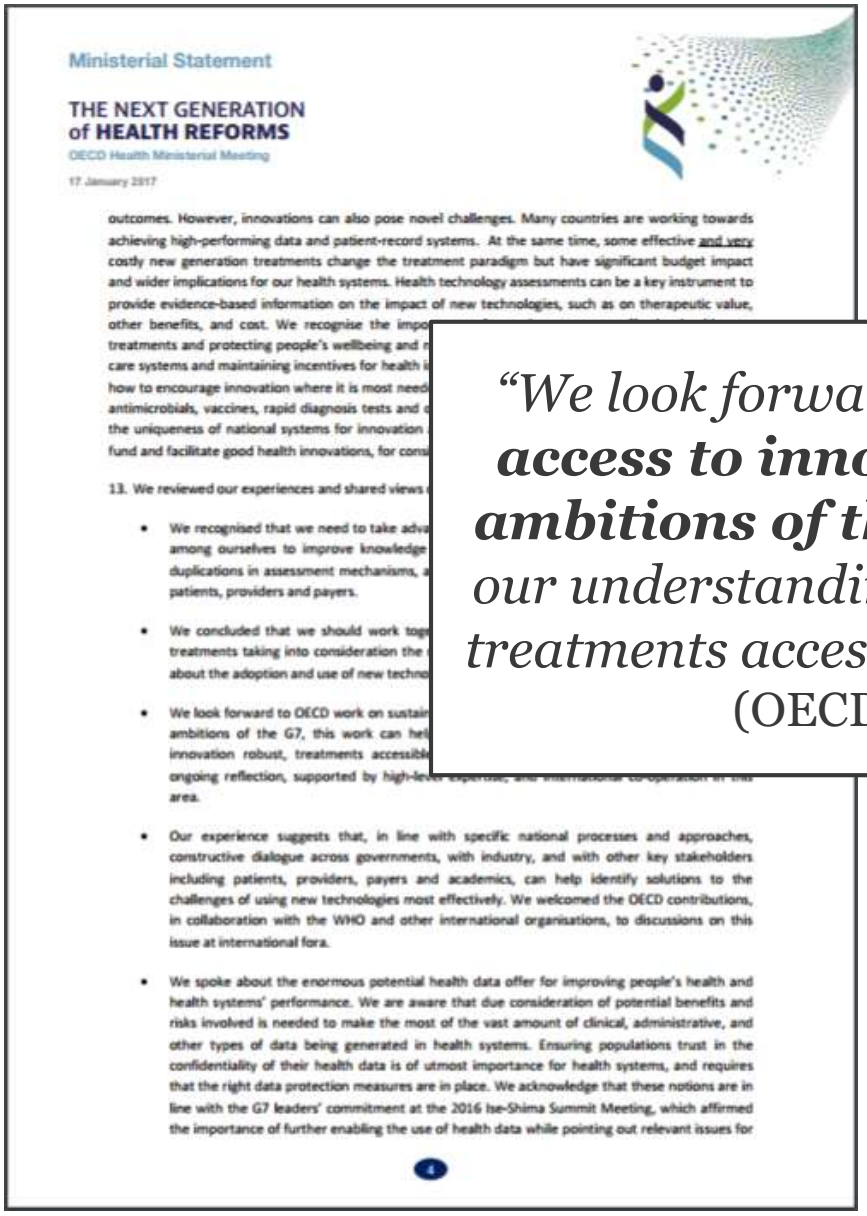
PHARMACEUTICAL INNOVATION AND ACCESS TO MEDICINES

Valérie Paris, OECD
“Facing the Challenges: Equity, Sustainability and Access”
International Conference
Lisbon, 30 November 2018

OCDE
DES POLITIQUES MEILLEURES POUR UNE VIE MEILLEURE



Ministerial Statement

THE NEXT GENERATION of HEALTH REFORMS

OECD Health Ministerial Meeting

17 January 2017

outcomes. However, innovations can also pose novel challenges. Many countries are working towards achieving high-performing data and patient-record systems. At the same time, some effective and very costly new generation treatments change the treatment paradigm but have significant budget impact and wider implications for our health systems. Health technology assessments can be a key instrument to provide evidence-based information on the impact of new technologies, such as on therapeutic value, other benefits, and cost. We recognise the impo
treatments and protecting people's wellbeing and
care systems and maintaining incentives for health
how to encourage innovation where it is most need
antimicrobials, vaccines, rapid diagnosis tests and
the uniqueness of national systems for innovation
fund and facilitate good health innovations, for cons

13. We reviewed our experiences and shared views

- We recognised that we need to take adv
among ourselves to improve knowledge
duplications in assessment mechanisms,
patients, providers and payers.
- We concluded that we should work tog
treatments taking into consideration the
about the adoption and use of new techno
- We look forward to OECD work on sustai
ambitions of the G7, this work can hel
innovation robust, treatments accessib
ongoing reflection, supported by high-le
area.
- Our experience suggests that, in line with specific national processes and approaches, constructive dialogue across governments, with industry, and with other key stakeholders including patients, providers, payers and academics, can help identify solutions to the challenges of using new technologies most effectively. We welcomed the OECD contributions, in collaboration with the WHO and other international organisations, to discussions on this issue at international fora.
- We spoke about the enormous potential health data offer for improving people's health and health systems' performance. We are aware that due consideration of potential benefits and risks involved is needed to make the most of the vast amount of clinical, administrative, and other types of data being generated in health systems. Ensuring populations trust in the confidentiality of their health data is of utmost importance for health systems, and requires that the right data protection measures are in place. We acknowledge that these notions are in line with the G7 leaders' commitment at the 2016 Ise-Shima Summit Meeting, which affirmed the importance of further enabling the use of health data while pointing out relevant issues for

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*"We look forward to **OECD work on sustainable access to innovative medicines**. In line with the **ambitions of the G7**, this work can help us improve our understanding of ways to keep innovation robust, treatments accessible and health systems sustainable."*
(OECD Ministerial Statement, 2017)

OECD acting as Secretariat

- Analytical work
- Stakeholder consultations
- High-level expert group

Objectives of the report

- Highlight **main challenges governments are facing** in ensuring appropriate access to innovative medicines to all those in need.

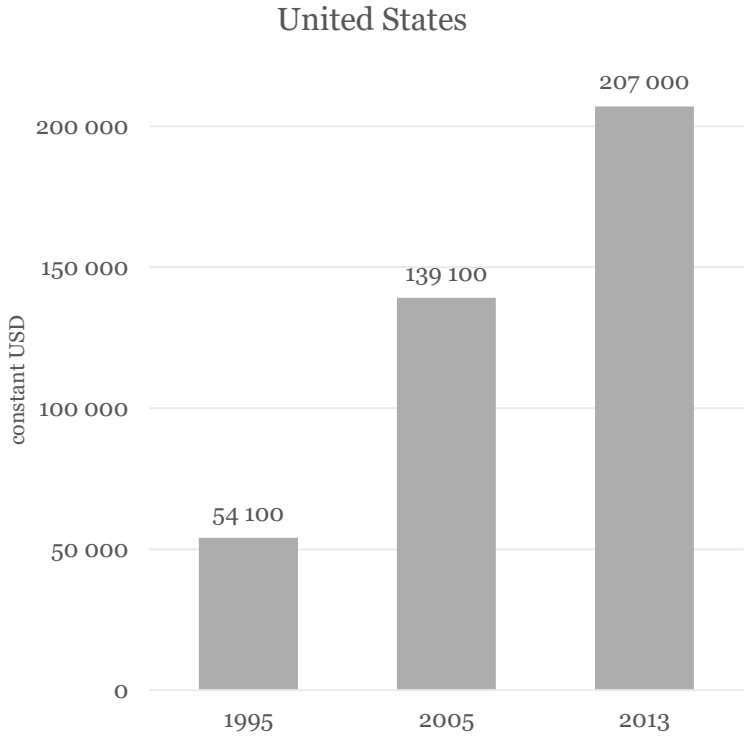
- **Propose policy options**, while stressing for each of them the expected benefits and potential costs, drawing from available evidence.

Challenges for policy makers:

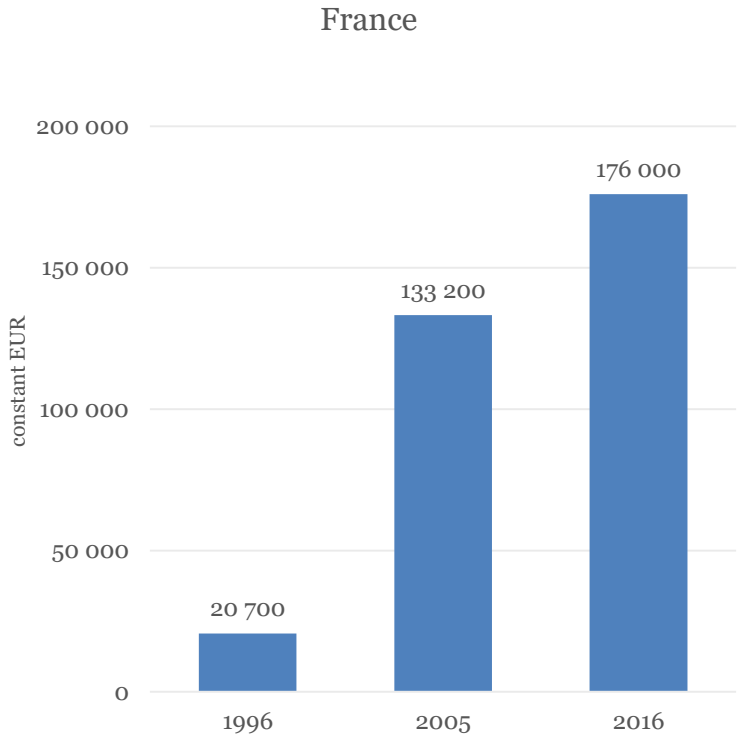
- **Launch prices in some disease areas are increasing at a pace that does *not always* coincide with improvements in benefits** (oncology, orphan drugs)
- This raises **access problems** in some countries
- Payers struggle to provide access to breakthrough medicines because of **unaffordable budget 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



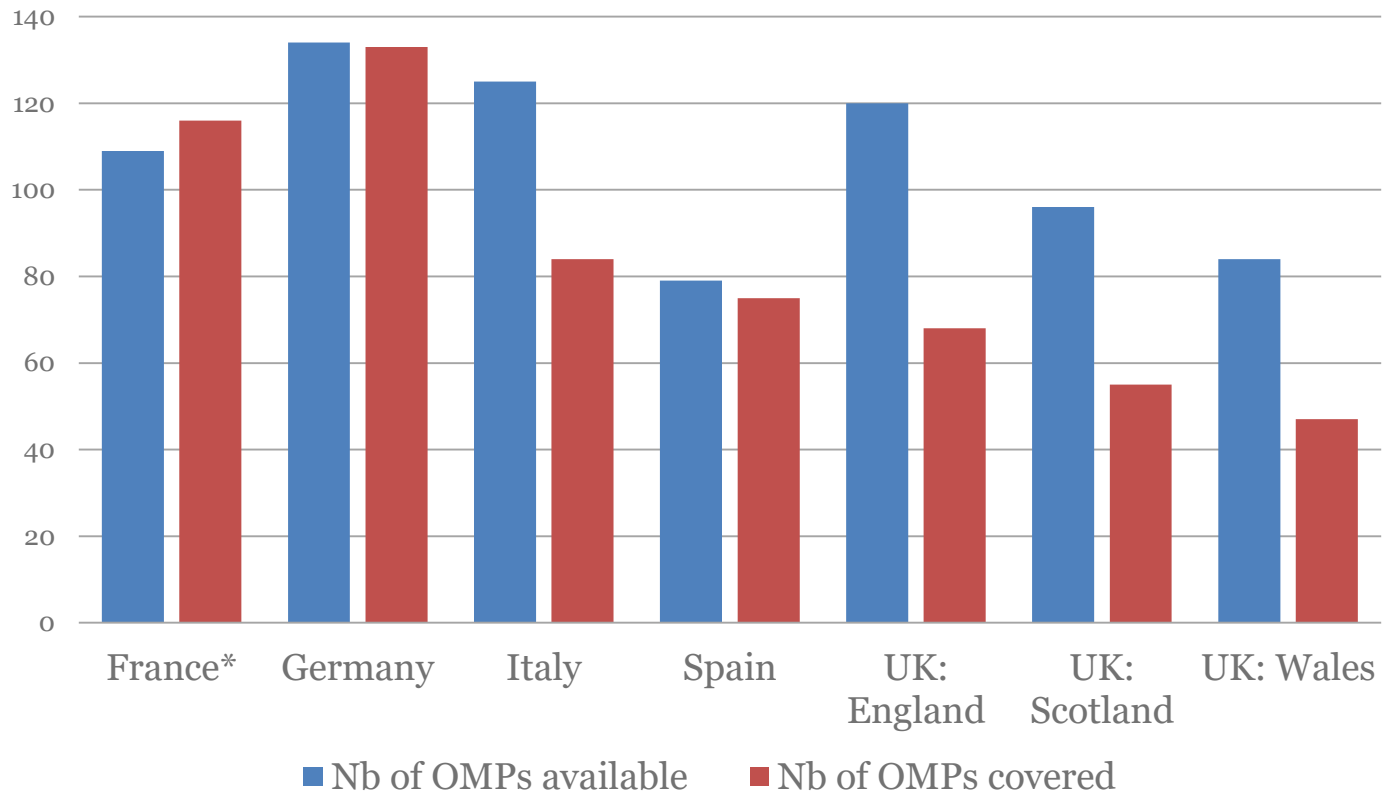
Source: Howard D.H. et al 2015 Pricing in the Market for Anticancer Drugs. *Journal of Economic Perspectives* 29 (1): 139-62.



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

Medicines are not always affordable to patients

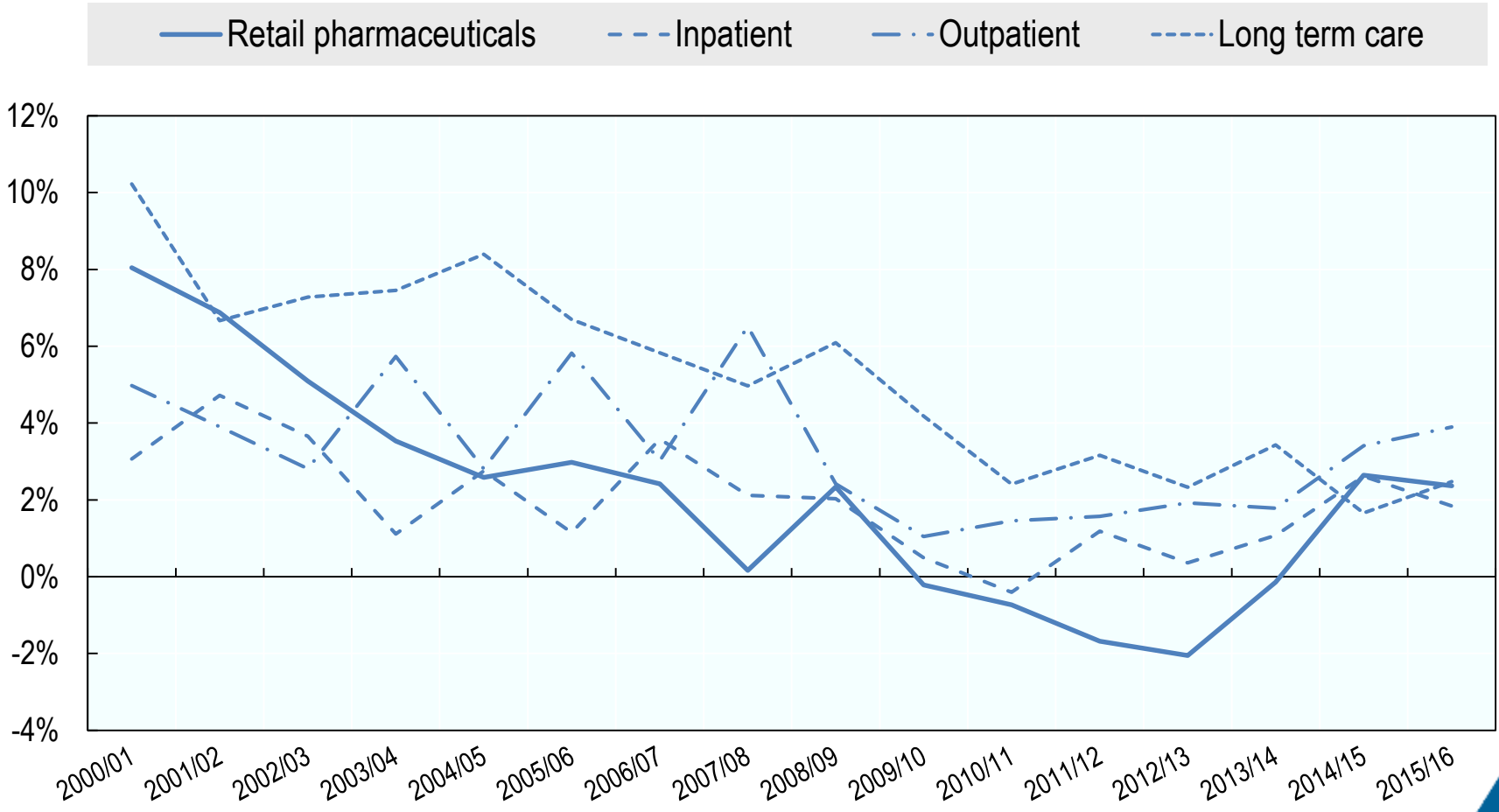
Availability and coverage of 143 orphan medical products (OMPs) approved centrally by the EMA in five EU countries between 2000 and May 2016



* 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

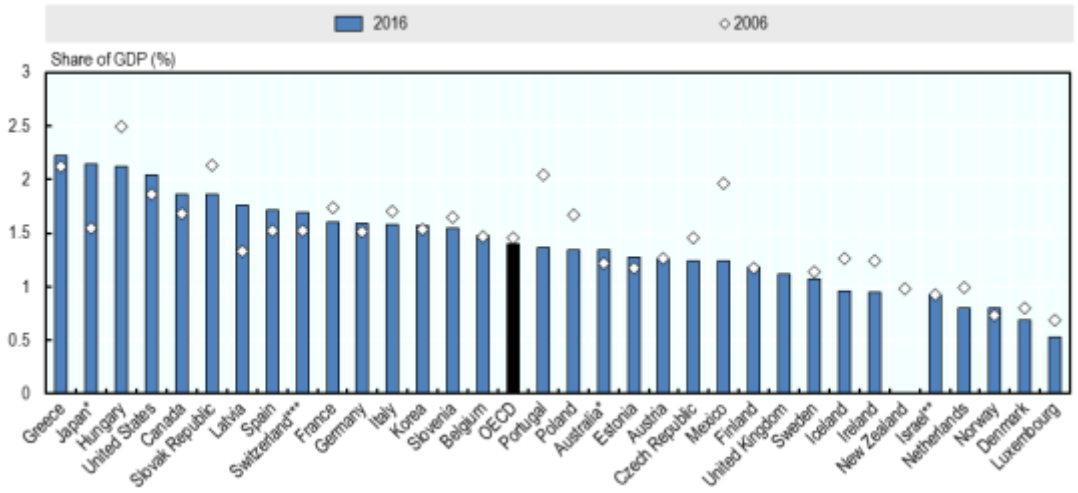
Do these prices threaten sustainability of health spending?

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

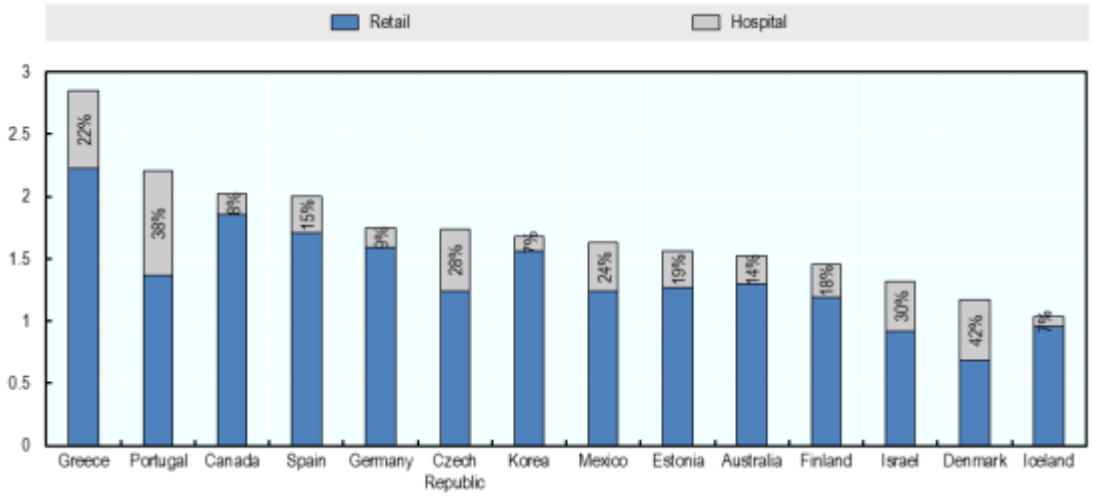


Do these prices threaten sustainability of health spending?

Retail pharmaceutical expenditure, as share of GDP



Total pharmaceutical 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

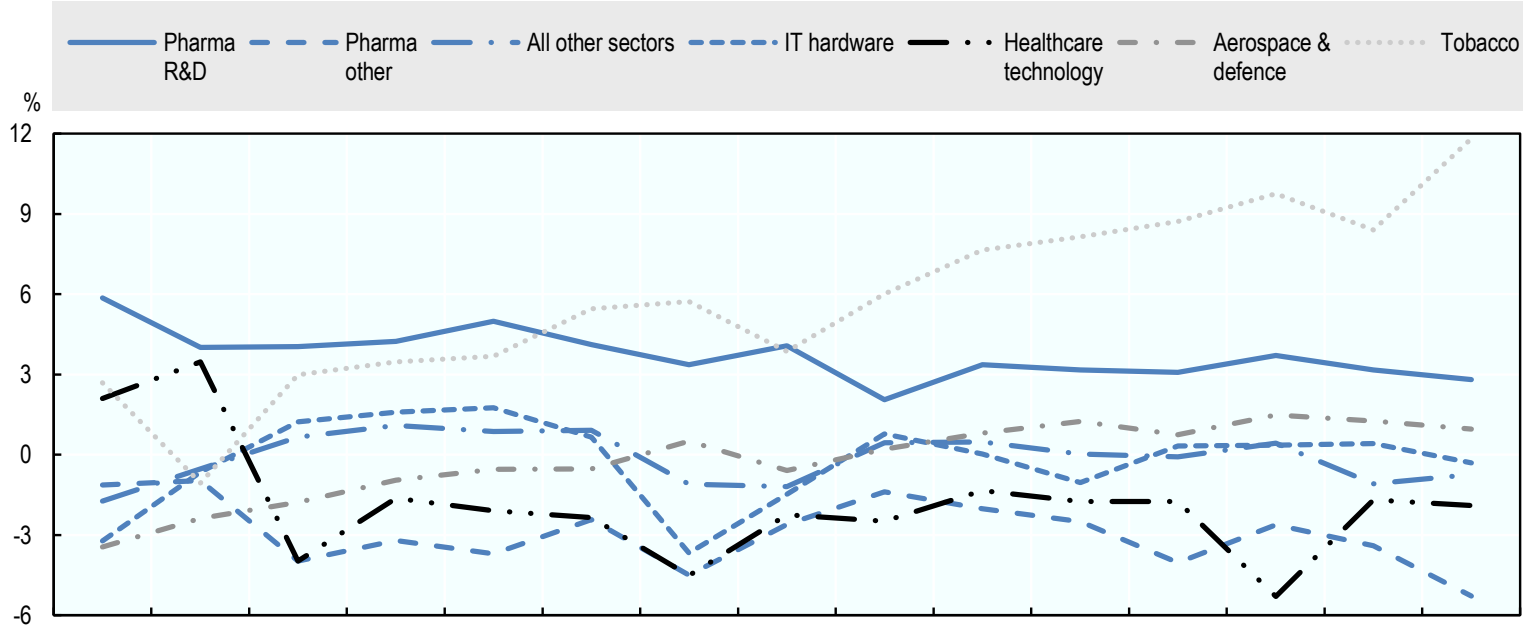
R&D is riskly, costly, mainly supported by private investors, profitability is high

- 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



Source: OECD 2018 Pharmaceutical Innovation and Access to Medicines

Guiding principles to develop policy options to respond to challenges

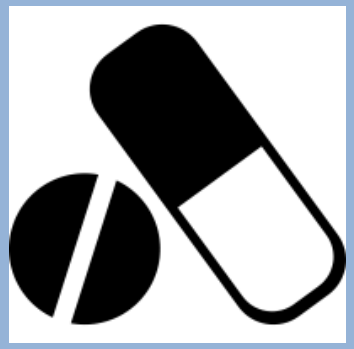
- Overall objective: increase value (efficiency) of spending on pharmaceuticals
- Maintain differential (or tiered) pricing.
- Implement a rule-based, predictable, system.
- Foster competition throughout the pharmaceutical system in order to improve the value of pharmaceutical spending
- Increase transparency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