Policy options to deal with high-cost medicines – Survey with European policy-makers

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Objective

To survey whether and which **pricing and reimbursement policy options** European countries have been implemented for **new premium-priced medicines**.

Methodology:

- **Cross-country survey** with **policy-makers responsible for pharmaceutical pricing and reimbursement** in 42 countries (all EU Member States, 9 further European countries and 5 non-European countries) for pricing and reimbursement policies in **out-patient and in-patient sectors**.
- **Responses** were received from **27 European countries** and **Canada,** data as of February – March 2014

Scope: 'New / Innovative' medicines
Common definition is lacking.
From a public health perspective, the level of **innovativeness of a medicine** is primarily defined by the **benefits the medicine generates for patients**. These benefits can be in the therapeutic or clinical domain, the quality of life domain, but also in the socio-economic domain. Examples of benefits in the socio-economic domain include a medicine that would prevent (expensive) hospital admissions or that would enable patients to work.
(Source: Vienna WHO CC Glossary)

Scope: high-priced medicines
No clear international definition.
The **high price itself might not be the decisive criterion**, but also **the use / demand** for the product resulting in high costs for the treatment of the patient.
A broad definition of a new premium-priced medicine in this research context is one whose acquisition cost is greater than 10,000 Euro per patient for a yearly therapy for the public payer and which is replacing an existing medicine (whose costs public payers were already paying).

Results

Country specific definition on high-priced medicines?	
No	**21 countries**: BE, DK, CA, CH, ES, EE, EL, FI, HR, HU, LV, LU, MT, NL, NO, PL, RS, SI, SE, SK, UK
Development	**AT:** a definition on high-cost and specialized medicines was developed at time of the survey
Country-specific definition	**AL, CZ, FR, IS, IT**

Pricing and reimbursement in the out-patient sector	Pricing and reimbursement in the in-patient sector
Overall, the rules for pricing and reimbursement of new premium-priced medicines **do not differ** from the ones for the other medicines	In principle, **no specific P + R procedures** for premium-based medicines in many countries, but specific funding models, processes, schemes: e.g. DK, NO
Increased **use of HTA** and **pharmacoeconomic evaluations**	**Funding outside the DRG system:** individual product reimbursement (AT, BE, EE, FI, FR)
Frequent use of price-volume agreements, managed-entry agreements, risk-sharing schemes and **similar** was reported from some countries (e.g. ES, FR, PL, HU; SK – 'conditional categorization')	**Special agreements between hospitals and social health insurance**: costs for medicines used in hospitals are (partly) funded by social health insurance (FR, EL, NL – new arrangement since 2013, SI; NO – TNF and MS medicines & (since 2014) some oncology medicines are funded by hospitals
	Special programs: LV, PL
	Special funds: Cancer Drug Fund (UK)

Horizon scanning was reported only from few countries (Canada, Italy, UK).

Reported challenges
- **Concerns about access and sustainability**, in the light of balancing the need to provide access to new high-cost medicines with given budgetary restraints,
- **Question about value-for-money** of the new medicines, **with limited data and evidence** available about the added value,
- **Issue on pricing**, on how to be able to reduce the price of these medicines, particularly given the frequent use of the external price referencing policy, and
- **Concerns about limited coordination between sectors** (out-patient / in-patient sector and different payers/jurisdictions)
- **New biological medicines**

Discussion and conclusion

Though European governments were concerned with the cost issue due to new medicines, **specific pricing and reimbursement policies have yet to be thought through in a systematic manner.** Prioritization processes will increasingly be required for the introduction of new medicines. **Lessons learned: Prioritization should incorporate the principles of collaboration and transparency**: Cooperation between countries in Europe and stakeholder dialogues could be further strengthened. This needs to involve better balancing of the value of innovation with equitable, affordable patient access.

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