



PHARMACEUTICAL INNOVATION AND ACCESS TO MEDICINES

Valérie Paris, OECD
STAMP Meeting, 15 March 2019



Objectives of the report

- Highlight **main challenges governments are facing** in ensuring appropriate access to innovative medicines to all those in need.
- **Propose policy options**, while stressing for each of them the expected benefits and potential costs, drawing from available evidence.





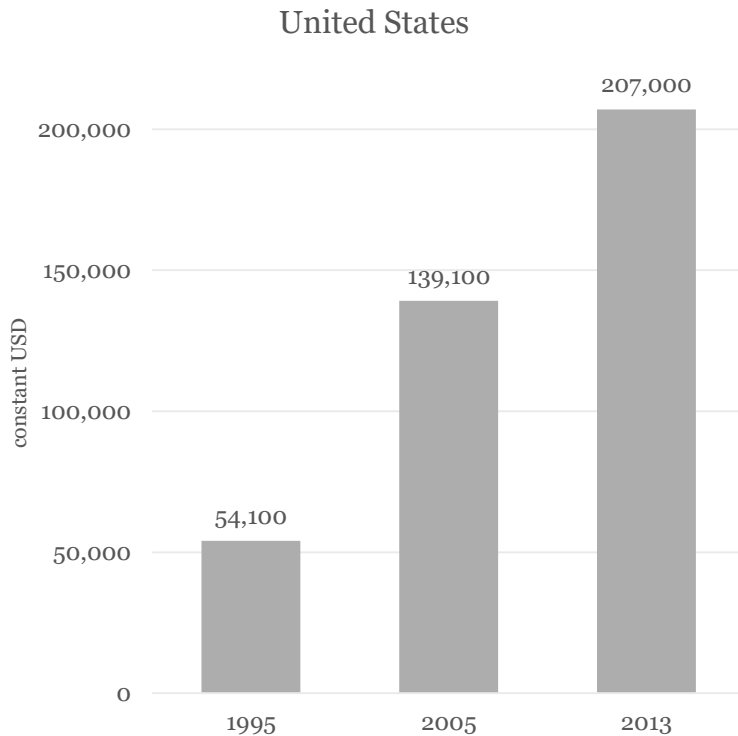
Challenges for policy makers:

- **Launch prices in some disease areas are increasing at a pace that does *not always* coincide with improvements in benefits** (oncology, orphan drugs)
- This raises **access problems** in some countries
- Payers struggle to provide access to breakthrough medicines because of **unaffordable budget impact**
- **Increases in list prices** of existing on-patent medicines (U.S.)
- **Sharp price increases** are observed for off-patent products in *de facto* monopoly position in several countries
- Some unmet medical needs **are not adequately addressed** by current investments in R&D

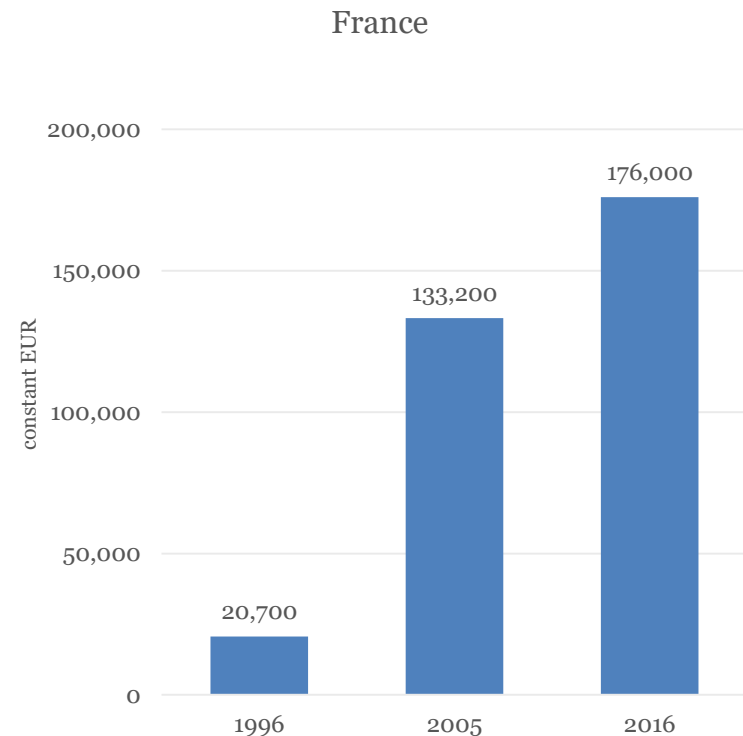


High prices are not always associated with high clinical benefits

Average list prices of cancer medicines per life-year gained, inflation-adjusted at product launch



Source: Howard D.H. et al 2015 Pricing in the Market for Anticancer Drugs. *Journal of Economic Perspectives* 29 (1): 139-62.

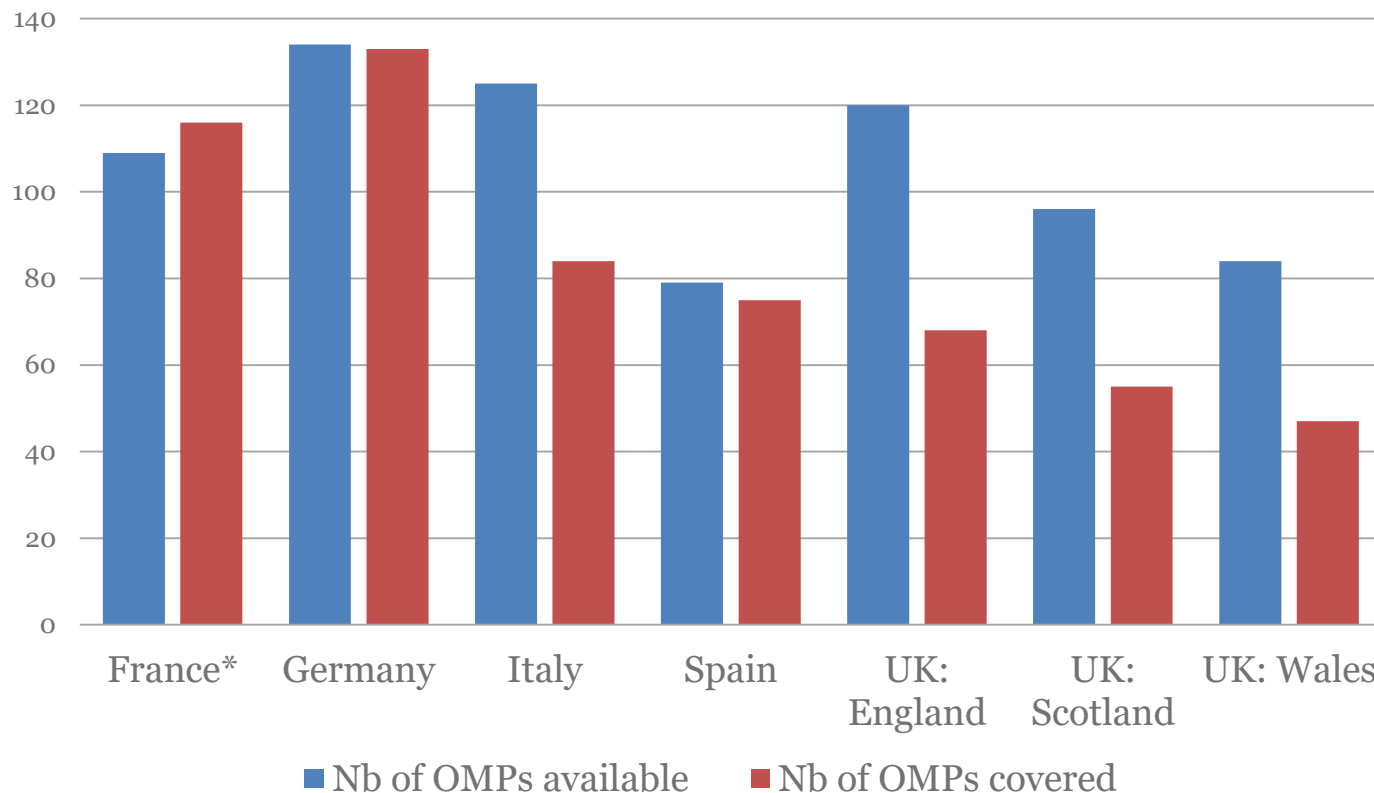


Source: CNAMTS 2017. Propositions pour l'Assurance Maladie pour 2018. Paris.



Medicines are not always affordable to patients

Availability and coverage of 143 orphan medical products (OMPs) approved centrally by the EMA in five EU countries between 2000 and May 2016

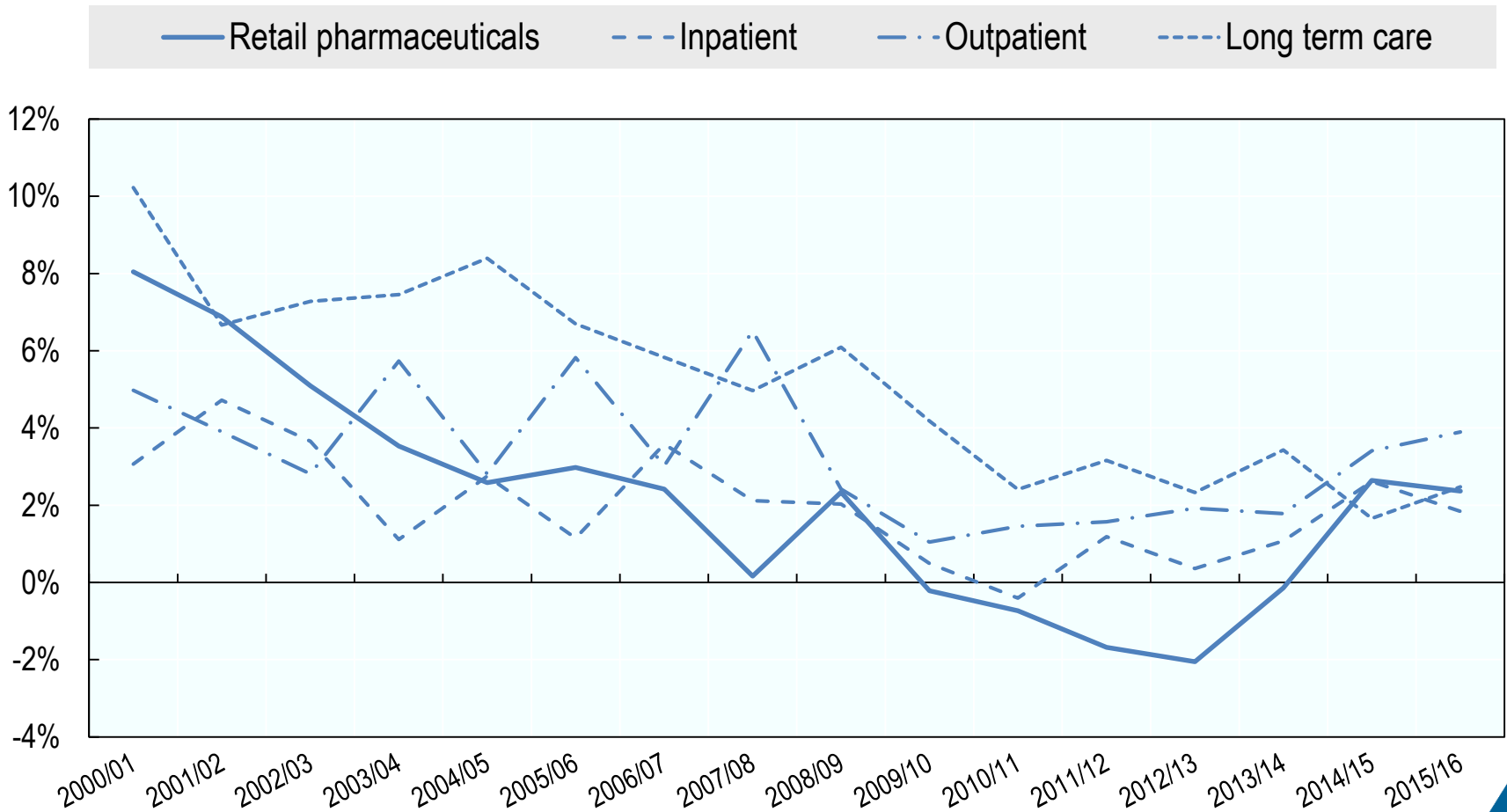


* In France, innovative medicines responding to high unmet needs may be available to patients before marketing authorisation through “temporary authorisation for use”, fully covered by health insurance. Source: Zamora et al., 2017



Do these prices threaten sustainability of health spending?

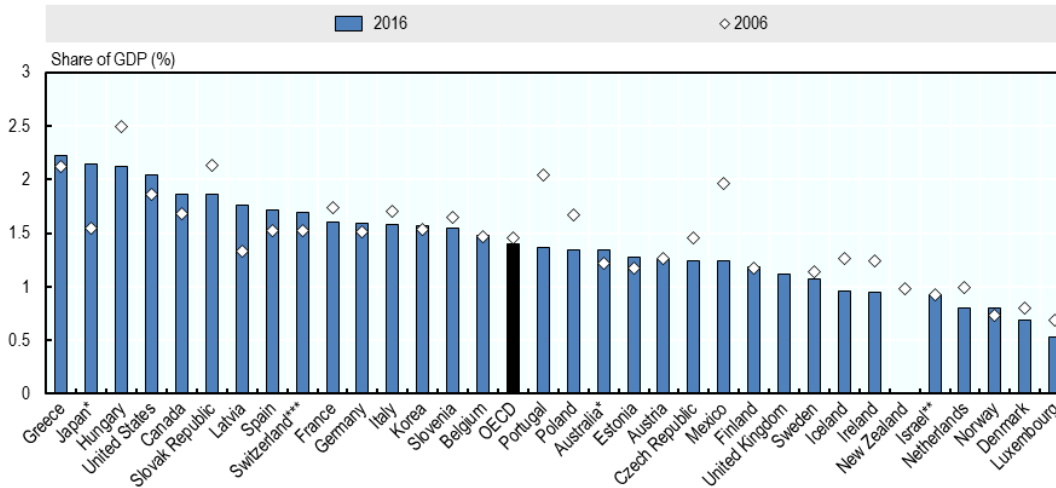
Annual growth of selected health care services, OECD average, 2000-2016



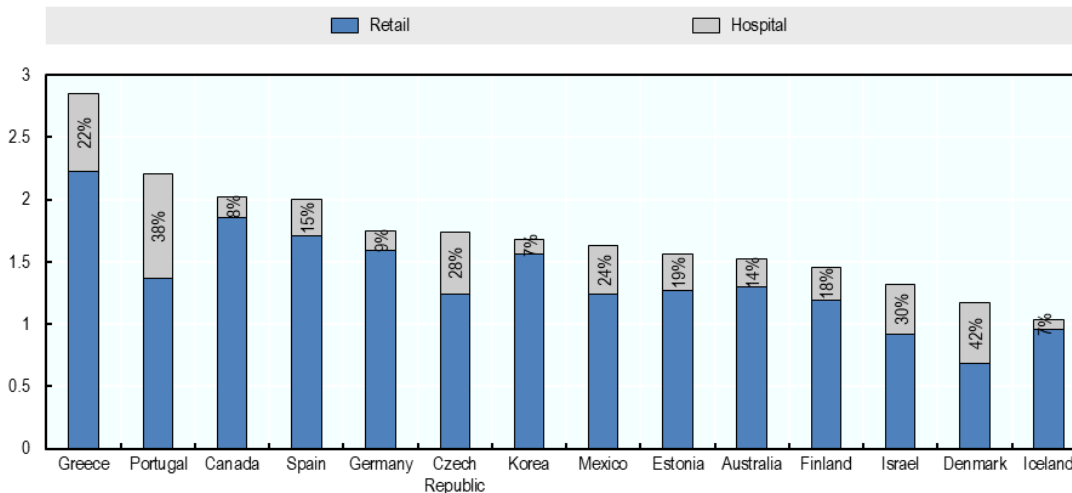


Do these prices threaten sustainability of health spending?

Retail pharmaceutical expenditure, as share of GDP



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

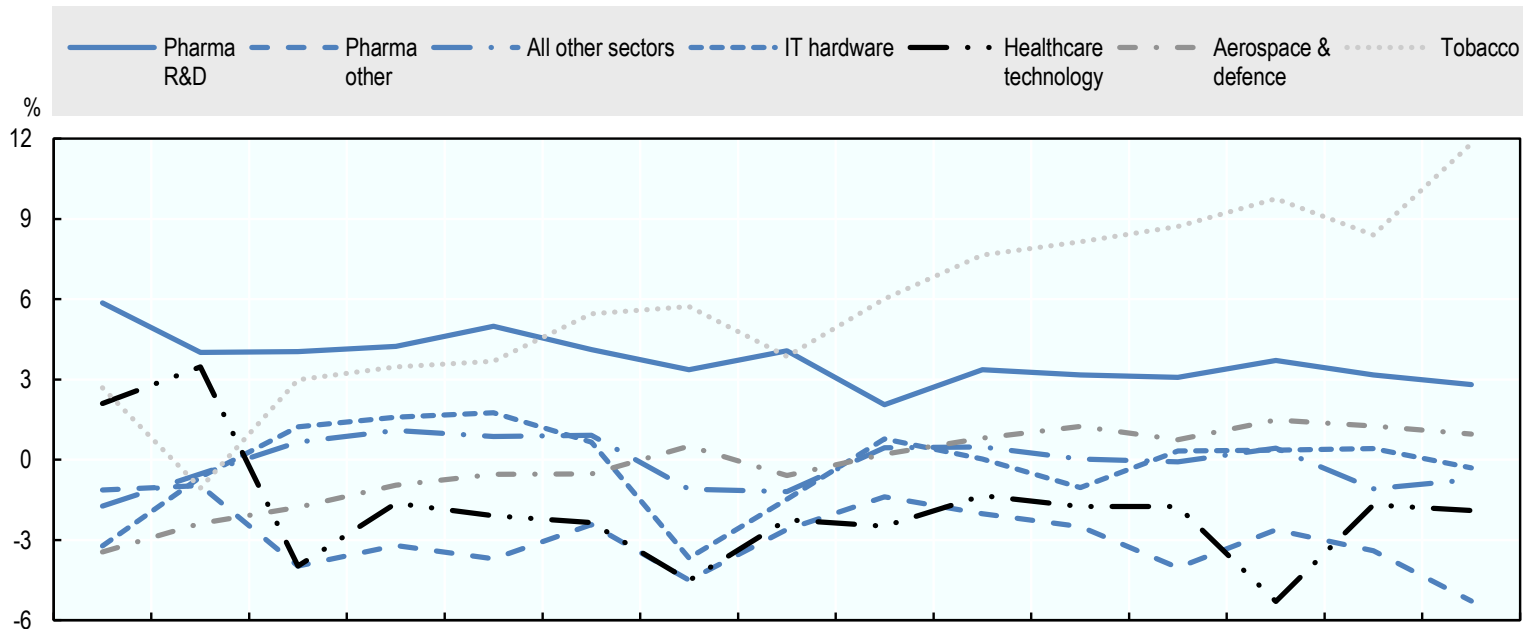
Source: OECD 2018 Pharmaceutical Innovation and Access to Medicines



R&D is risky, costly, mainly supported by private investors, profitability is high

- Development of medicines is risky and costly: the probability of marketing authorisation of a medicine entering Phase 1 trials is estimated to be 14%
- However, risk-adjusted profitability in the industry overall is relatively high and stable
 - Economic profits of 2% to 6% in the R&D-based industry between 2002 and 2016
 - R&D-based industry more profitable than many other sectors

Return on assets less cost of capital in the R&D-based pharmaceutical and other selected industries, 2002 - 2016





Guiding principles to develop policy options to respond to challenges

- Overall objective: **increase value** (efficiency) of spending on pharmaceuticals
- **Maintain differential** (or tiered) pricing.
- Implement a **rule-based, predictable, system**.
- **Foster competition** throughout the pharmaceutical system in order to improve the value of pharmaceutical spending
- **Increase transparency** to restore trust in the system.



Policy options to respond to current challenges

Restore trust and dialogue between industry and other stakeholders



Reduce the costs of R&D and accelerate market access



Improve efficiency of pharma spending and determine WTP



Develop new types of push and pull incentives





Restoring trust and dialogue between industry and other stakeholders

- **Publishing authoritative information on industry activities and the risks, costs and returns from R&D.** Develop a relevant set of indicators and collect data on a regular basis.
- **Increasing price transparency in pharmaceutical markets.** The growing disconnect between list prices and transaction prices has a number of drawbacks. Full transparency might be difficult to reconcile with tiered pricing (and parallel trade) but some improvement is needed.
- **Improving horizon scanning activities and encouraging co-operation at regional level.**



Reducing R&D costs, accelerate access

- **Harmonising regulatory requirements, encourage mutual recognition.** Potential to reduce costs of clinical trials but requires agreement among agencies on outcome measurement.
- **Accelerating market access for medicines with significant potential benefit.** Continue current efforts; Ensure compliance of companies with post-marketing evidence requirements and appropriate patient information.



Increasing pharma spending efficiency

- **Facilitating cooperation in health technology assessment (HTA).** Potential to avoid duplication, reduce costs and share capacities; Better fit at regional level, among countries with similar standards of care; Can only address clinical aspects not economic impact.
- **Encouraging cooperation in price negotiations, contracting or procurement.** Already happening. Potential to benefiting both countries (increased negotiating power) and companies (reduced transactions costs). Envisaged for countries of similar income levels.
- **Assessing the performance of medicines in routine clinical practice and adjust coverage conditions and prices.** Increase knowledge about performance of treatments, revise practice guidelines or coverage and pricing conditions. Raises methodological issues. Becoming more common and is expected to develop in pharmaceutical care.



Increasing pharma spending efficiency

- **Promoting competition in on-patent markets, notably through tendering by indication.** Tenders not conceived as “the winner takes all” to allow therapeutic choice and keep several suppliers. Companies bids determine which medicine is recommended as the preferred first-line treatment.
- **Promoting competition in off-patent markets:** accelerate generic market entry
- **Exploring bundled payments for episodes of care in oncology.** Expected to promote rationale use of medicines and fight perverse incentives to use most expensive medicines



Determining willingness to pay for new treatments

- **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.
- **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



Developing and adjusting pull and push incentives to encourage innovations in areas with unmet needs

- **Better targeting push incentives** to the development of unmet medical needs and attach access conditions to public funding of development.
- **Continue to explore market entry rewards** (pull incentives) to encourage R&D for unmet medical needs.
- **Consider amending orphan drug legislation.** To better target drugs whose development would not occur without such incentives



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