





Price Determinants and Pricing Policies Concerning Potentially Innovative Health Technologies: A Scoping Review

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Background

Healthcare decision-makers are facing the challenge of finding a balance between supporting innovation, ensuring equitable access to beneficial pIHTs, and financial sustainability of health. Pricing of pIHTs can be based on different policy interventions and implementation methods. Depending on the applied intervention, the price of pIHTs can be based on different technology-related determinants.

So far, no comprehensive review concerned stakeholder views on pIHT price determinants, nor pIHT-focused pricing policies and their impact on patient access and financial sustainability.

Aim

Mapping of existing evidence & identification of knowledge gaps:

- pIHT price determinants based on stakeholder views
- pIHT pricing policies applied in EEA and/or OECD member states
- Effect of pricing policies on patient access and sustainability

134 records included (103 scientific, 31 grey literature records)

Pricing policies applied in EEA/OECD countries: 124 records

• Pricing pharmaceuticals vs. medical devices: 132 vs. 2 records

Databases (n = 469)

CORDIS (n = 51)

Search (n = 94)

AIM (n = 46)

BEUC (n = 52)

EFPIA (n = 13)

Health Action

International (n = 41)

<u>(n = 723)</u>

Google Advanced

<u>Organisation websites</u>

Records

removed *before*

Duplicates

<2014 (n = 69)

(n = 204)

• Stakeholder views on price determinants: 15 records

Records removed

before screening:

(n = 2,546)

Records excluded

Exclusion by humans:

insufficient evidence

(n = 4,377)

(Dis-)advantages of pricing policies

dentification of scientific publications via databases

Web of Science Core

Google Scholar

Records screened

Eligible records

before snowballing

Studies included in review after snowballing (n = 134)

(n = 116)

(n = 150)

(n = 4,777)

Methods

Scoping review of scientific and grey literature in English published between January 2014 and September 2023

Strategy

Scientific publications: MedLine, Embase, Web of Science, Google Scholar Grey literature: BASE, stakeholder organisation websites, Google Advanced Search

Selection, Data Extraction & Synthesis

Title-abstract screening (n = 4,777)

- Use of ASReview 1.2.1; stopping rule: 100 irrelevant articles in a row Full-text review (n = 399)
- Eligibility assessment based on 13 exclusion criteria, e.g.:
 - involvement of stakeholder views
- pricing policies applied in EEA/OECD member state concerning new pIHTs

Snowballing and manual addition (n = 23)

Extraction of data relevant to review questions

Results

Price determinants (stakeholder views)

Value-based: added therapeutic value, uncertainty, unmet need, innovation, delivery efficiency Cost-based: R&D including R&D failures, public funding, M&A; production, overhead; profit margin Reference-based: prices of treatments of similar value; restricted EPR application Other: Target population, treatment rate, current/future R&D investments, competition

Pricing policy interventions

Reference-based: EPR as primary or supporting pricing tool (DK, US)

Cost-based: limited to specific drugs Value-informed: clinical value assessment or economic evaluation to inform price setting Free pricing: primary or partial component; restrictions: time/cost-effectiveness Other: Tendering; 340B Pricing Program (US; ceiling price for outpatient drugs); PMP (JP)

Medical devices: Cost-based; clinical / economic evaluation (KR)

Price implementation methods

Price negotiations: often informed by value assessment and/or reference price Multi-indication pricing: single price, weighted average price, cost-effective price at all indications, price differentials Orphan drug pricing: general policy/free pricing;

facilitating faster market entry (FR, KR) Price transparency: net prices mostly confidential, ex-factory list prices often disclosed, wholesale/retail prices in some countries

ICER (n = 27)Exclusion by AI (stopping ISPOR (n = 165)rule): n = 2,636NICE (n = 68)OECD (n = 137)Records sought PhRMA (n = 152)Irretrievable WHO (n = 22)records (n = 1)(n = 400)<u>Records excluded (n = 283)</u>: not in English (n = 31)Records assessed comments/replies to previous publications (n = 27) (n = 399)opinion papers (n = 22) not concerning EEA/OECD countries methods/policies (n = 91) not concerning pIHTs (n = 23) concerning generics/biosimilars (n = 1)

Figure 1: PRISMA flow diagram

Impacts and (dis-)advantages

Free pricing: affordability issues vs. early availability

Reference-based: Short-term improvements vs. price inequities, launch strategies; resourceintensive, benchmark for domestic price setting Cost-based: may increase affordability; potential arbitrary price calculation

Value-informed: improved affordability, better budget allocation vs. difficult implementation Other: improved access (340B Pricing Program); innovation promotion questioned (PMP)

Impacts and (dis-)advantages

Price negotiations: improved affordability without availability delay

Multi-indication pricing: potential expenditure decrease; complex implementation, costly administration of suitable data systems Price transparency: lower prices & spending, realistic price referencing; evidence inconclusive

Abbreviations: DK, Denmark; EPR, External price referencing; FR, France; JP, Japan; KR, South Korea; M&A, mergers and acquisitions; PMP, Price Maintenance Premium; R&D, research and development; US, United States.

Conclusions

Additional records included (n = 23):

Snowballing (n = 19)

Manually added (n = 4)

- In many EEA/OECD member states, a mix of pricing policy interventions and price implementation methods is applied.
- Policy interventions of different types are often used to inform price negotiations.
- EPR is linked to access-related shortcomings; value-informed pricing is viewed more favourably by the literature.

Identified research gaps:

- Elicited stakeholder views on price determinants
- Environmental aspects considered in pricing
- Pricing of medical devices





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References

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