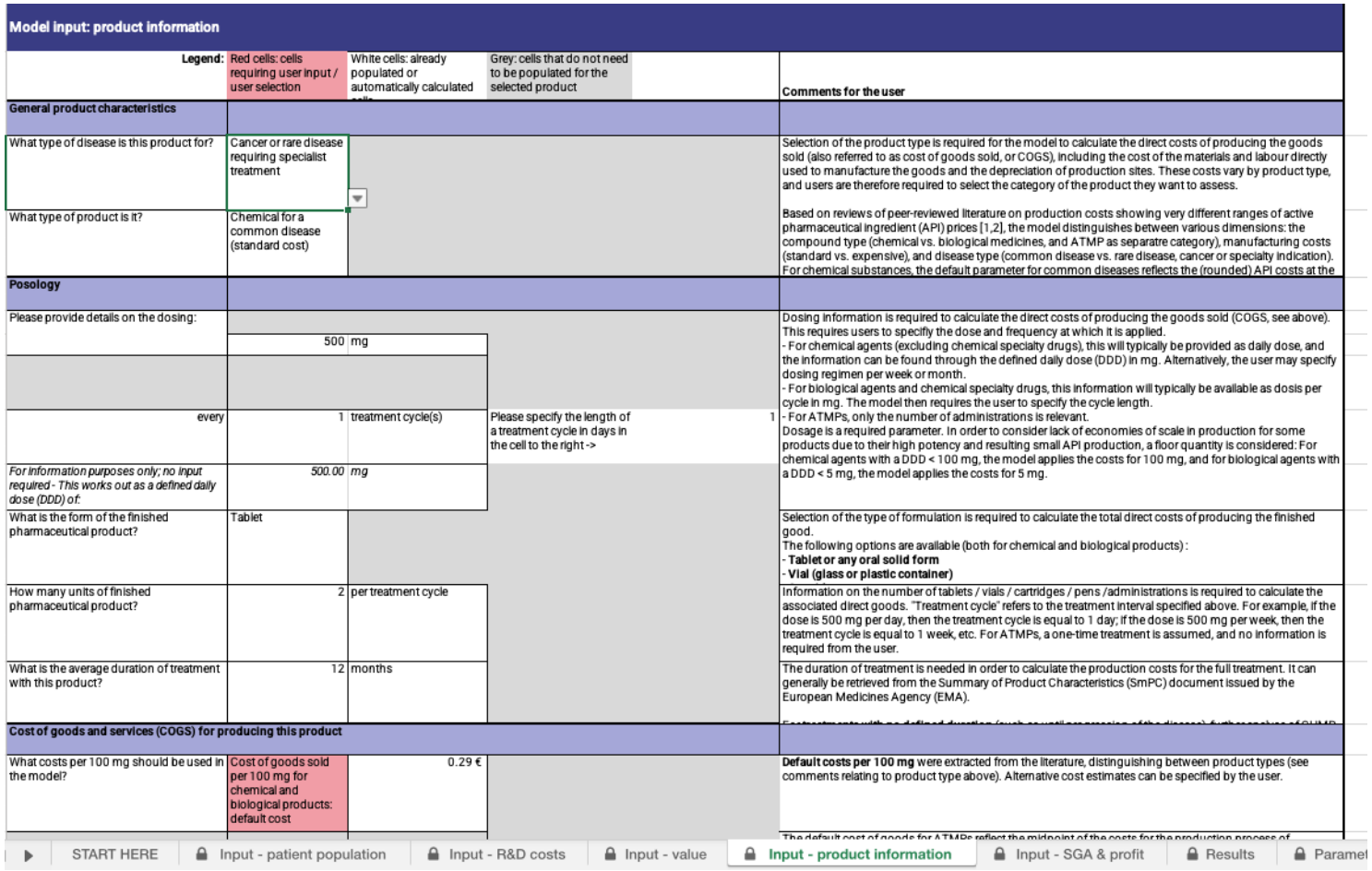
- Added therapeutic value
- Quality of clinical evidence
- High unmet medical need
- Societal value[3]

- Return on public investment

Compulsory or **optional** (user's choice)
Range for most parameters (user's choice)

Technical implementation

In **Excel®**: Blueprint for operationalisation and implementation; used for validation by stakeholders



Model input: product information

Legend:	Red cells: cells requiring user input / user selection	White cells: already populated or automatically calculated	Grey: cells that do not need to be populated for the selected product		Comments for the user
General product characteristics					
What type of disease is this product for?	Cancer or rare disease requiring specialist treatment				Selection of the product type is required for the model to calculate the direct costs of producing the goods sold (also referred to as cost of goods sold, or COGS), including the cost of the materials and labour directly used to manufacture the goods and the depreciation of production sites. These costs vary by product type, and users are therefore required to select the category of the product they want to assess. Based on reviews of peer-reviewed literature on production costs showing very different ranges of active pharmaceutical ingredient (API) prices [1,2], the model distinguishes between various dimensions: the compound type (chemical vs. biological medicines, and ATMP as separatre category), manufacturing costs (standard vs. expensive), and disease type (common disease vs. rare disease, cancer or specialty indication). For chemical substances, the default parameter for common diseases reflects the (rounded) API costs at the
What type of product is it?	Chemical for a common disease (standard cost)				
Posology					
Please provide details on the dosing:					Dosing information is required to calculate the direct costs of producing the goods sold (COGS, see above). This requires users to specify the dose and frequency at which it is applied. - For chemical agents (excluding chemical specialty drugs), this will typically be provided as daily dose, and the information can be found through the defined daily dose (DDD) in mg. Alternatively, the user may specify dosing regimen per week or month. - For biological agents and chemical specialty drugs, this information will typically be available as dosis per cycle in mg. The model then requires the user to specify the cycle length. - For ATMPs, only the number of administrations is relevant. Dosage is a required parameter. In order to consider lack of economies of scale in production for some products due to their high potency and resulting small API production, a floor quantity is considered: For chemical agents with a DDD < 100 mg, the model applies the costs for 100 mg, and for biological agents with a DDD < 5 mg, the model applies the costs for 5 mg.
	500	mg			
every	1	treatment cycle(s)	Please specify the length of a treatment cycle in days in the cell to the right ->	1	
For information purposes only; no input required - This works out as a defined daily dose (DDD) of:	*500.00*	*mg*			
What is the form of the finished pharmaceutical product?	Tablet				Selection of the type of formulation is required to calculate the total direct costs of producing the finished good. The following options are available (both for chemical and biological products) : - **Tablet or any oral solid form** - **Vial (glass or plastic container)**
How many units of finished pharmaceutical product?	2	per treatment cycle			Information on the number of tablets / vials / cartridges / pens /administrations is required to calculate the associated direct goods. "Treatment cycle" refers to the treatment interval specified above. For example, if the dose is 500 mg per day, then the treatment cycle is equal to 1 day; if the dose is 500 mg per week, then the treatment cycle is equal to 1 week, etc. For ATMPs, a one-time treatment is assumed, and no information is required from the user.
What is the average duration of treatment with this product?	12	months			The duration of treatment is needed in order to calculate the production costs for the full treatment. It can generally be retrieved from the Summary of Product Characteristics (SmPC) document issued by the European Medicines Agency (EMA).
Cost of goods and services (COGS) for producing this product					
What costs per 100 mg should be used in the model?	Cost of goods sold per 100 mg for chemical and biological products: default cost	0.29 €			**Default costs per 100 mg** were extracted from the literature, distinguishing between product types (see comments relating to product type above). Alternative cost estimates can be specified by the user.

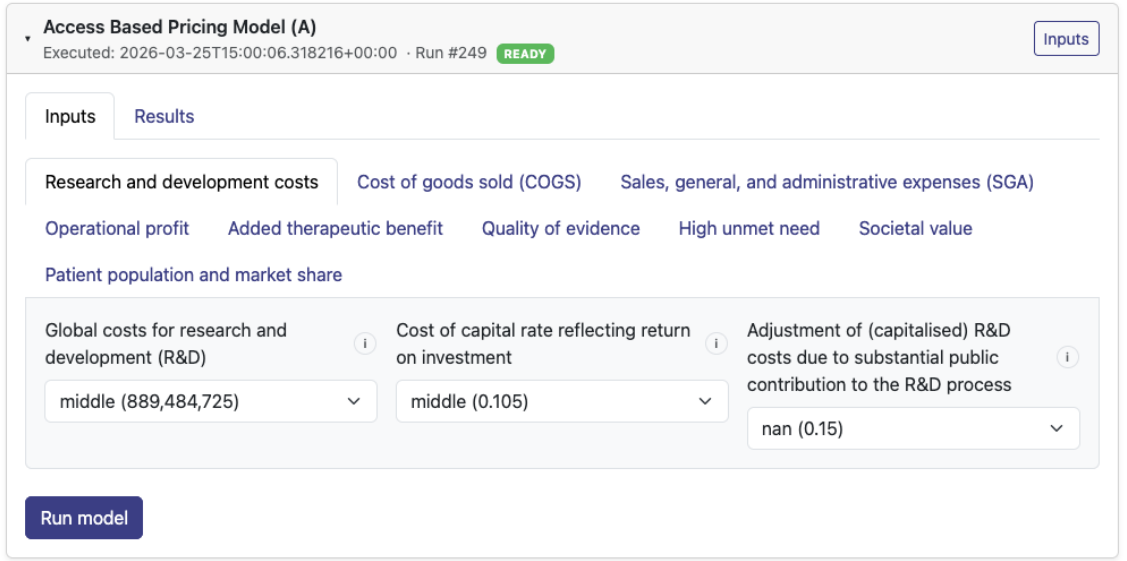
START HERE | Input - patient population | Input - R&D costs | Input - value | Input - product information | Input - SGA & profit | Results | Paramet

ASCERTAIN

Technical implementation

R: Facilitation of open-access use of the pricing model; backend of web interface for ASCERTAIN Policy Support Tool

```r
calc_abp <- function(
  prev_input,                    # 01. Prevalence at beginning of time
                                 # horizon (percentage)
  prev_denom_choice,             # 02. Prevalence denominator (1, 100, 100000);
  inc_input,                     # 03. Incidence
  inc_denom_choice,              # 04. Incidence denominator (1, 100, 100000);
  tr_rate_choice,                # 05. Treatment rate (default, low, high, or custom)
  tr_rate_custom = NULL,         # 05a. Custom treatment rate (if "custom" is selected for
                                 # `tr_rate_choice`; value between >0 and 1; NULL by default)
  competition,                   # 06. Existence of two competitors entering the market
                                 # during the time horizon (yes, no)
  rui_choice,                    # 07. Relative utilisation index representing market uptake
                                 # (normal, fast, breakthrough)
  dose,                          # 08. designated (total) dose in mg to be given during one
                                 # treatment cycle (NOTE: doses in grams must be
                                 # converted into mg!); for common disease: equal to DDD
  comp,                          # 09. compound type (chemical, biological, ATMP)
  cont,                          # 10. container type (tablet, vial, cartridge, pen)
  c_cont_custom = NULL,          # 10a. cost custom container type (not one of the given types)
  n_cont,                        # 11. number of compound containers for the dose per cycle (minimum 1)
  tr_duration,                   # 12. treatment duration (in months; for ATMPs: equal to number
                                 # of administrations)
  days_in_cycle,                 # 13. number of days in a treatment cycle (for daily
                                 # treatment administrations: 1 to be inputted)
  c_rd_choice,                   # 14. (uncapitalised) R&D costs (default, low, high, or custom)
  c_rd_custom = NULL,            # 14a. (uncapitalised) custom R&D cost amount (if "custom" is
                                 # selected for `c_rd_choice`; NULL by default)
  r_coc_choice,                  # 15. cost of capital (CoC) rate (default, high, or custom)
  r_coc_custom = NULL,           # 15a. custom CoC rate (if "custom" is selected for
                                 # `r_coc_choice`; NULL by default)
  val_adj_ropi_choice = "none",  # 16. Optional adjustment of (capitalised) R&D costs due to substantial
                                 # public contribution to the R&D process (none [default], preset, custom)
  val_adj_ropi_custom = NULL,    # 16a. Custom adjustment factor for substantial public R&D contribution
                                 # based on `val_adj_ropi_choice`; between 0 and 1
  val_atb_choice,                # 17. Premium for added therapeutic benefit (ATB; none, minor, moderate,
                                 # major, custom) [Brinkhuis et al., 2024]
  val_atb_custom = NULL,         # 17a. Custom premium for added therapeutic benefit (if "custom"
                                 # is selected for `val_atb_choice`; between 0 and 10 for
                                 # reasonable range)
  val_qoe_choice = "none",       # 18. Optional ATB premium adjustment for substandard quality of
                                 # evidence (QoE) based on available trial data based on GRADE Framework
                                 # assessment (none [default], preset, custom)
```



ASCERTAIN

ASCERTAIN pricing model algorithm

$$ABP = \underbrace{\frac{\beta_{RD} \times (1 + \beta_{O\_CoC})}{n_{pat}}}_{\text{R\&D cost}} \times \underbrace{(1 + (\gamma_{ATB} \times (1 - \gamma_{O\_QoE} + \gamma_{O\_UMN}) + \gamma_{O\_soc} - \beta_{O\_ROPI}))}_{\text{Value-based reward}} + \underbrace{(\beta_{COGS} + \beta_{SGA})}_{\text{Cost of production / sales}} \times \underbrace{(1 + \beta_{prof})}_{\text{Operational profit}}$$

β = cost-based determinants:

R&D cost

- Default: median global **out-of-pocket costs** for bringing a new product to market (incl. cost of failure; RD) = 889.5 million Euros[1]
- **European share** of global cost based on GDP among markets for new products (33.78% of EEA + G7)
- ***Optional*: cost of capital** (minimum required return on investment; CoC), set by default at 10.5%
- ***Optional*: adjustment for return on public investment** (ROPI)
- Distributed across **expected patient population** in the European Economic Area (EEA) (n_pat) over 10 years

Example: R&D cost per patient for an indication with incidence of 7 per 100.000 population

Median **global out of pocket R&D costs** (including cost of failure): 889.484.725 €

x 33,78% **share of Europe** (GDP EEA /EEA + G7)
= 300.5 millions €

divided by

Incidence 7/100.000 x EEA population (456 mio) / **prevalence**: 0

x 50% **treatment rate** of the indication

x **uptake** (utilisation index: 8% year 1, 37% year 2, 54% year 3, ..., -> 100% from year 8 on)

x 100% **market share frontier** (MSF) as first-in-indication – **competitor** with 50%/33% MSF after years 4 and 6

= 58.423 patients

Sources:
[1] Wouters et al. JAMA. 2020;323(9): 844-853
[2] Dolon. 2023. https://www.efpia.eu/media/msadqxbf/revision-
[3] Ledley et al. JAMA. 2020;323(9): 834-43

ASCERTAIN pricing model algorithm

$$ABP = \underbrace{\frac{\beta_{RD} \times (1 + \beta_{O\_CoC})}{n_{pat}}}_{\text{R\&D cost}} \times \underbrace{(1 + (\gamma_{ATB} \times (1 - \gamma_{O\_QoE} + \gamma_{O\_UMN}) + \gamma_{O\_soc} - \beta_{O\_ROPI}))}_{\text{Value-based reward}} + \underbrace{(\beta_{COGS} + \beta_{SGA})}_{\text{Cost of production / sales}} \times \underbrace{(1 + \beta_{prof})}_{\text{Operational profit}}$$

β = cost-based determinants:

R&D cost

- Default: median global **out-of-pocket costs** for bringing a new product to market (incl. cost of failure; RD) = 889.5 million Euros[1]
- **European share** of global cost based on GDP among markets for new products (33.78% of EEA + G7)
- ***Optional*: cost of capital** (minimum required return on investment; CoC), set by default at 10.5%
- ***Optional*: adjustment for return on public investment** (ROPI)
- Distributed across **expected patient population** in the European Economic Area (EEA) (n_pat) over 10 years

Cost of production / sales (COGS and SGA)

- **Compound-type-specific production cost** per 100 mg (for chemicals and biologicals) / per administration (for cell and gene therapies)
- Accocunting for finished pharmaceutical product form, overfill, and logistics
- Accounting for treatment duration and posology
- Including cost of **sales and general administration** (SGA) at 82.75% of COGS [2]

Example: chemical specialty drug for a rare disease

COGS: 5.06 € / 100mg
x 500mg in 2 tablets (x 0.42€ formulation) per day
+ 20% logistics
x 12 months treatment

= 11,293 € per full treatment over 10 years

plus

Sales and general administration: 82.75% of COGS

Sources:
[1] Wouters et al. JAMA. 2020;323(9): 844-853
[2] Dolon. 2023. https://www.efpia.eu/media/msadqxbf/revision-of-the-general-pharmaceutical-legislation-gpl-impact-assessment.pdf
[3] Ledley et al. JAMA. 2020;323(9): 834-43

ASCERTAIN

ASCERTAIN pricing model algorithm

$$ABP = \frac{\beta_{RD} \times (1 + \beta_{O\_CoC})}{n_{pat}} \times (1 + (\gamma_{ATB} \times (1 - \gamma_{O\_QoE} + \gamma_{O\_UMN}) + \gamma_{O\_soc} - \beta_{O\_ROPI})) + (\beta_{COGS} + \beta_{SGA}) \times (1 + \beta_{prof})$$

R&D cost

Value-based reward

Cost of production / sales

Operational profit

Example: cost per treatment over 10 years for a chemical specialty for rare indication

9,670 € *(incl. CoC)*

11,293 € + 9,345 €

6,067 €

sed determinants:

R&D cost

- Default: median global **out-of-pocket costs** for bringing a new product to market (incl. cost of failure; RD) = 889.5 million Euros[1]
- **European share** of global cost based on GDP among markets for new products (33.78% of EEA + G7)
- ***Optional*: cost of capital** (minimum required return on investment; CoC), set by default at 10.5%
- ***Optional*: adjustment for return on public investment** (ROPI)
- Distributed across **expected patient population** in the European Economic Area (EEA) (n_pat) over 10 years

Cost of production / sales (COGS and SGA)

- **Compound-type-specific production cost** per 100 mg (for chemicals and biologicals) / per administration (for cell and gene therapies)
- Accocunting for finished pharmaceutical product form, overfill, and logistics
- Accounting for treatment duration and posology
- Including cost of **sales and general administration** (SGA) at 82.75% of COGS [2]

Operational profit

- **Profit over operational costs**
- Calculated as average EBIDTA in the pharmaceutical industry (29.4%)[3] x operational costs (COGS and SGA)

Sources:
[1] Wouters et al. JAMA. 2020;323(9): 844-853
[2] Dolon. 2023. https://www.efpia.eu/media/msadqxbf/revision-of-the-general-pharmaceutical-legislation-gpl-impact-assessment.pdf
[3] Ledley et al. JAMA. 2020;323(9): 834-43

ASCERTAIN

ASCERTAIN pricing model algorithm

$$ABP = \underbrace{\frac{\beta_{RD} \times (1 + \beta_{O\_CoC})}{n_{pat}}}_{\text{R\&D cost}} \times \underbrace{(1 + (\gamma_{ATB} \times (1 - \gamma_{O\_QoE} + \gamma_{O\_UMN}) + \gamma_{O\_soc} - \beta_{O\_ROPI}))}_{\text{Value-based reward}} + \underbrace{(\beta_{COGS} + \beta_{SGA})}_{\text{Cost of production / sales}} \times \underbrace{(1 + \beta_{prof})}_{\text{Operational profit}}$$

γ = value-based determinants:

Value-based reward

- **Added therapeutic benefit (ATB):**
  - ATB category selected by user out of four ATB tiers: negative/not quantifiable/no added therapeutic benefit; minor added therapeutic benefit; moderate added therapeutic benefit; major added therapeutic benefit [1]
  - ATB premium over R&D cost according to ATB tier: default premiums for the four tiers determined through a stakeholder survey (0%; 10%; 30%; 50% of R&D costs), but adjustable by user
- ***Optional*: quality of clinical evidence (QoE)** – downwards adjustment of the premium allocated according to ATB due to limitations in the clinical evidence;[2,3] default adjustment of -50% of ATB premium based on survey
- ***Optional*: high unmet medical need (UMN)** – upwards adjustment of the premium allocated according to ATB for products addressing a high UMN, based on user evaluation; default adjustment of +35% of ATB premium based on survey
- ***Optional*: societal value (soc)** – additional premium over R&D costs based on (non-clinical) societal value, such as productivity gains, impact on informal carers, environmental impact, equity and ethics;[4-6] default premium 30% based on survey

Sources:
[1] Brinkhuis et al. BMJ 2024; 384 :e077391
[2] The GRADE Working Group. 2024. https://book.gradepro.org
[3] Guyatt et al. BMJ. 2008;336(7651): 995-8
[4] Breslau et al. Int J Technol Assess Health Care. 2023;39(1): e31
[5] Lakdawalla et al. Value Health. 2018;21(2): 131-9
[6] Paris & Belloni. 2013. https://www.oecd.org/en/publications/value-in-pharmaceutical-pricing_5k43jc9v6knx-en.html

ASCERTAIN pricing model algorithm

$$ABP = \frac{\beta_{RD} \times (1 + \beta_{O\_CoC})}{n_{pat}} \times (1 + (\gamma_{ATB} \times (1 - \gamma_{O\_QoE} + \gamma_{O\_UMN}) + \gamma_{O\_soc} - \beta_{O\_ROPI})) + (\beta_{COGS} + \beta_{SGA}) \times (1 + \beta_{prof})$$

R&D cost

Value-based reward

Cost of production / sales

Operational profit

Example: ABP = 41,935 € per treatment (3,495 € per month)

9,670 € *(incl. CoC)*

4,835 € - 2,418 € + 1,692 € + 2,901 € - 1,451 €

11,293 € + 9,345 €

6,067 €

based determinants:

Value-based reward

- **Added therapeutic benefit (ATB):**
  - ATB category selected by user out of four ATB tiers: negative/not quantifiable/no added therapeutic benefit; minor added therapeutic benefit; moderate added therapeutic benefit; major added therapeutic benefit [1]
  - ATB premium over R&D cost according to ATB tier: default premiums for the four tiers determined through a stakeholder survey (0%; 10%; 30%; 50% of R&D costs), but adjustable by user
- ***Optional*: quality of clinical evidence (QoE)** – downwards adjustment of the premium allocated according to ATB due to limitations in the clinical evidence;[2,3] default adjustment of -50% of ATB premium based on survey
- ***Optional*: high unmet medical need (UMN)** – upwards adjustment of the premium allocated according to ATB for products addressing a high UMN, based on user evaluation; default adjustment of +35% of ATB premium based on survey
- ***Optional*: societal value (soc)** – additional premium over R&D costs based on (non-clinical) societal value, such as productivity gains, impact on informal carers, environmental impact, equity and ethics;[4-6] default premium 30% based on survey

Sources:
[1] Brinkhuis et al. BMJ 2024; 384 :e077391
[2] The GRADE Working Group. 2024. https://book.gradepro.org
[3] Guyatt et al. BMJ. 2008;336(7651): 995-8
[4] Breslau et al. Int J Technol Assess Health Care. 2023;39(1): e31
[5] Lakdawalla et al. Value Health. 2018;21(2): 131-9
[6] Paris & Belloni. 2013. https://www.oecd.org/en/publications/value-in-pharmaceutical-pricing_5k43jc9v6knx-en.html

ASCERTAIN

Preliminary results based on draft model – results are subject to change

Active substance	Onasemnogene abeparvovec	Nusinersen	Nivolumab	Trifluridine / tipiracil
Brand name	Zolgensma	Spinraza	Opdivo	Lonsurf
Indication	SMA type 1	SMA 5Q	Melanoma	Metastatic gastric cancer
Prevalence or yearly incidence	4,787 patients (Thielen 2022)	1.22 / 100,000	254.9 / 100,000 / year	22.2 / 100,000 / year
Number of patients in EEA	2,421	2,710	2,851,471	248,343
Type of product	ATMP	Chemical specialty (standard cost)	Biological (standard cost)	Chemical specialty (standard cost)
Posology	Single administration	1 vial x 12 mg per 4 months (+1 vial in y1)	2 vials x 240 mg per 4 weeks	4 tablets x 20/8.19 mg per day
Treatment duration	once	120 months	24 months	2 months
R&D costs (incl. CoC) per patient	233,358 €	208,492 €	198 €	2,275 €
Value reward	134,181 €	119,883 €	114 €	1,308 €
COGS	36,000 €	22,715 €	1,545 €	485 €
SGA	29,790 €	18,641 €	1,278 €	402 €
Operational profit	19,342 €	12,103 €	830 €	261 €
ABP per treatment	**452,671 €**	**381,834 €**	**3,965 €**	**4,731 €**
Net price Germany 2021	1,945,000 €	2,566,099 €	131,599 €	5,850 €
Net price Belgium 2020	1,143,855 €	1,665,617 €	93,568 €	7,191 €
Average difference ABP to net prices	***-71%***	***-82%***	***-96%***	***-27%***

Preliminary results from empirical evaluation with 4 products (*study in progress with larger sample*)

- ABP < current net prices in Belgium and Germany for all products

Sources for net prices in Germany and Belgium:
[1] Hendrickx et al. 2023. https://www.aim-mutual.org/wp-content/uploads/2023/11/Solidaris-Impact-Fair-price-in-Belgium-01-2023-def.pdf
[2] Muth et al. 2021. https://www.aim-mutual.org/wp-content/uploads/2021/10/TK_AIM-Fair-Pricing-Calculator-EN_Rev.pdf

ASCERTAIN

WP4 (pricing models) core team

ASCERTAIN

Maximilian Salcher-Konrad

Gesundheit Österreich

Email: maximilian.salcher@goeg.at

Anne Hendrickx

AIM

Email: anne.hendrickx@solidaris.be

Nicolas Xander

Erasmus University Rotterdam

Email: xander@eshpm.eur.nl

Please get in touch with us if you have any questions or comments!

More on ASCERTAIN on https://www.access2meds.eu/