Generalitat de Catalunya
Departament de Salut

CatSalut
Servei Català de la Salut

Management of innovation: exchange of experiences.

Focus on Hepatitis C

Dr Josep Torrent-Farnell
Head of Medicines Department of the Catalan Health Service (CatSalut)

May 10th, 2017

Mind the gap

How to manage the up take of new medicines

Quality

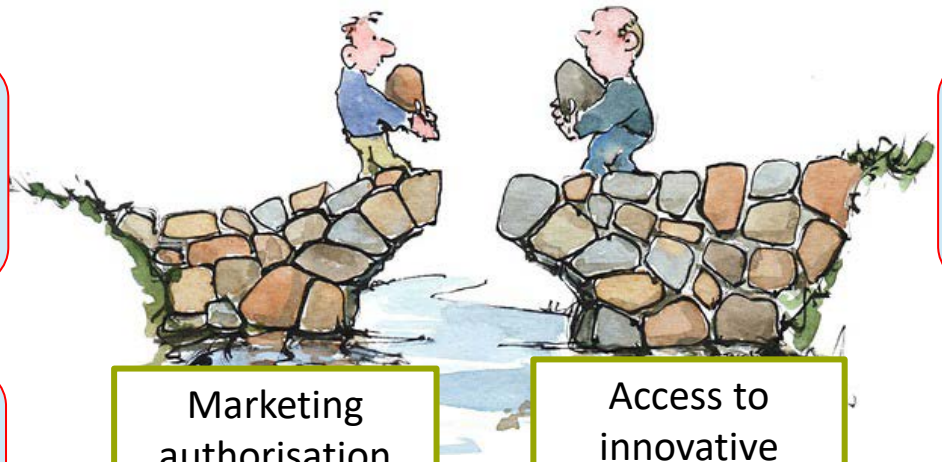
Efficacy

Safety

Clinical added value

Efficiency

Affordability



Marketing authorisation

Access to innovative medicines

EMA B/R Balance

HTA Appraisals

Innovative medicines as a challenge for national health services...

Payers' perspectives

- ✓ Encourage the safe, effective and efficient use of medicines
- ✓ Evaluate and optimize health outcomes
- ✓ Ensure equity in access
- ✓ Ensure sustainability and viability

Obtaining better health outcomes in a financially sustainable environment

Measures adopted for the uptake of new medicines to treat the Hepatitis C

1

Favour the early acces to patients (severe cases – June 2014 – 219 patients)

2

Health Technology Assessment Programme: determine the added clinical value, harmonizes the use of medicines and guarantee equity in access in Catalonia

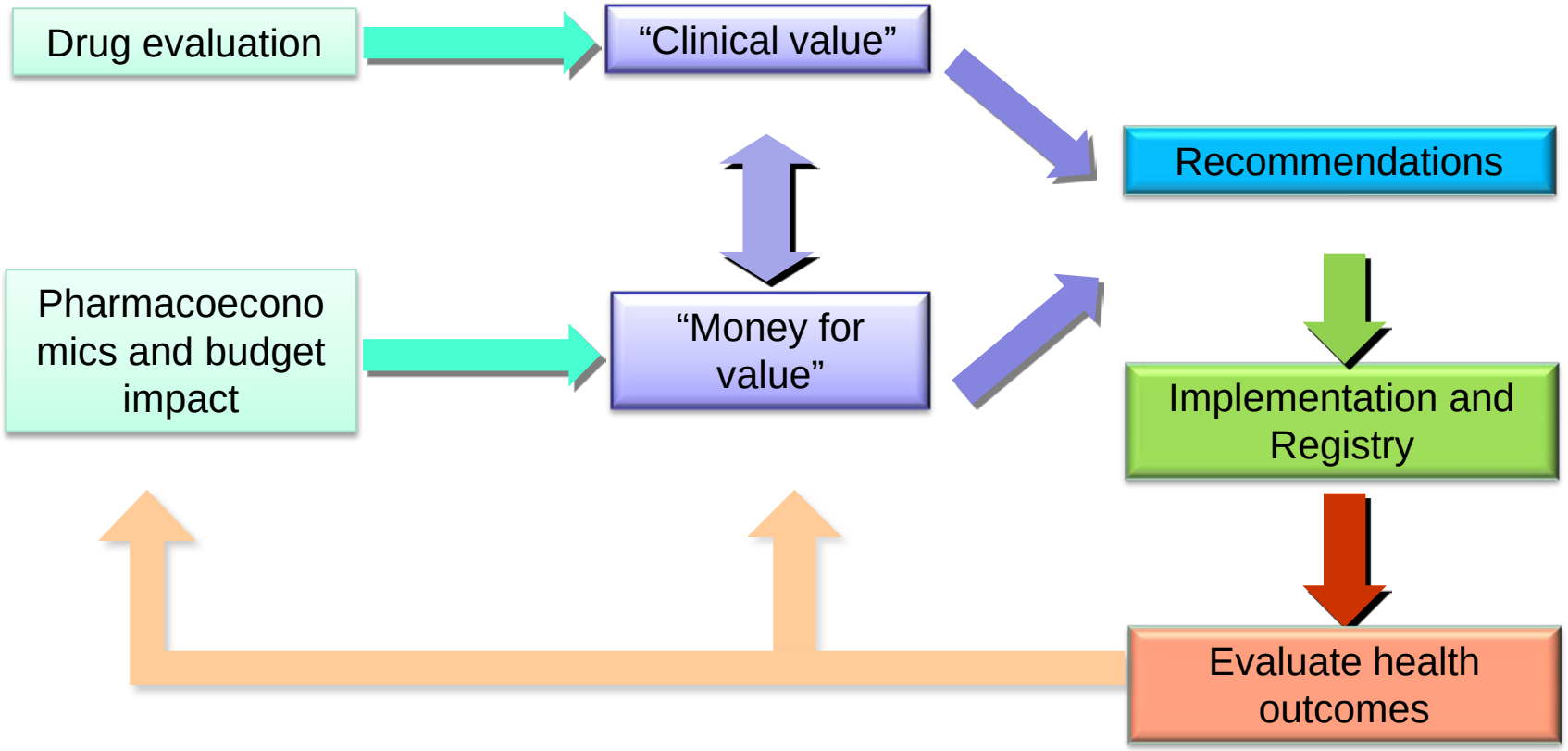
3

Registry and study of the outcomes obtained: real life results

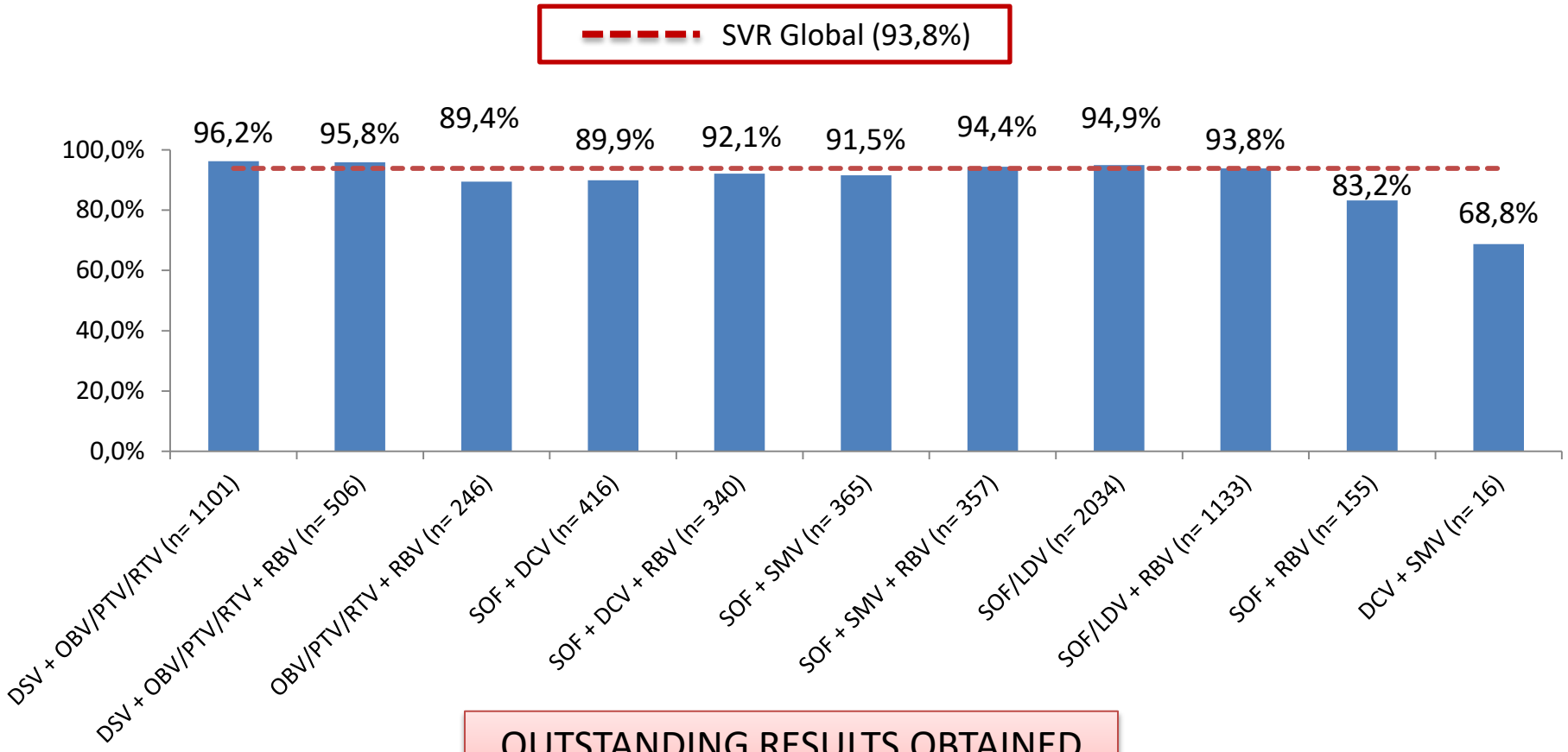
4

Widening management schemes to spur access for innovative medicines (financial agreements with industries)

Health Technology Assessment Programme:
Program to improve access to innovative medicines



Outcomes obtained from Registry
Sustained virological response (SVR) (n=6.669*)



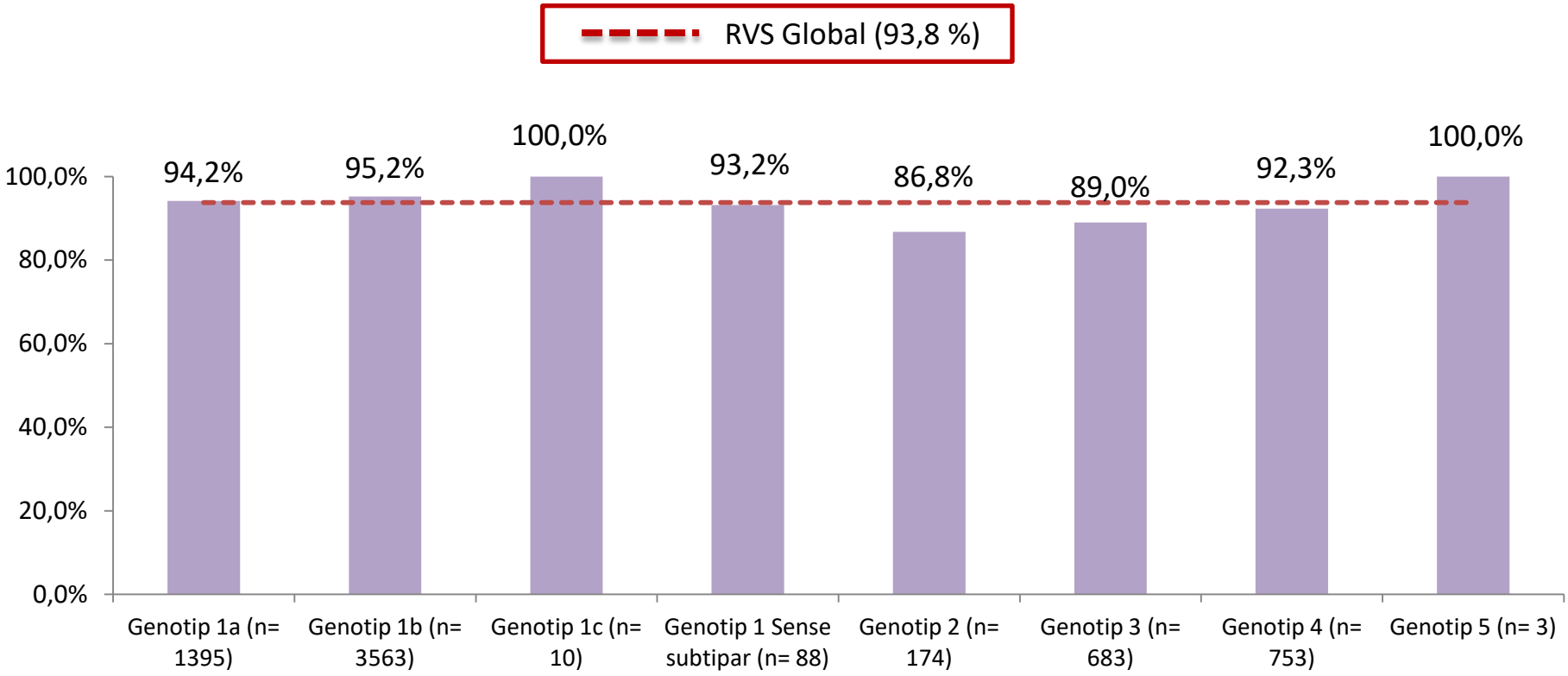
OUTSTANDING RESULTS OBTAINED WITH NEW TREATMENTS

Drug	Abreviatura
Boceprevir	BOC
Daclatasvir	DCV
Dasabuvir	DSV
Ombitasvir/paritaprevir/ritonavir	OBV/PTV/RTV
Peginterferó	PEG

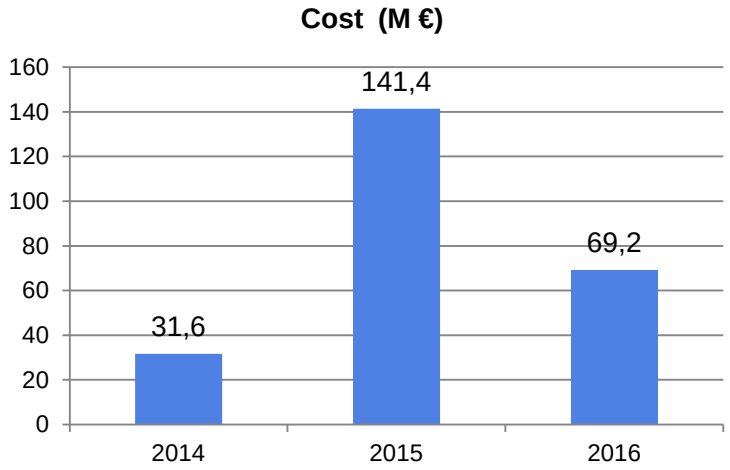
Drug	Abreviatura
Simeprevir	SMV
Sofosbuvir	SOF
Sofosbuvir/Ledipasvir	SOF/LDV
Ribavirina	RBV
Telaprevir	TEL

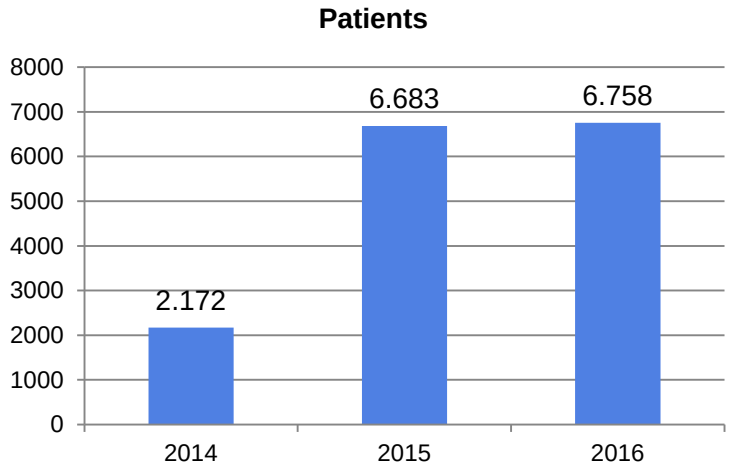
Outcomes obtained from Registry

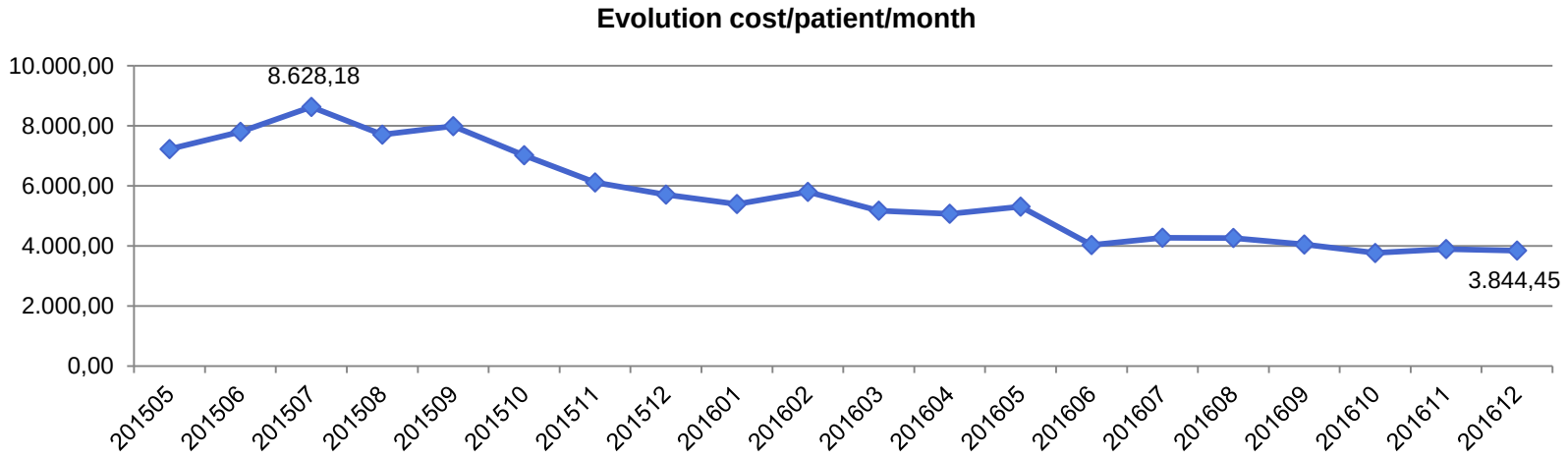
Sustained virological response (SVR) (n=6.669*)
According genotype



Budgetary impact and population treated







The case of orphan medicines

High prices with higher uncertainties regarding the outcomes provided

EXPERT REVIEWS

Access to orphan drugs in Europe: current and future issues

Expert Rev. Pharmacoeconomics Outcon

BJCP British Journal of Clinical Pharmacology

Access to orphan drugs despite poor quality of clinical evidence

Alain G. Dupont[1,2] & Philippe B. Van Wilder[2]

[1]Commission for Reimbursement of Medicines and [2]Department of Clinical Pharmacology and Pharmacotherapy, Vrije Universiteit Brussel, Brussels, Belgium

Appl Health Econ Health Policy (2013) 11:1–3
DOI 10.1007/s40258-012-0004-y

EDITORIAL

Cost-Effectiveness Assessment of Orphan Drugs

A Scientific and Political Conundrum

Steven Simoens · Eline Picavet · Marc Dooms · David Cassiman · Thomas Morel

Simoens
http://ww

IAL

Morel *et al. Orphanet Journal of Rare Diseases* 2013, **8**:198
http://www.ojrd.com/content/8/1/198

OJRD ORPHANET JOURNAL OF RARE DISEASES

RESEARCH Open Access

Reconciling uncertainty of costs and outcomes with the need for access to orphan medicinal products: a comparative study of managed entry agreements across seven European countries

Thomas Morel[1*], Francis Arickx[2], Gustaf Befrits[3], Paolo Siviero[4], Caroline van der Meijden[5], Entela Xoxi[4] and Steven Simoens[1]

REVIEW Open Access

Pricing and reimbursement of orphan drugs: the need for more transparency

Picavet *et al. Orphanet Journal of Rare Diseases* 2013, **8**:164
http://www.ojrd.com/content/8/1/164

OJRD ORPHANET JOURNAL OF RARE DISEASES

RESEARCH Open Access

Clinical evidence for orphan medicinal products-a cause for concern?

Eline Picavet[1*], David Cassiman[2], Carla E Hollak[3], Johan A Maertens[4] and Steven Simoens[1]

Patients expectations

The importance of early access to medicines for patients suffering from rare diseases

Authors
***Pauline Evers**, Levenmetkanker ("Living with cancer"), European Genetic Alliance Network (EGAN), the Netherlands, Patients' organisations representative at the Committee for Orphan Medicinal Products (COMP), European Medicines Agency (EMA) UK; **Lesley Greene**, European Organisation for Rare Diseases (EURORDIS), Vice President, CLIMB UK (Children Living with Inherited Metabolic Diseases), COMP Vice-chair, Patient's organisations representative at COMP, EMA, UK; **Mario Ricciardi**, University of Verona, Italy, Cystic Fibrosis Europe, Lega Italiana Fibrosi Cistica, Italy, Patients' organisations representative at COMP, EMA UK.*

hampers diagnosis and development of effective treatments.[2]

The effects of rare diseases on the wellbeing of patients and their families are profound and continue throughout the entire patient's life. The first challenge faced by rare disease patients and their relatives is obtaining an accurate d
lengthy obstacle race c
and public awareness
clinical experience and
by some healthcare p
share feelings of isola
about the condition ar
achieve. More often th
to decades, because s
be too vague or simil

CAMPAIGN FOR ACCESS To MEDICINES FOR PEOPLE WITH RARE DISEASES

EURORDIS
Rare Diseases Europe

feder
entidad de utilidad pública
FEDERACIÓN ESPAÑOLA DE ENFERMEDADES RARAS

Danos tu opinión | ¿Buscas ayuda? | ¿Quieres ayudar?

Descargas
Colaboradores
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Mapa web

Somos la voz de más de 3 millones de personas en España

Enfermedades raras | Actualidad | Quienes somos | Servicios | Testimonios | Movimiento Asociativo | Ayúdanos

Más del 40% de personas con ER no tiene tratamiento

+ A -

Volver

La Federación Española de Enfermedades Raras (FEDER) denuncia que más del 40% de las personas con enfermedades poco frecuentes no dispone de tratamiento o si dispone, considera que no es el adecuado. Y así lo trasladará en el VII Congreso Internacional de Medicamentos Huérfanos y Enfermedades Raras que da comienzo hoy en Sevilla.

Esta problemática, junto con las principales necesidades del colectivo de personas con enfermedades poco frecuentes, fue comunicada al Ministro de Sanidad, Alfonso Alonso, en la reunión que mantuvo con Juan Carrión y Alba Ancochea, Presidente y Directora de la Federación, el pasado 3 de Febrero.

En esta línea, la Federación ha preparado al Ministro un informe donde se recogen los principales datos que reflejan la situación actual con respecto a las prioridades de la Federación en el 2015. Entre estas propuestas se encuentra facilitar el acceso al tratamiento adecuado a las personas con enfermedades poco frecuentes así como garantizar un diagnóstico rápido y riguroso.

"Desde FEDER consideramos que para poder garantizar el acceso a estos tratamientos es necesario asegurar un acceso ágil y equitativo a medicamentos de uso vital para las personas con ER en el Sistema Nacional de Salud (SNS)" incide Juan Carrión.

Una de cada cuatro personas con enfermedades poco frecuentes tiene difícil o imposible acceder a los productos que necesita, por ello FEDER solicita que se armonicen los criterios entre las CCAA y el Ministerio para evitar el retraso y minimizar el riesgo de inequidad frente al acceso a estos tratamientos

La Conferencia EUROPLAN II marca el camino en 2015

El pasado viernes, 21 de Noviembre, tuvo lugar la clausura de la Conferencia EUROPLAN II. A través de este acto se presentaron a la Administración las principales propuestas sobre las líneas de trabajo que deben seguirse para continuar en la mejora de la calidad de vida de las personas con enfermedades...

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Challenges and changes to face up

Affordability

Economic-social context

Regulatory changes

Perspectives of professionals

Mass media

Research impact

Access and inequities

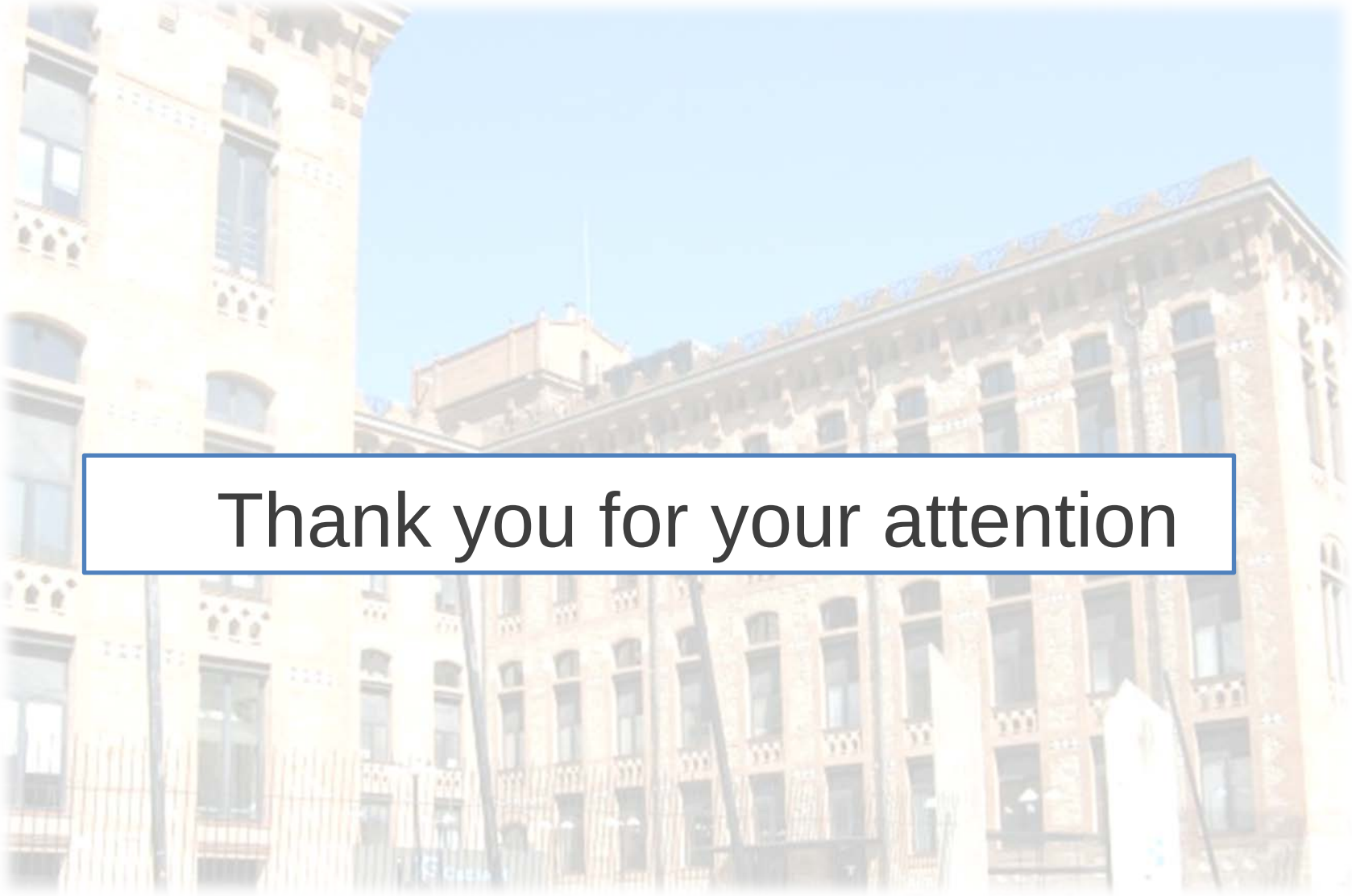
Patients/society expectatives

Some conclusions and food for thought...

- The uptake of innovative medicines has become a challenge that national health systems must face up
- Public health system have to work to response to patients' needs and expectations
- Medicines with high budgetary impact might need special efforts and measures to handle these drugs within each NHS
- Dialogue among all the stakeholders is mandatory to get a success: including active patient participation
- Despite the measures adopted and the outstanding results obtained, the budget impact in hepatitis C treatments is very high. **It would be affordable if several "hepatitis C drugs-like" were approved yearly?**
- Additionaly, **how to manage extremely high budgetary impacts when the outcomes are often modest (like observed for some orphan drugs)?**

Medicines and public health systems: ¿which is the destination?

Destiny must be a system that allows the incorporation of **innovation** that presents **added value**, **sustainable** for health systems and focused on the **needs of patients**


Thank you for your attention