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European Federation of Pharmaceutical Industries and Associations

LESSONS FROM EUROPE

* October 6, 2015






* EFPIA Japan Days

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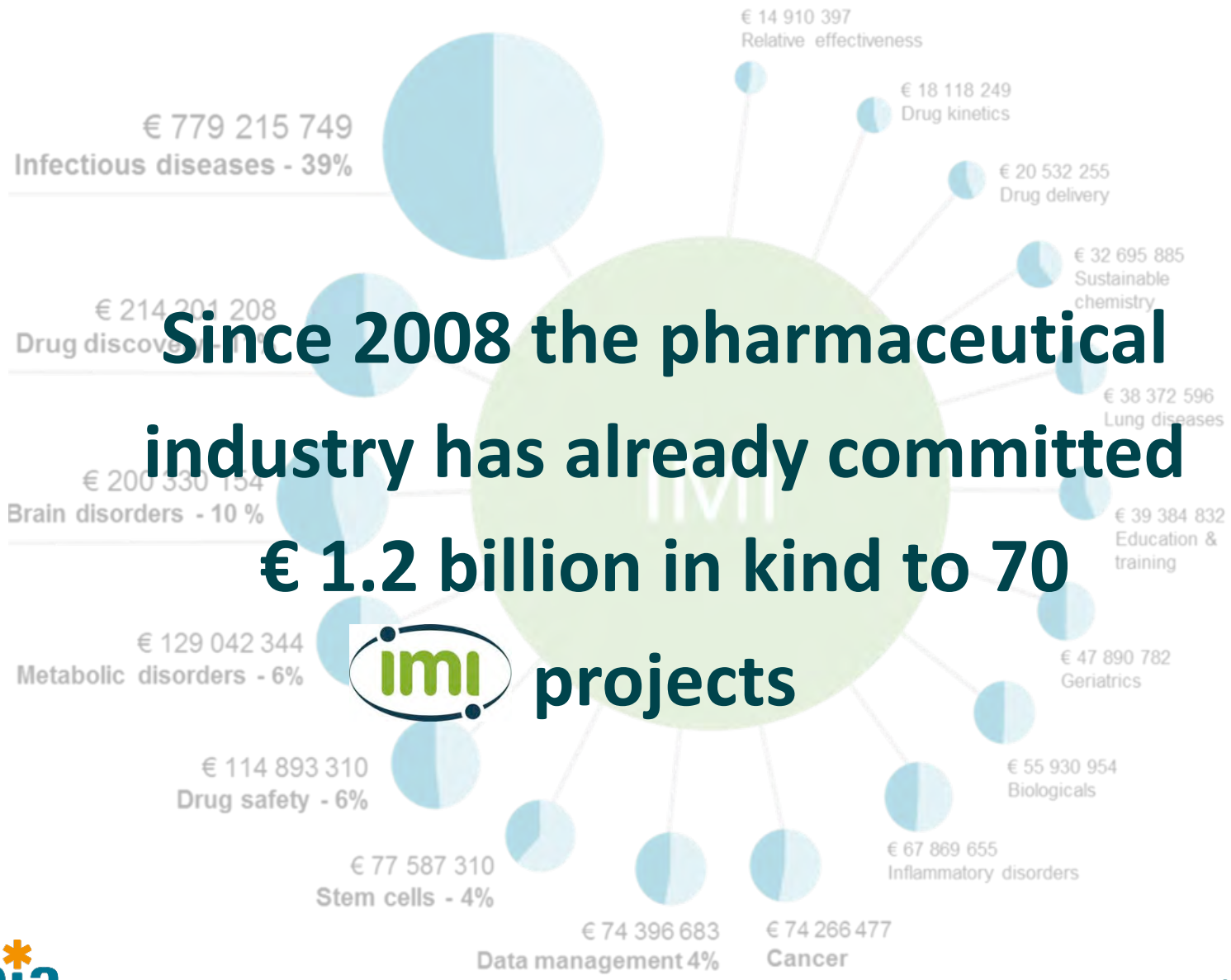
www.efpia.eu

The Innovative Medicines Initiative: the largest public-private partnership for health research worldwide

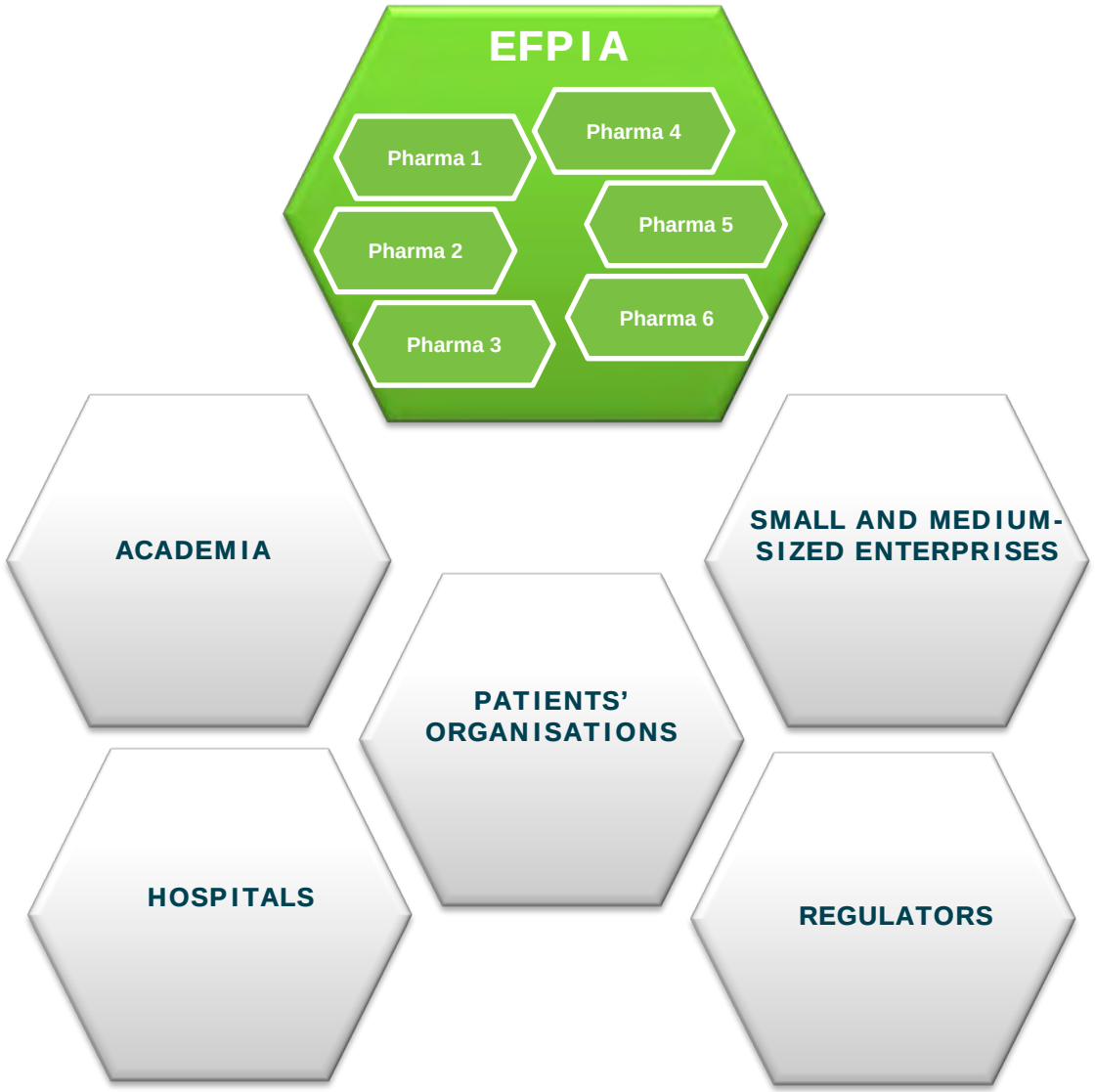
tackles grand health & societal challenges

Ebola	Resistant infections	Dementias	Diabetes
Pain	Safety	Prevention	Health outcomes
Big Data	Early Patient Access	Environment	3Rs



Since 2008 the pharmaceutical industry has already committed € 1.2 billion in kind to 70 projects

a typical IMI consortium



over 7000 researchers
59 public-private consortia

Towards integrated healthcare solutions

Focused: stratified medicines and healthcare priorities

Healthcare solutions: **prevention** and **treatment**

End-to-end: R&D, regulatory, access/healthcare practice

Collaborations across stakeholders groups: regulators, payers, users,

Multi-sector: within and beyond life sciences to develop and test new ideas in real life conditions

*Priority medicines for Europe and the World

Overview

- **A neutral platform** to engage with public partners (R&D, patients, regulators, health authorities...) to resolve their and industry problems at the same time

- **A source of funding for pharmaceutical research** – all activities carried by public partners in the public-private consortium are financed by the EU

- **An industry driven agenda:** the industry defines the agenda and the topics, but the consortium is an “arranged marriage” – and it works!

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Experience with HTA in Europe






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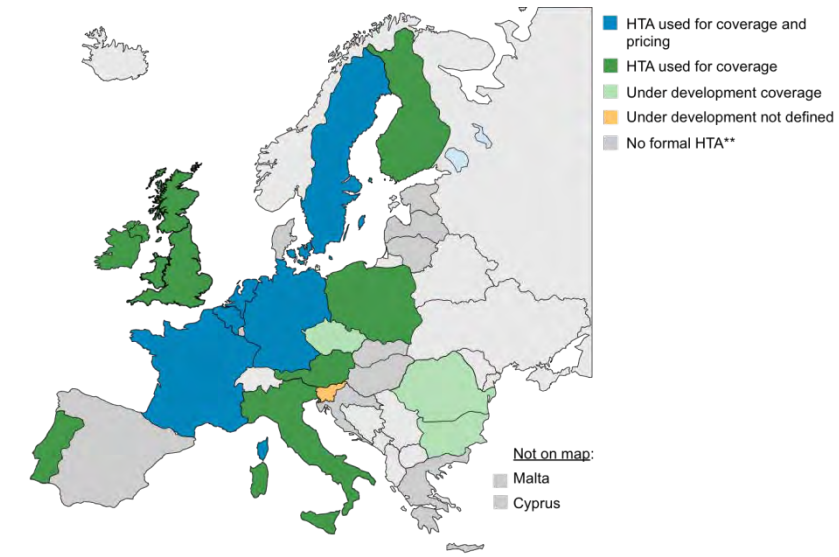
HTA vs International Reference Pricing



Source: CRA expertise; *UK has been divided in England and Scotland; **At national level

International Referencing Price rules in Europe

Country	IRP used	Formal/ Informal	Calculation used	Price referenced	Medicines	Frequency of re-referencing (months)	Number of reference countries (Basket)	Number of times the country is referenced
Austria	Y	F	Average	MNF	Reimbursed	_	26	16
Belgium	Y	I	Average	MNF	Reimbursed	Undefined	6	16
Bulgaria	Y	F	Lowest	MNF	POM	6	17	11
Croatia	Y	F	90% of AVG of 3	PPP		12	3	4
Cyprus	Y	F	Average	PPP	Imported Med	12	4	10
Czech Republic	Y	F	Avg lowest 3	MNF	All	36	20	14
Denmark	Y	I	Avg price	PPP	Hospital-only	_	9	15
Estonia	Y	F	Lowest	MNF	Reimbursed	6	3	12
Finland	Y	I	No calculation scheme	PPP	Reimbursed	Up to 60	29	14
France	Y	I/F	Average	MNF	Innovative Med	60	4	19
Germany	Y	I	Not defined	MNF	Innovative Med	_	15	17
Greece	Y	F	Avg lowest 3	MNF	All	6	22	14
Hungary	Y	F	Lowest	PPP	Reimbursed	12	30	14
Ireland	Y	F	Average	MNF	Innovative Med	24	9	13
Italy	Y	I/F	Average	MNF	Reimbursed	24	26	13
Latvia	Y	F	Third lowest	MNF	Reimbursed	12	30	13
Lithuania	Y	F	Average	MNF	Reimbursed	12	8	14
Luxembourg	Y	I	Average	MNF	All	18	_	9
Malta	Y	F	Average	MNF	All	18	11	9
Netherlands	Y	F	Average	PPP	POM	6	4	15
Norway	Y	F	Avg lowest 3	PPP	POM	12	9	3
Poland	Y	I	Benchmark in negotiations	MNF	Reimbursed	24	30	13
Portugal	Y	F	Average	MNF	POM	12	3	13
Romania	Y	F	Lowest	MNF	Reimbursed	12	12	11
Slovakia	Y	F	Avg lowest 3	MNF	Reimbursed	6	26	14
Slovenia	Y	F	Lowest	MNF	Reimbursed	6	3	13
Spain	Y	I	Lowest	MNF	Innovative Med	_	17	15
Sweden	N	_	_	_	_	_	_	13
Switzerland	Y	F	Average	MNF		36	6	
UK	Y	I	_	_	_	_	_	17

Comparison: recent German vs. French evaluations

Comparison of Product Evaluations and Reimbursement Price Achieved (launches from 2011-2013)

	G-BA Rating[1]	HAS ASMR Rating	Negotiated reimbursed price
Zelboraf	Considerable	Moderate	-53
Gilenya	Minor	Minor	-31
Esbriet	Not Quantifiable	Minor	-27
Victrelis	Not Quantifiable	Moderate	-21
Brilique	Considerable	Minor	-11
Halaven	Minor	Minor	-8
Incivo	Not Quantifiable	Moderate	-8
Yervoy	Considerable	Minor	-7
Zytiga	Considerable	Moderate	-4
Edurant	Minor	No add. benefit	25
Eviplera	Minor	No add. benefit	27

Lower price in DE than FR

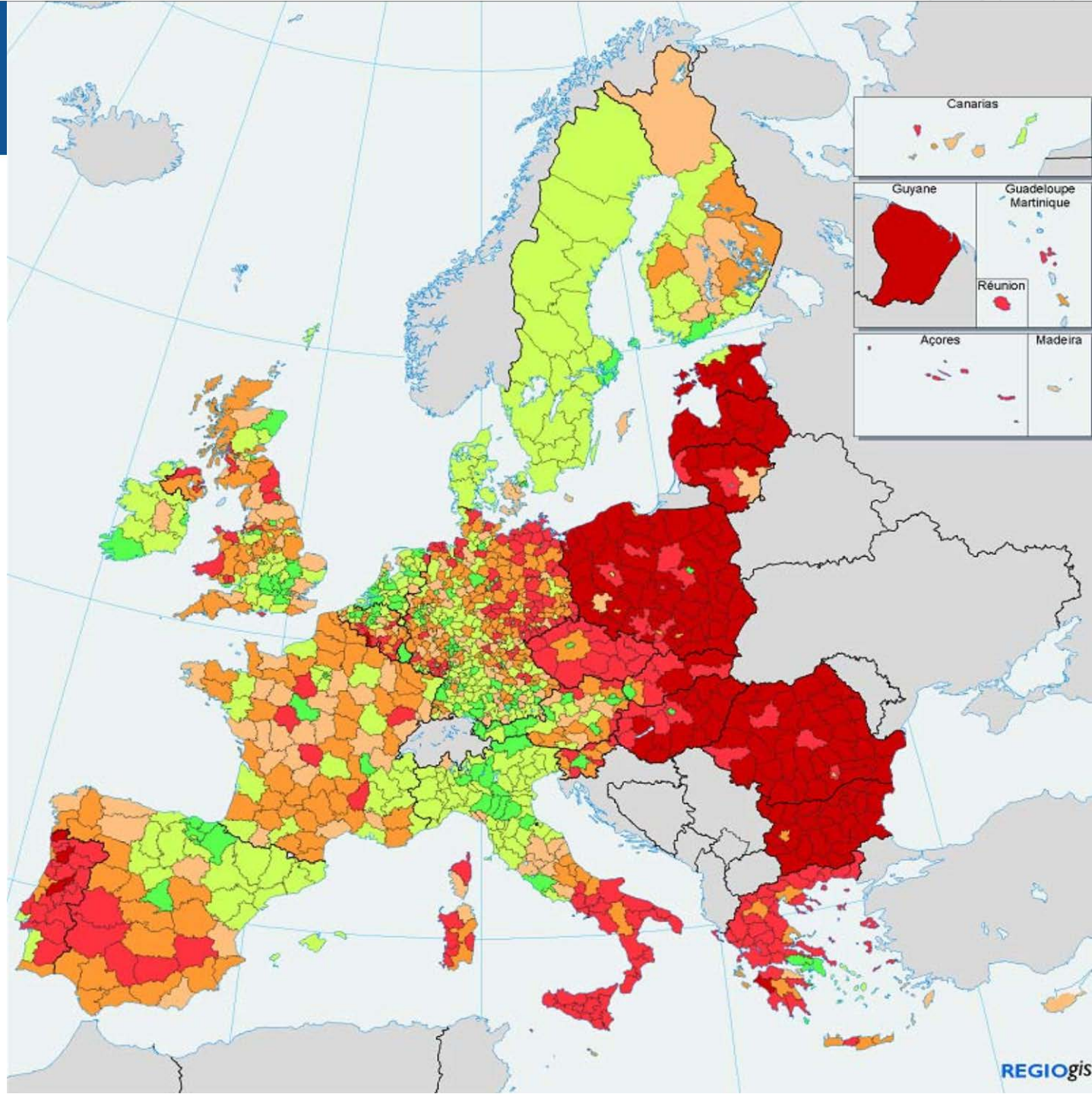
Lower price in FR than DE

[1] Rating is the final G-BA rating given after initial IQWiG assessment

Source: IMS Consulting Group analysis, GBA, ASNM

- Scores suggest G-BA ratings are more positive than ASMRs
- Factors include benefit in sub-populations & comparator choice
- Recent German assessments resulted in lower prices than lower ASMRs in France, even when German rating was higher than French ASMR
- Only in extreme cases, where the French evaluation finds no additional benefit and GBA is positive, German reimbursed prices exceeded those in France

GDP/head(PPS) of NUTS3 regions



Despite current heterogeneity: agreement to work together

- No agreement on standards for economic evaluation (UK, Sweden, Germany, France all different); and differences in ability to pay
- Free movement of people allows for cross-border health care, and can justify collaboration on HTA
- Recent experience shows that negotiations ("business to business") more important; health economics can at most inform a multi-criteria decision model
- For medicines: consensus that countries should collaborate on a report on relative efficacy at the time of launch, excluding economic considerations
- European Commission plans Joint Action with countries (building on EUnetHTA, to prepare for "joint work from 2020"
- Increased focus on managed entry agreements (to handle scientifiv and economic uncertainty); a life-cycle approach; and real-world evidence (closely linked to evolution of regulatory science).

Shaping European Relative Efficacy Assessment to improve access to medicines in Europe

European access problem	* Large access differentials across Europe * New medicines reach some countries with long delays * In some countries, certain products are not available at all
driven by fragmented clinical assessments	* Different assessment approaches lead to inconsistent access decisions * Inconsistent evidence requirements create duplication and market access delays
European assessment can improve access	* Harmonisation of data requirements and assessment approach can accelerate assessments and end duplication * EU-wide view on clinical performance can reduce access differentials
if performed in parallel to market authorisation and in lieu of national assessment	* European clinical assessment must be separate from marketing authorization process, but done concurrently to save time * It must be integrated in national market access processes to avoid duplication
covering clinical aspects only	* Economic assessments must be local to account for diversity in health systems * Industry remains opposed to economic value assessment at EU level

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Thank You!






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