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Innovative policies to achieve sustainable drug prices – a literature review

The objective of this study was to facilitate an evidence-based discourse on innovative policy options to reduce drug prices at market launch. We reviewed the literature to make an inventory of options, analyzed the underlying evidence, and selected promising policies.

Background: Access to medicines is essential to secure people's right to health. High expenditure on novel anticancer drugs threatens this right and, considering finite resources, the financial sustainability of care. Innovative solutions are needed and highly discussed.

Methodology: We performed a systematic scoping review to identify policy options to reduce drug prices at market launch that are relevant to oncology and high-income countries. We inventoried policy options, categorized publications based on evidence, and analyzed quantitative articles. To select promising options, we identified main price mechanisms, rated policies based on their system disruption and potential price impact. Finally, we asked European experts in the field of oncology and health regulation to rate proposals and challenge our selection of promising policies.
Region covered: We screened globally and selected for the EURO region. *Time period*: 2001-2019

Results: We screened 4775 articles and selected 80 articles that we used to produce an inventory of policy options in the intellectual property, pricing, and the research & development environment. 22 articles used a quantitative approach but, overall, there was low available evidence. We identified promising options of which experts prioritized transparency and combined purchasing. Two-part-pricing and de-linkage were the most controversial policies.

Conclusions and lessons learned: Although it is important to reform pharmaceutical regulation to secure access to medicines, a coordinated approach to structurally evaluate proposals is lacking. Quantitative methods are rarely used, and current evidence is insufficient to structurally evaluate proposals. We advise testing proposals with small-scale experiments, dynamic simulations, and pilots.

Classification of included articles according to their evidence

Evidence		Study type	IP	Pricing	R&D	Mix	Total
Quantitative	**Empirical**	Policy evaluation	1	1			**2**
		Market dynamics evaluation		4	3		**7**
	Mathematical	Dynamic, numerical	2				**2**
		Static, numerical	5		1		**6**
		Static, abstract		6			**6**
	Subtotal		**8**	**11**	**4**	**0**	**23**
Qualitative	**Conceptual**	Framework to score policy options	1	1		1	**3**
		Systematic review				3	**3**
		Theoretical model	10	4	4		**18**
	Opinion	Perspective	11	9	7	6	**33**
	Grand total		**30**	**25**	**15**	**10**	**80**

Inventory of policy options

= no = weak = medium = strong

	Price mechanism	Evidence	System Disruption
Intellectual property	Increase competition		Low
	Earlier generic entry		Low
			Low
			Medium
			Medium
	Increase competition *de-linkage*		High
			High
			High
	Control prices		Medium

	Price mechanism	Evidence	System Disruption
Pricing	Reduce prices for subsets of population or drugs		Low
			Low
			Medium
	Control prices		Medium
			Medium
	Increase information to improve competition		Medium

	Price mechanism	Evidence	System Disruption
R&D	Reduce R&D costs		Medium
			Medium
			High
	Increase competition		Medium
			High
			High
	Recoup investments		Medium
	Reduce granted benefits		High

Promising policies to reduce drug prices are: transparency, de-linkage, two-part-pricing, public research, orphan drug reform, and public clinical trials.

There is **limited quantitative evidence** available.

We advise **structurally testing policy options** with pilots and simulation models.

Transparency: Public knowledge of drug prices, R&D costs, and /or clinical trial results.

Two-part-pricing: A subscription payment method that consists of an entry fee (to access the product) and a small usage fee (per unit sold).

Orphan drug reform: Stricter orphan drug regulation to account for often high profitability and for decreasing population sizes with targeted therapies.

De-linkage: Decoupling the innovation and the production process. Replacing patents with alternative tools to incentivize innovation.

Public research: Extending the role of publicly funded research beyond basic research to launch drugs at sustainable prices.

Public clinical trials: Installing a public agency to conduct clinical trials and, thus, reduce waste, increase information, and lower the financial barrier of clinical trials.

What is the effect of lower prices on profitability, private investments, and on the innovation pipeline of novel drugs?

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