Asia-Pacific Economic Cooperation

APEC Life Sciences Innovation Forum

Enhancing Innovative Healthcare Financing in Pursuit of Strong and Resilient Health Systems: Financing Solutions for Durable Cures

October 28, 2021

8:00 am EDT / 2:00 pm CEST / 7:00 pm ICT/WIB

8:00 pm HKT/SGT/CST/PHST / 9:00 pm JST/KST

Asia-Pacific Economic Cooperation

Eric Obscherning

Associate Director
C&M International

Enhancing Innovative Healthcare Financing in Pursuit of Strong and Resilient Health Systems: Financing Solutions for Durable Cures

Asia-Pacific Economic Cooperation

Mark Trusheim

Strategic Director & Visiting Scientist,
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Massachusetts Institute of Technology

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APEC Life Sciences
Innovation Forum

NEWDIGS

FoCUS

Financing and Reimbursement
of Cures in the US

Financing Solutions for Durable cures

28 October 2021

Mark Trusheim

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MIT CENTER FOR BIOMEDICAL INNOVATION

Massachusetts
Institute of
Technology

FoCUS: Sustainable Access for Durable Therapies via Downstream Innovation

>90 organizations & 350 individuals engaged

Focus of FoCUS: An MIT NEWDIGS Consortium

On—

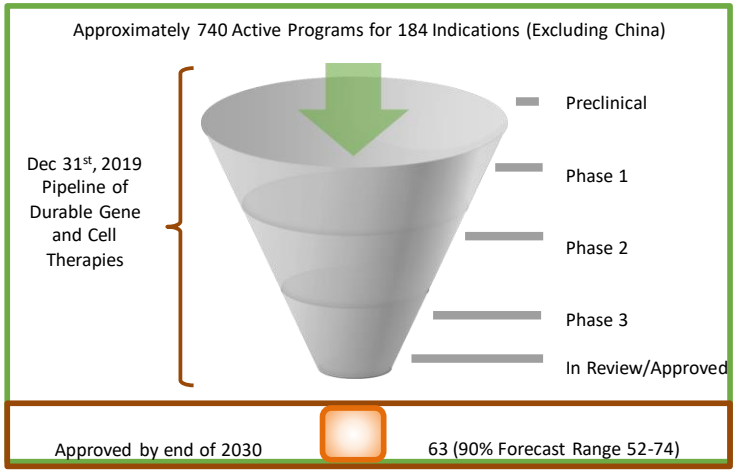
Creating **precision financing solutions**

***Not* on—**

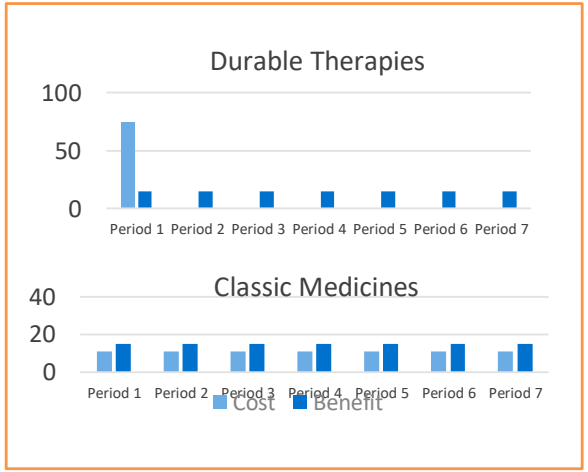
Setting value or price

Emerging Durable Therapies Driving New Payment Models

50-75 Therapies Approved for the US Market by 2030



Durable Therapies Distill Payments Upfront



Three financial challenges exacerbated

Payment timing
One-time high cost

Performance risk:
Effectiveness & durability

Actuarial risk:
Likelihood of encountering a case

Patient Impact of Regenerative Medicine

40%
of patients with R/R DLBCL treated with **CAR-T Threapy** experienced a complete response

60%
of patients with R/R B-Cell ALL treated with **CAR-T Therapy** experienced a complete response

58%
of patients with R/R B-Cell NHL treated with **CAR-T Therapy** experienced a complete response

55%
of patients treated with **Gene Therapy** showed an improvement of 2+ light levels darker after treatment

Precision Financing Solutions To Meet The Challenges

Multi-year performance-based annuities

Short-te milestone- contra

Orphan Reinsurer and Benefit Manager (ORBM) and Risk Pools

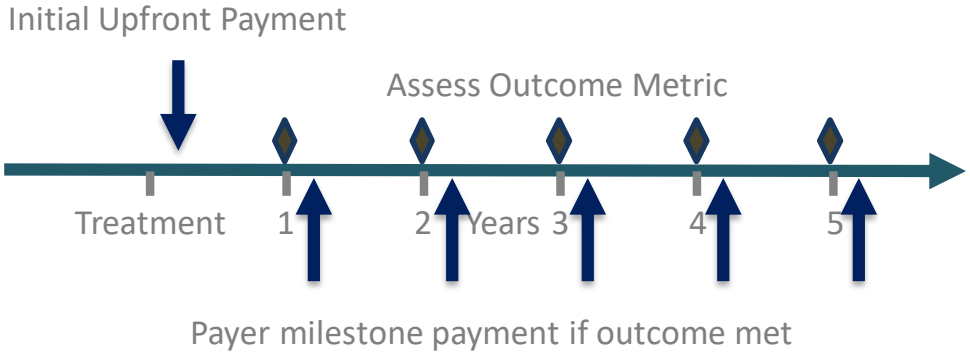
Warranty Model

NETFLIX

Subscription Model

Performance-based Annuities Address the Three Challenges

- **Payment Timing**: Match payments to cost avoidance
- **Performance Uncertainty**: Effectiveness & Durability
- **Actuarial Uncertainty**: partial patient level reinsurance on demand

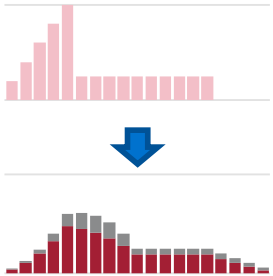


Performance-Based Annuities Address More than Outcomes Uncertainty

The three financial challenges

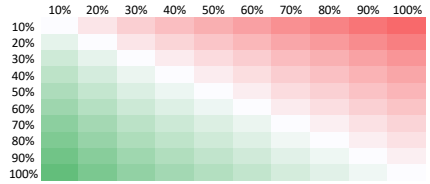
Payment timing
One-time high cost

Surges Smoothed



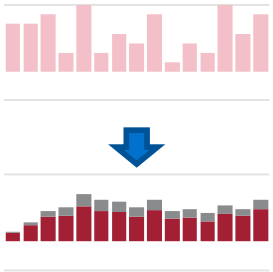
Performance risk:
Effectiveness & durability

Pay for value actually received not *a priori* estimated value

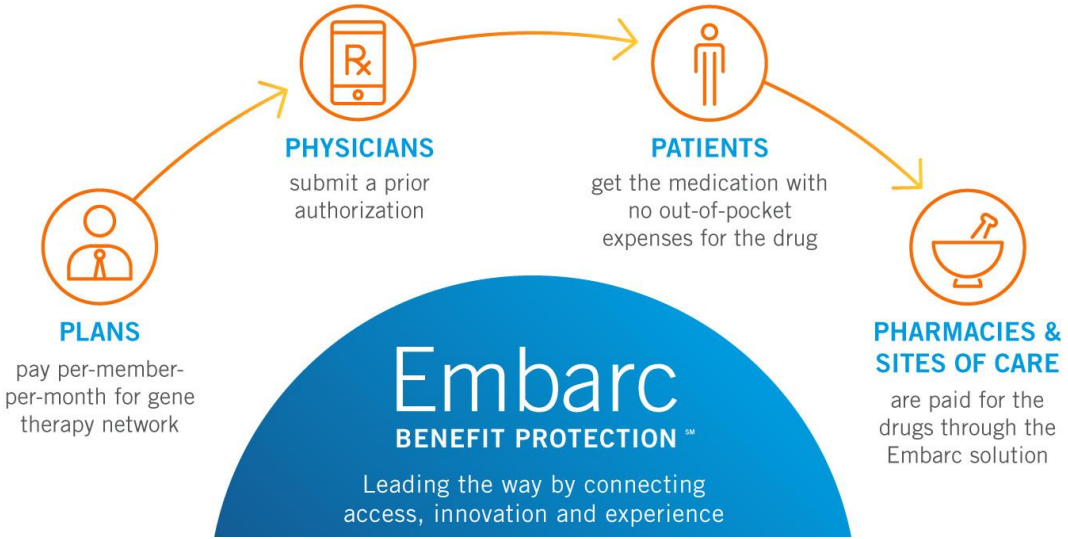


Actuarial risk:
Likelihood of receiving a case

Volatility Reduced



US Insurer Cigna Offering ORBM-Lite: Embarc



Beginning with 2 Gene Therapies

 Source: http://lab.express-scripts.com/lab/insights/specialty-medications/delivering-on-the-promise-of-modern-medicine

All Approaches Must Address US Issues

- **Patient mobility and performance data collection**
- **Risk sharing**
  - Participation or exclusion of providers
  - Interaction with reinsurance and stop-loss insurance
- **Legal & Regulatory**
  - **Medicaid drug price reporting and rebate** need adapting to multi-year performance structures
  - **Anti-Kickback Statute to define explicit safe harbor**
  - **FDA communication guidelines to enable appropriate performance metrics** Clinical trial endpoints often not practical for clinicians or present in data systems

No Perfect Precision Financing Designs Yet Created

		Payment Timing	Performance	Actuary	US Status	
Short-term milestone contracts					Multiple Agreements	
Warranty Model					Agreements In Negotiation	
Multi-year performance annuities					Pilot Stalled Medicaid Best Price	
ORBM and Risk Pools					Proposed Private Sector	
Subscription Model	NETFLIX				State Demonstrations	

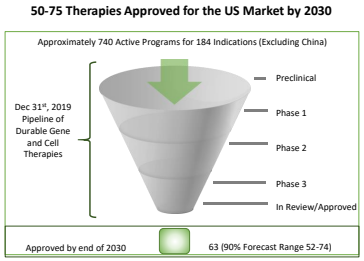
FoCUS Open Resources

FoCUS

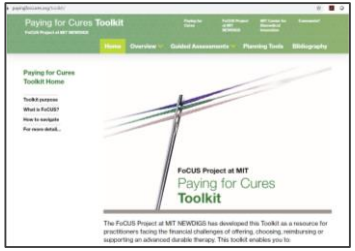
Go to: Https://payingforcures.MIT.edu

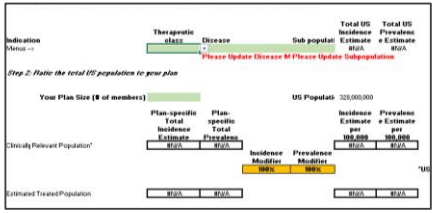
Research Briefs and Peer-Reviewed Publications

Unique Gene and Cell Therapy Pipeline Impact Modeling



On-line Toolkit to Educate and Support Practitioners Developing Financing Solutions





Public Speaking Engagements

Educational Events

Design Labs

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Asia-Pacific Economic Cooperation

Dino Sepulveda

Head of Department of HTA and Evidence-Based Medicine, Ministry of Health, Chile;

Executive Secretary, Ministerial Advisory Commission on Rare Diseases

Enhancing Innovative Healthcare Financing in Pursuit of Strong and Resilient Health Systems: Financing Solutions for Durable Cures

- **Risk-sharing agreements:**
- **The experience of the 4th decree of the Ricarte Soto Law**

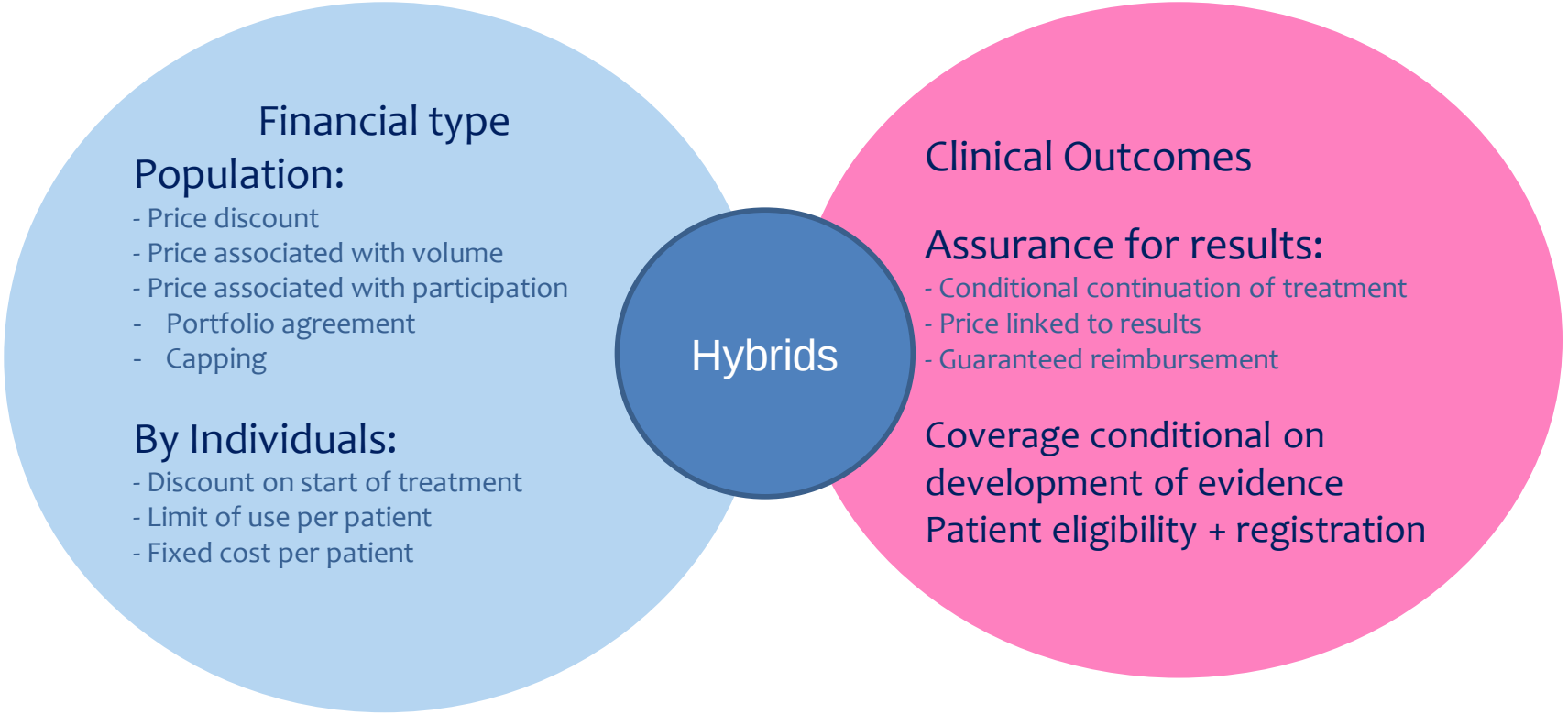
• Content

- Introduction
- Taxonomy
- RSA in the evaluation process in 4th Decree of Ricarte Soto Law
- RSA in technologies prioritised in 4th Decree of Ricarte Soto Law
- Barriers to implementation
- Endpoints

• Introduction

- **What is a risk-sharing agreement (RSA)?**
- An agreement between a provider [pharmaceutical company] and a payer/provider that allows access (coverage and reimbursement) to a health technology under certain conditions.
- These contracts have the potential benefits of allowing early access to technologies for patients and reducing uncertainty about their use's effectiveness, cost-effectiveness, and financial impact under real-world conditions.
- They are also referred to as Entry Management Agreements, Patient Access Schemes, Evidence-Based Coverage, etc.

Taxonomy of risk-sharing agreements

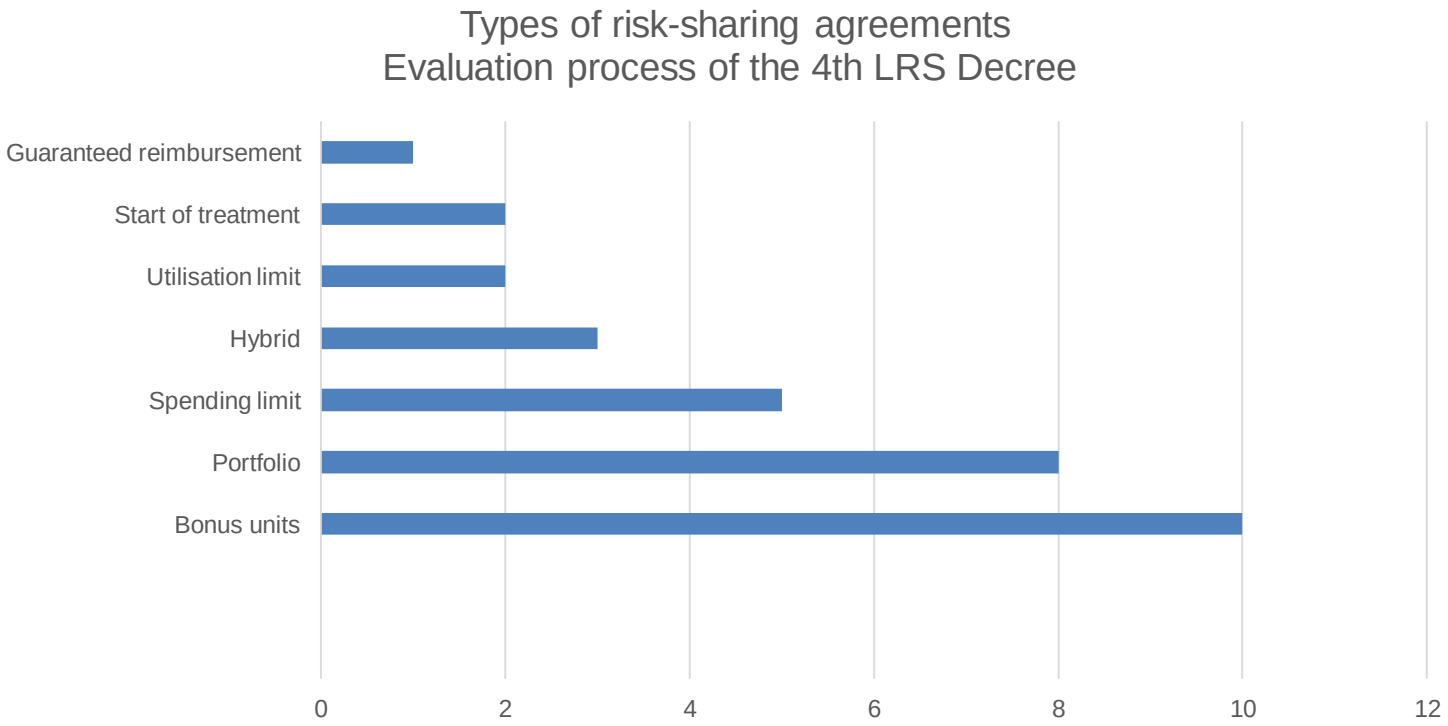


Courtesy of Mr. Sergio Poblete, on the basis of Poblete (2020)

• Risk-sharing agreements - Evaluation process 4th LRS decree

- The number of drug intention-of-price letters received for the fourth LRS decree was **103** from 32 different suppliers, covering 62 drugs.
- 70 of the quotations (68%) considered price discounts or other types of RSA.
- 65 quotations were submitted with discounts.
- There were 31 RSA proposals (other than price discounts) (28%).

Courtesy of Mr. Sergio Poblete, on the basis of Poblete (2020)



Courtesy of Mr. Sergio Poblete, on the basis of Poblete (2020)

Limitation of Risk-sharing agreements implementation

Public procurement law
Within the Public Procurement Act framework, certain agreements such as portfolio or volume-related price agreements cannot be implemented.

The inertia of the purchasing process
Implementing risk-sharing arrangements involves changing the basis on which medicines are traditionally procured.

Purchasing logic
The purchasing entity (CENABAST) operates by centralising and aggregating demand. Risk-sharing agreements require modifying this modus operandi.

Information systems
The public health system does not have global clinical registry systems to monitor the evolution of clinical outcomes.

Non-understanding of benefits
Most public sector actors see these initiatives as a way for the industry to hide prices. As a result, there is no appreciation of budgetary benefits or of paying for health effects in practice.

Lack of skills
International experience shows that risk-sharing arrangements are complex in terms of design and implementation, requiring specialised technical teams to carry them out.

Courtesy of Mr. Sergio Poblete, on the basis of Poblete (2020)

• Key points

- The experience of the 4th LRS decree is pioneering for the public health sector in terms of risk-sharing agreements.
- Laboratory proposals are mainly financial, conditioned by the feasibility of implementation and technologies with high budgetary uncertainty.
- International experience indicates that ARC requires a proactive role of the public funder/payer (selective).
- There is no "gold standard" risk-sharing agreement. It will depend on health technology and uncertainty.
- The main challenge is to move forward in the area of implementation.
- It requires the generation of competencies within the public health system that allow the formulation of this type of contract and the development of specific infrastructure (information systems) that will enable the monitoring and follow-up of this type of agreement.

• References

Grimm, Sabine, et al. "Framework for analysing risk in health technology assessments and its application to managed entry agreements." *Sheffield: University of Sheffield* (2016).

Antonanzas, Fernando, et al. "The use of risk-sharing contracts in healthcare: theoretical and empirical assessments." *PharmacoEconomics* 37.12 (2019): 1469-1483.

Poblete, Sergio. "Acuerdos de riesgo compartido para medicamentos de alto costo en Chile." *Revista Estudios de Políticas Públicas* 6.2 (2020).

Ricarte Soto Law, Chile: https://leyricartesoto.minsal.cl/#/articulos/informacion-por-decreto
/


Ministerio de
Salud
Gobierno de Chile

Asia-Pacific Economic Cooperation

Goffredo Freddi

Executive Director, Policy & Communications at MSD Italy

Enhancing Innovative Healthcare Financing in Pursuit of Strong and Resilient Health Systems: Financing Solutions for Durable Cures

The Fund for Innovative Drugs: the Italian experience

Goffredo Freddi
Executive Director
Policy & Communication
MSD Italy

October 28th 2021

Overview

For more than a century, we have been inventing to solve some of the greatest challenges to people's health and well-being around the world

Businesses
Prescription medicines, vaccines, biologic therapies, animal health products

2020 revenues
$48 billion; 56% of sales come from outside the United States

Headquarters
Kenilworth, New Jersey, U.S.

Merck & Co., Inc.
This is our legal name and is listed on the New York stock exchange under the symbol "MRK"

16.7K
people employed in research and development

422M
people reached through our major programs and partnerships

$13.6B
invested in R&D in 2020

$3.1B
total philanthropy in 2019

Our giving

How public pharmaceutical spending is currently funded in Italy?

The creation of the Funds for Innovative Drugs (2017)

Universal coverage mostly funded by general taxation

~€ 120 B

National Healthcare Fund

7.0%

Cap for retail spending

7.65%

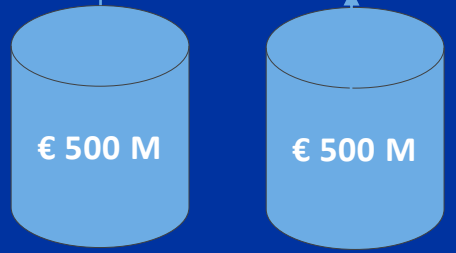
Cap for pharma spending at hospital level

- Chronic overshoot of the cap for pharma spending at hospital level
- Savings in the pharma spending at retail level (i.e., € 1 B) not used to mitigate the overshoot in the other cap
- The overshoot of the budget for pharma spending at hospital level **risks to limit patient access to innovative drugs**

From 2017 onwards (on top of the two caps)

Molecules labelled as innovative by the Italian Drug Agency (36-month inclusion in the Funds)

Molecules included in the Funds are **excluded from Companies' payback + fast track inclusion in national/regional formularies**



To be labelled as innovative, the drugs must prove an important therapeutic need, therapeutic added value and quality of evidence

How does the Drug Agency evaluate whether a drug is innovative or not?

1. ***Therapeutic need (maximum/Important)*** *- absence/limited therapeutic options*			
2. ***Therapeutic value added (maximum/Important)*** *- > efficacy demonstrated on clinically relevant outcomes*			
3. ***Quality of evidence (High/Medium)*** *- trials and mature OS data as major drivers*			
	FULL INNOVATION • *No Payback* • *Fast access to hospital formularies*	**CONDITIONAL INNOVATION** • *Fast access to hosp.ital formularies*	**NO INNOVATION**

Two major changes from the creation of the Funds:

- **3-year inclusion in the Fund granted to therapeutic indications rather than to the single molecule**
- **The Funds, originally foreseen for the 2017-2019 period, are now structural**

Did the Funds for Innovative Drugs prove to be an effective measure?

- The evaluation on the effectiveness of the Funds for Innovative Drugs must meet two primary endpoints

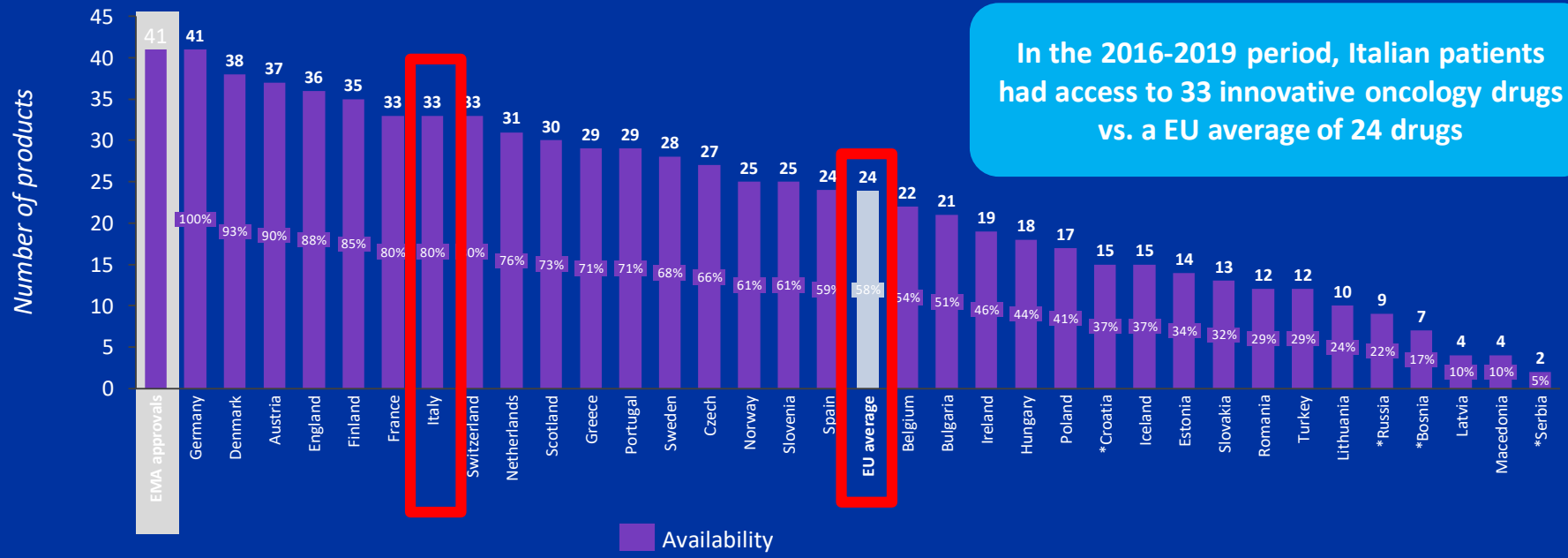
The **rate of availability**, measured by the number of medicines available to Italian patients, and the **time to availability**, measured by the days between EMA MA and the date of availability to Italian patients

The overall **affordability** of the Italian Healthcare System

Focus on Innovative Oncology Drugs

IQVIA "Patients W.A.I.T. Indicator 2020 Survey" (April 2021)

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 2020. For most countries this is the point at which the product gains access to the reimbursement list



In the 2016-2019 period, Italian patients had access to 33 innovative oncology drugs vs. a EU average of 24 drugs

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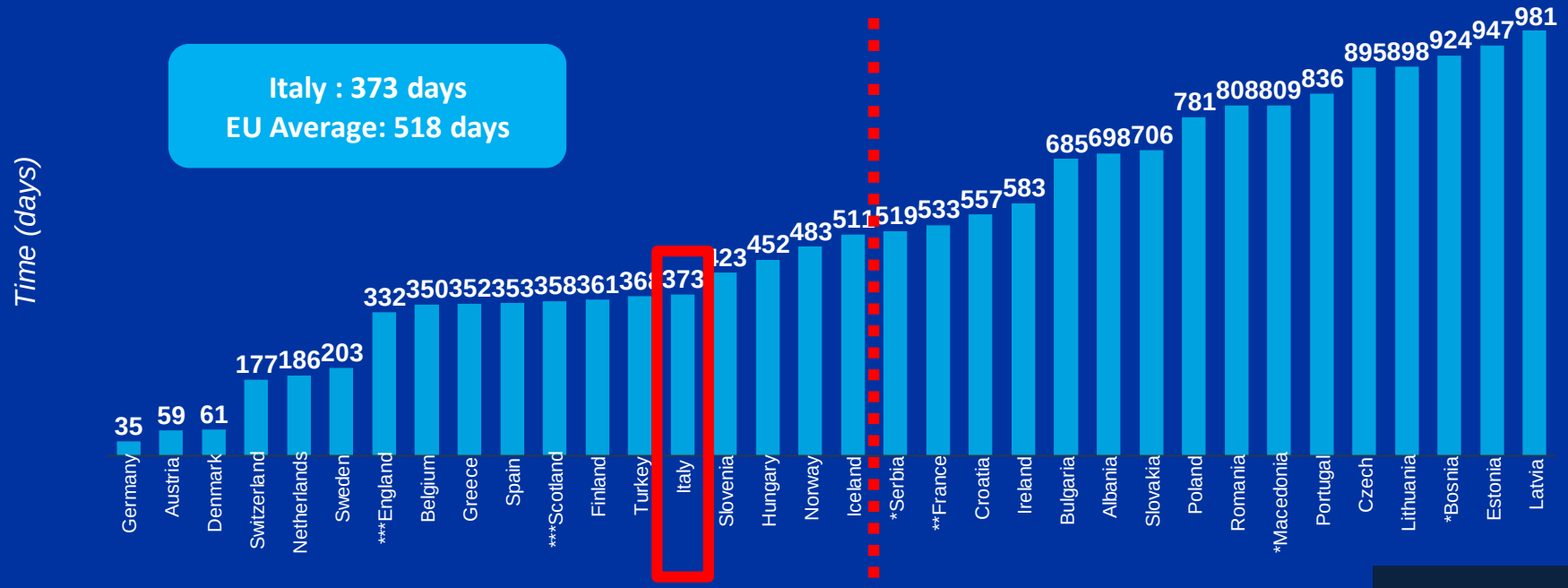
Focus on Innovative Oncology Drugs

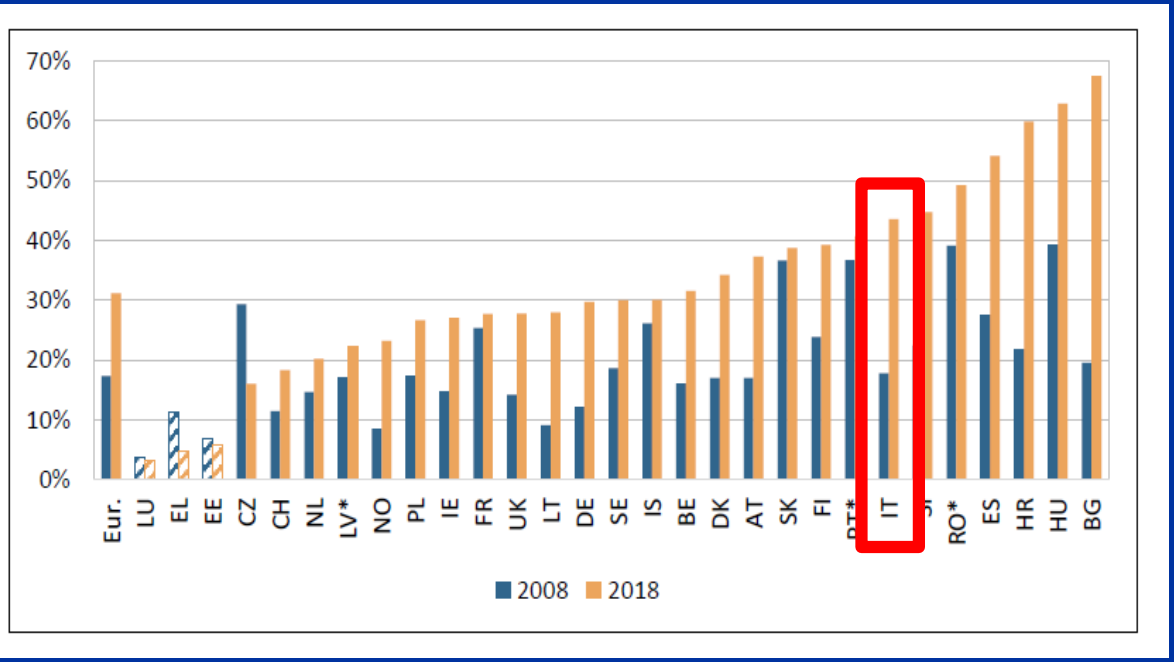
IQVIA "Patients W.A.I.T. Indicator 2020 Survey" (April 2021)

The **time to availability** (previously know as length of delay) is the days between EMA marketing authorisation and the date of availability to patients in European countries



Did the Funds contribute to the affordability of the Italian NHS?

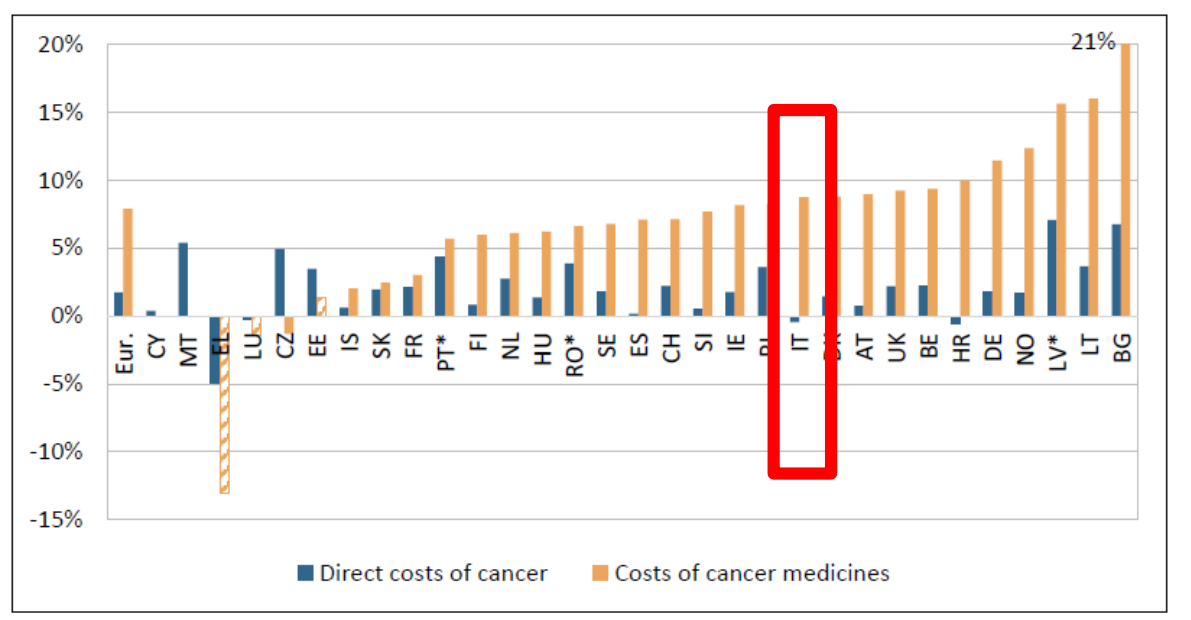
"Comparator Report on Cancer in Europe 2019 – Disease Burden, Costs and Access to Medicines" (IHE)



- According to the findings of the study, Italy is among the countries with the highest increase of the spending on oncology drugs (direct costs) in the 2008-2018 period

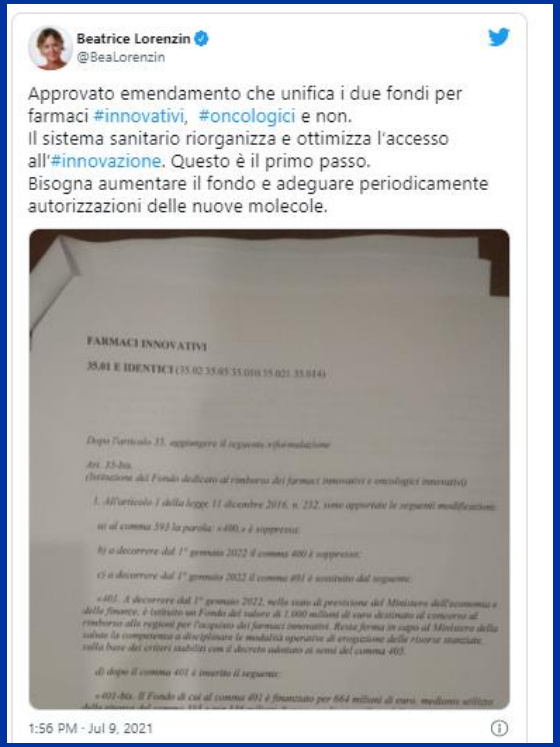
Did the Funds contribute to the affordability of the Italian NHS?

"Comparator Report on Cancer in Europe 2019 – Disease Burden, Costs and Access to Medicines" (IHE)



- **At the same time, Italy is the only country which, while increasing the spending on oncology drugs, decreased the overall healthcare spending for oncology patients in the 2008-2018 period, thus contributing to the overall affordability of the Italian NHS**

Latest changes in the Funds for Innovative Drugs



July 2021: One single Fund (€ 1 B) for Innovative Drugs

Non binding Parliament opinion – backed by the Italian Ministry of Economy – asking the Government to **increase the financial allocation for the Fund for Innovative Drugs**

July 2021

Italy to increase resources for innovative drugs

APM - **Italy is planning to increase resources for drugs recognised as innovative in a €6 billion boost to national health funding over the next three years.**
Ministers approved the 'Draft Budgetary Document for 2022'.
On healthcare, it was announced that, compared with 2021, the National Health Fund will be increased by €2 billion each year until 2024. **New resources will be allocated to the fund for innovative drugs and for spending on vaccines and drugs to contain the Covid-19 pandemic**

October 2021

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Thank You!

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Crowell & Moring

Questions?