



EMERGING APPROACHES

Valérie Paris, OECD
The 2nd Global Forum on Fair Pricing
Johannesburg, 11-13 April 2019



Challenges for policy makers

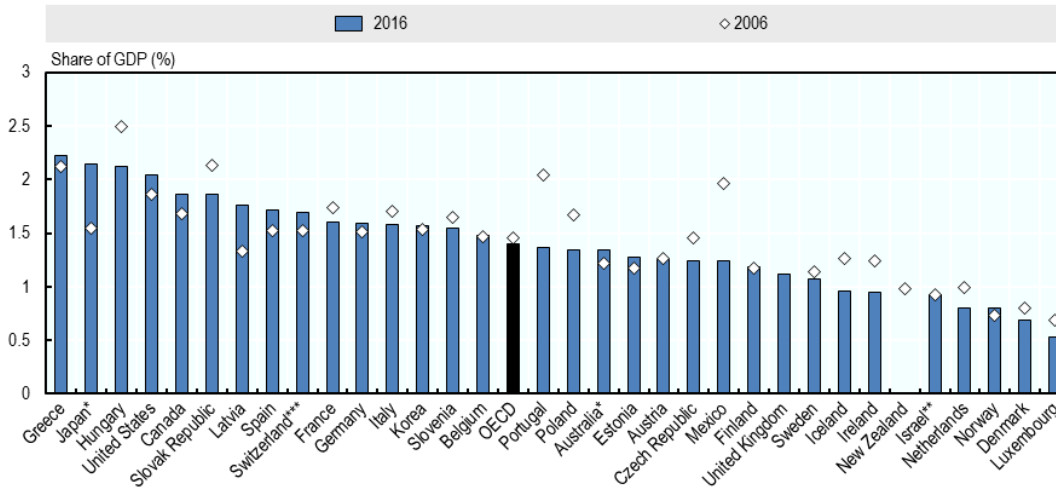


- **Launch prices increasing in some therapeutic areas (oncology, rare diseases)**
- ***Not always associated great health improvements***
- **Increases in list prices** of existing on-patent medicines (U.S.)
- **Sharp price increases for some off-patent products**
- Some unmet medical needs **are not adequately addressed** by current investments in R&D
- **Uncertainties on clinical benefits of medicines with early approval**

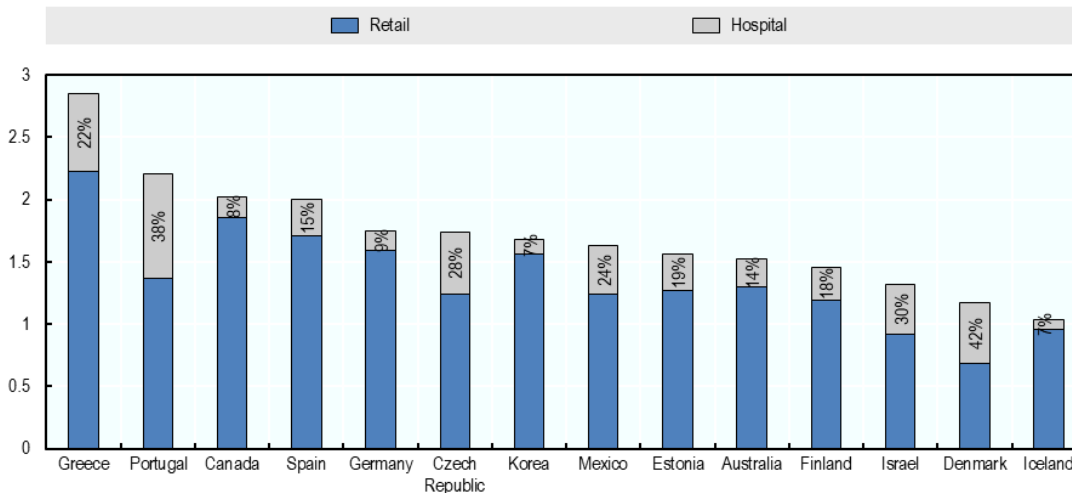


Do these prices threaten sustainability of health spending?

Retail pharmaceutical expenditure, as share of GDP, 2006-2016



Total pharmaceutical expenditure, as share of GDP



- Retail pharmaceutical expenditure has been stable, as a share of GDP, between 2006 and 2016
- But “retail expenditure” is only a part of the story and we miss standardized information on hospital spending
- Oncology big driver of expenditure growth (10-15% of pharma spending in 2015 in G7)
- Expenditures on orphan medicines increasing rapidly



Options for coping with high price/budget impact

1. Shift the costs to consumers and patients (increase in premiums and cost-sharing)
2. Delay, deny or restrict coverage
⇒ **Generating access problems**
3. Displace spending from other medicines or other parts of the system
⇒ **Potentially reducing “value of health expenditure”**
4. Accept increases in pharmaceutical/health expenditures
⇒ **Crowding out other public expenditures**



Strategies to cope with high prices rather than disruptive options

- 1 Horizon scanning, spending projections, strategies to manage budget constraints
- 2 Setting rules, defining willingness to pay
- 3 Addressing uncertainties and associated risks
- 4 Promote healthy off-patent markets



Horizon scanning, spending projections

OECD 2018 Survey on Pharmaceutical Expenditure and Budgeting

- 23 respondents (of 40 OECD/EU)
- Only 6 currently perform formal horizon scanning, but cooperation projects to start
- Most countries develop projections for pharmaceutical expenditures, 6 make these projections public

	Embedded in overall spending projections	Stand-alone exercise
Covering pharmaceutical spending as a whole	Estonia , France, Ireland, Japan, Latvia, Norway	Austria, Malta, Netherlands , Portugal, Sweden
Projections developed separately for sub-categories	Belgium, Luxembourg	Australia , Cyprus, Czech Republic, Lithuania

Note: Countries in bold publish their projections

Source: 2018 OECD Survey on Pharmaceutical Expenditure and Budgeting

Source: OECD report to be published – Provisional results, not definitive



Manage budget constraints

OECD 2018 Survey on Pharmaceutical Expenditure and Budgeting

- 23 respondents (of 40 OECD/EU)
- 14 have pharma budget, 10 set pharma spending caps → they need strategies to remain within limits

Table 1.2. OECD and EU countries with a budget and/or a cap on pharmaceutical spending according to the 2018 Survey

Responding countries reporting setting a budget or a cap for public pharmaceutical expenditures

	Cap	No Cap
Budget	Belgium, Cyprus, Estonia, Ireland, Italy, Latvia, Malta, Poland	Australia, Lithuania, Netherlands, New Zealand, Norway (outpatient), Sweden
No budget	Czech Republic, France	Austria, Finland, Korea, Japan, Luxembourg, Portugal, Switzerland,

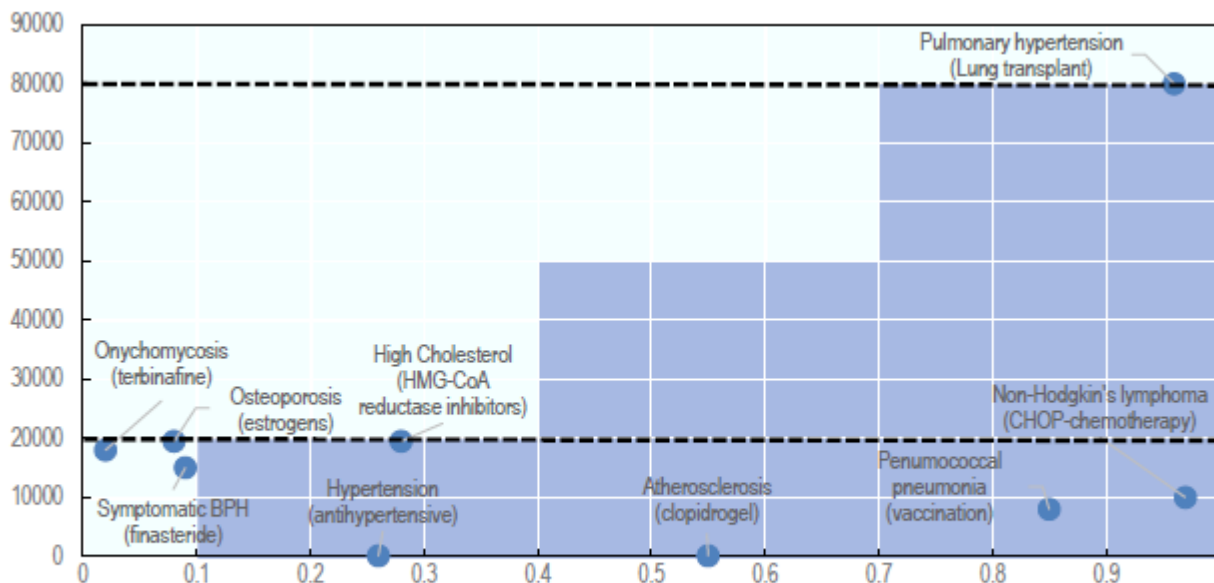
Note: The table only reflects information on “macro-economic caps” on pharmaceutical expenditure. Countries may have caps on specific products or classes of products even when they have no macro-economic cap.

Source: 2018 OECD Survey on Pharmaceutical Expenditure and Budgeting



Defining consensual, explicit and firm criteria for coverage and pricing

- Establish fair and transparent decision-making process
- WTP may differ across therapeutic areas and across countries - should ideally include consideration of value and budget impact.
- Would help decision-makers resist to pressure from lobby groups
- Would be more predictable for industry.



Differential cost-effectiveness thresholds according to disease severity

Note: X-axis represents the burden of disease expressed as "proportional shortfalls".

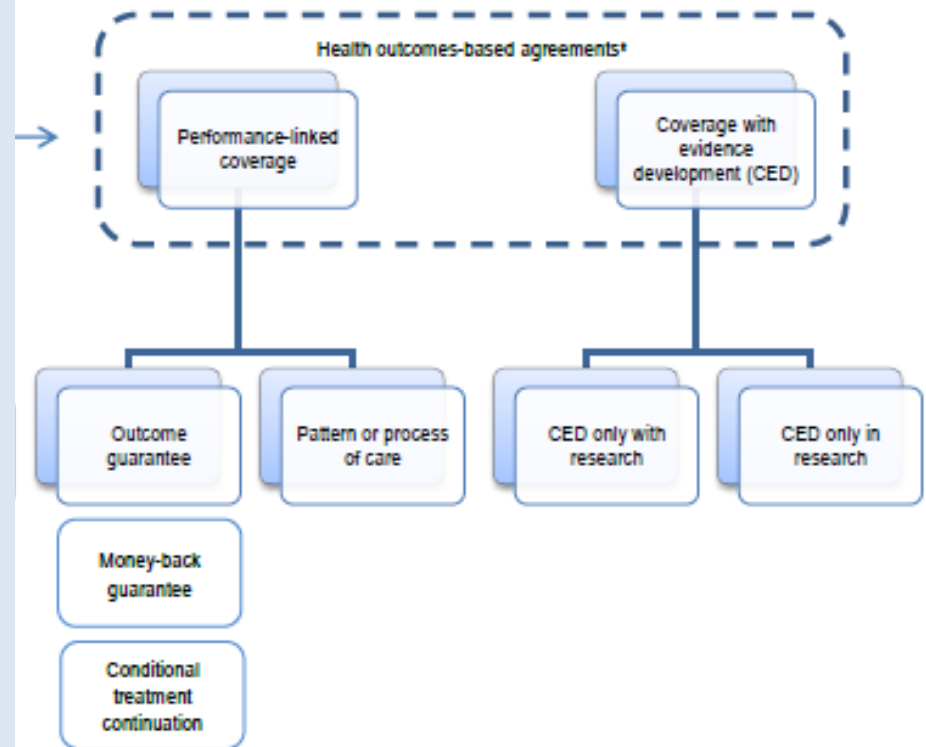
Source: Adapted from Stolk et al., 2004) and Zwaap et al. (2015).



Addressing uncertainties on clinical benefits

Optimising the use of performance-based agreements

- Limit to products with high uncertainty on clinical benefits or cost-effectiveness;
- Harmonise outcomes definition and measurement
- Make sure new knowledge is shared beyond parties to the agreement
- Better design agreements to create incentives for manufacturers to generate new knowledge





Off-patent markets – Prevent rather than cure (1)

- **Beyond highly mediatised cases** (e.g. United States EpiPen +500% in 10 years, Daraprim +5000% overnight)
- **Worrying trends :**
 - In some markets, many off-patent molecules with single providers in *de facto* monopoly position (40% in US market)
 - Impact on generic price trends observed in several countries (Canada, United Kingdom)
- **Competition authorities can and do act and impose fines (Italy, UK, Austria), but:**
 - Cases are complex and costly,
 - All damages cannot be compensated (patients harmed by lack of access)



Off-patent markets – Prevent rather than cure (2)

- **Facilitate market entry of generic products after loss of market exclusivity (LoE) of originators:**
 - Allowing generics manufacturers to complete regulatory requirements prior to LoE
 - Readily accessible and easily searchable databases to compile patents and exclusivity status of originator medicines
 - Identify areas where generic competition is limited or lacking, to prioritise generic approval in these areas.
- **Encourage price competition**
 - Encourage competitive mechanisms in drug procurement, such as tendering or negotiations, avoiding single-supplier contracts and with appropriate safeguards to secure supply and preserve long term competition
 - When competition for market shares takes the form of discounting in the supply chain, impose price disclosure (e.g. Australia) to make sure discounts are finally passed on to public payers or consumers.
- **Competition authorities could play a greater role in regularly assessing off-patent markets**



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