

Introducing an Access-Based Pricing Model to Inform Negotiations and Decision-Making for Newly Authorised Medicinal Products

Nicolas Xander^{†,*}, Maximilian Salcher-Konrad[†], Anne Hendrickx[†], Frederick W. Thielen, Carin A. Uyl-de Groot
[†] All authors contributed equally to this research
^{*} Presenting author

Background

High prices of newly authorised medicinal products (MPs) contribute to affordability issues and access inequalities across countries. Increased uncertainty about MP effectiveness and unclear perspectives on how to address these in healthcare decision-making without overstraining healthcare budgets exacerbate these issues.

Aim

Development of an "access-based" pricing model for on-patent MPs:

- Reflecting and reconciling stakeholder views and priorities
- Incentivising innovation in balance with affordable patient access
- To inform price negotiations and healthcare decision-making, facilitating practical application by stakeholder groups involved in pricing

Methods

Step 1: Longlist of viable cost- and value-based price determinants based on scoping literature review and stakeholder preference elicitation



Step 2: Refinement and operationalisation of included price determinants through targeted literature reviews, expert interviews, stakeholder survey

Results I: Access-Based Price Definition

Costs
 Research & Development
 Making a new MP available

Value
 Reward of innovation
 Meaningful benefit to patients and health systems

Reconciliation of stakeholder interests with improving patient access as common goal

A price that ensures the development of and patient access to new and beneficial MPs, and incentivises further innovation

Results II: Model Operationalisation

Input: Price determinants attributed to four core components

- Research & Development (R&D) cost: Cost of developing a new product
- Operational cost: Cost of production and making product available
- Operational profit: (minimum) profit over operational cost
- Value-based reward: different value-related aspects to be reflected and rewarded by the user in the price

Output: Access-based price per patient, intended as additional reference point for price negotiations and decision-making procedures

Model utilisation:

- Compulsory and optional price determinants: allowing model adjustments according to user's context, needs, and preferences
- Default values/ranges to ensure operability; option to apply user-specified values to all price determinants
- Price per indication: Price must be re-calculated for new indications
- European price: Patient population in European Economic Area (EEA) as basis; adjustment for each country requires additional step

$$ABP = \frac{\beta_{RD} \times (1 + \beta_{CoC})}{n_{pat}} \times \left(1 + (\gamma_{ATB} * (1 - \gamma_{QoE} + \gamma_{UMN}) + \gamma_{soc} - \beta_{RoPI}) \right) + (\beta_{COGS} + \beta_{SGA}) \times (1 + \beta_{prof})$$

β_{RD} : out-of-pocket R&D cost (compulsory) including cost of failure; default: ~€889.5m¹
 β_{CoC} : annual cost of capital rate (optional) accounts for required return on investment; default: 10.5% p.a.^{1,2}
 EEA share of global (capitalised) costs: 33.78% based on GDP data for EEA + G7 states.

n_{pat} : patient population in the EEA expected to be treated within 10-year model time horizon (compulsory). Estimate based on:

- EEA population
- Prevalence, incidence, or prevalence/incidence mix
- treatment rate
- market share frontier (first-in-indication: 100%)
- on-patent competitors entering market; assumed to enter market after years 4 and 6³
- uptake based on relative utilisation index⁴; 100% utilisation assumed from year 8 on.

γ_{ATB} : premium for added therapeutic benefit (ATB; compulsory); four tiers (none, minor, moderate, major).⁵
 γ_{QoE} : ATB premium adjustment for low quality of evidence/structural uncertainty (optional).
 γ_{UMN} : premium for fulfilment of high unmet medical need (optional, linked to γ_{ATB}).
 γ_{soc} : premium for positive societal value (optional).
 β_{RoPI} : Reduction of (capitalised) R&D cost based on substantial public contribution to R&D (optional); reflected as reward reduction.

β_{COGS} : cost of goods sold (COGS; compulsory); informed by compound and container characteristics, dosage, use as oncologic treatment.
 β_{SGA} : sales, general, and administrative costs (as a percentage of COGS; compulsory); default: 82.75% of COGS.⁶

β_{prof} : operational profit margin, EBITDA-based (compulsory); default: 29.4%.⁷

Results III: Example

Hypothetical new treatment

- chemical, administered as tablet
- small indication: incidence 7/100,000
- first-in-indication treatment
- treatment duration: one year
- all optional parameters applied
- default values applied to all parameters

Estimated product price per patient:

Capitalised R&D costs: €7,215
 Value-based reward: €4,148
 Operational costs: €503
 Operational profit: €145
Total price (full treatment): €12,011
Total price (month): €1,001

Conclusions

This pricing model may provide valuable input to negotiators and decision-makers for determining MP prices contributing to improved patient access.

Further research:

- Comparison with known prices of reimbursed MPs
- Testing access-based prices on cost-effectiveness
- Model refinement through validation by stakeholders

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