Erasmus School of
Health Policy
& Management

Access and prices across the EU Affordability and sustainability of innovative medicines

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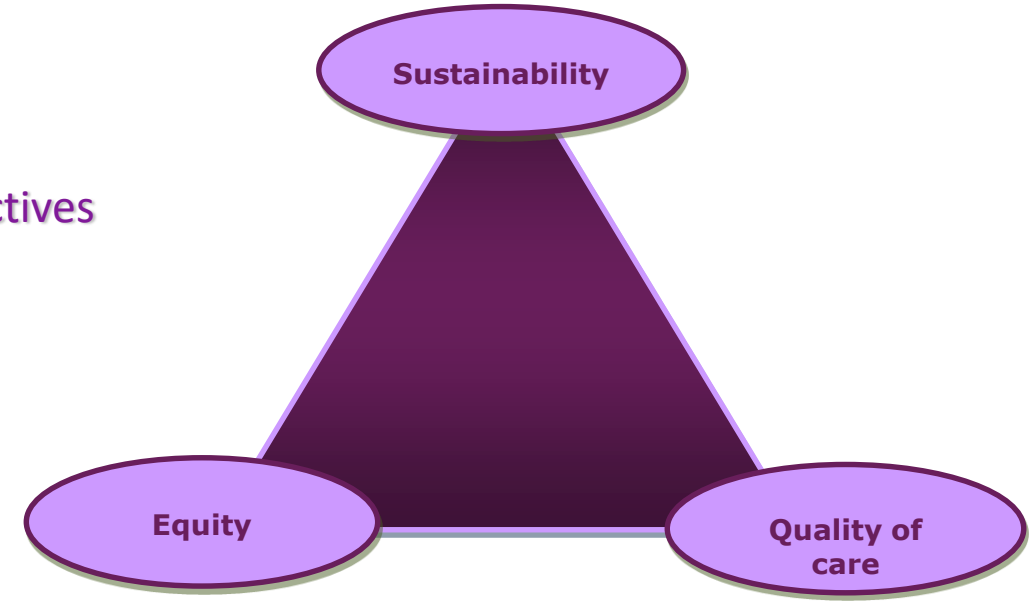
European Parliament, December 4, 2019

Erasmus University Rotterdam

Policy goals in health care

System objectives



Goal:
Ensuring affordable and equitable access for (all) patients to effective therapies in a sustainable manner

The good news (1)…..

Cancer survival in Europe 1999–2007 by country and age: results of EUROCARE-5—a population-based study

*Roberta De Angelis, Milena Sant, Michel P Coleman, Silvia Francisci, Paolo Baili, Daniela Pierannunzio, Annalisa Trama, Otto Visser, Hermann Brenner, Eva Ardanaz, Magdalena Bielska-Lasota, Gerda Engholm, Alice Nennecke, Sabine Siesling, Franco Berrino, Riccardo Capocaccia, and the EUROCARE-5 Working Group**

Summary

Background Cancer survival is a key measure of the effectiveness of health-care systems. EUROCARE—the largest cooperative study of population-based cancer survival in Europe—has shown persistent differences between countries for cancer survival, although in general, cancer survival is improving. Major changes in cancer diagnosis, treatment, and rehabilitation occurred in the early 2000s. EUROCARE-5 assesses their effect on cancer survival in 29 European countries.

Methods In this retrospective observational study, we analysed data from 107 cancer registries for more than 10 million patients with cancer diagnosed up to 2007 and followed up to 2008. Uniform quality control procedures were applied to all datasets. For patients diagnosed 2000–07, we calculated 5-year relative survival for 46 cancers weighted by age and country. We also calculated country-specific and age-specific survival for ten common cancers, together with survival differences between time periods (for 1999–2001, 2002–04, and 2005–07).

Findings 5-year relative survival generally increased steadily over time for all European regions. The largest increases from 1999–2001 to 2005–07 were for prostate cancer (73·4% [95% CI 72·9–73·9] *vs* 81·7% [81·3–82·1]), non-Hodgkin lymphoma (53·8% [53·3–54·4] *vs* 60·4% [60·0–60·9]), and rectal cancer (52·1% [51·6–52·6] *vs* 57·6% [57·1–58·1]). Survival in eastern Europe was generally low and below the European mean, particularly for cancers with good or intermediate prognosis. Survival was highest for northern, central, and southern Europe. Survival in the UK and Ireland was intermediate for rectal cancer, breast cancer, prostate cancer, skin melanoma, and non-Hodgkin lymphoma, but low for kidney, stomach, ovarian, colon, and lung cancers. Survival for lung cancer in the UK and Ireland was much lower than for other regions for all periods, although results for lung cancer in some regions (central and eastern Europe) might be affected by overestimation. Survival usually decreased with age, although to different degrees depending on region and cancer type.

Findings: 5-year relative survival generally increased steadily over time for all European regions.

Lancet Oncol 2014; 15: 23–34
Published Online December 5, 2013
http://dx.doi.org/10.1016/S1470-2045(13)70546-1

See Comment page 2
See Articles page 35
See Online for an author interview with Roberta de Angelis

*Members of the EUROCARE-5 Working Group are listed in the appendix

Centro Nazionale di Epidemiologia, Sorveglianza e Promozione della Salute, Istituto Superiore di Sanità, Rome, Italy (R De Angelis MSc, S Francisci PhD, D Pierannunzio PhD, R Capocaccia MSc); **Analytical Epidemiology and Health Impact Unit** (M Sant MD, P Baili MSc), **Evaluative Epidemiology Unit** (A Trama MD, F Berrino MD), **Department of Preventive and**

De Angelis et al. Lancet Oncology 2014;15:23-34

The good news (2): Many innovative (cancer) drugs

OPDIVO™
(nivolumab)
INJECTION FOR INTRAVENOUS USE 10 mg/mL

ORKAMBI®
(lumacaftor/ivacaftor)
200/125 mg • 100/125 mg tablets

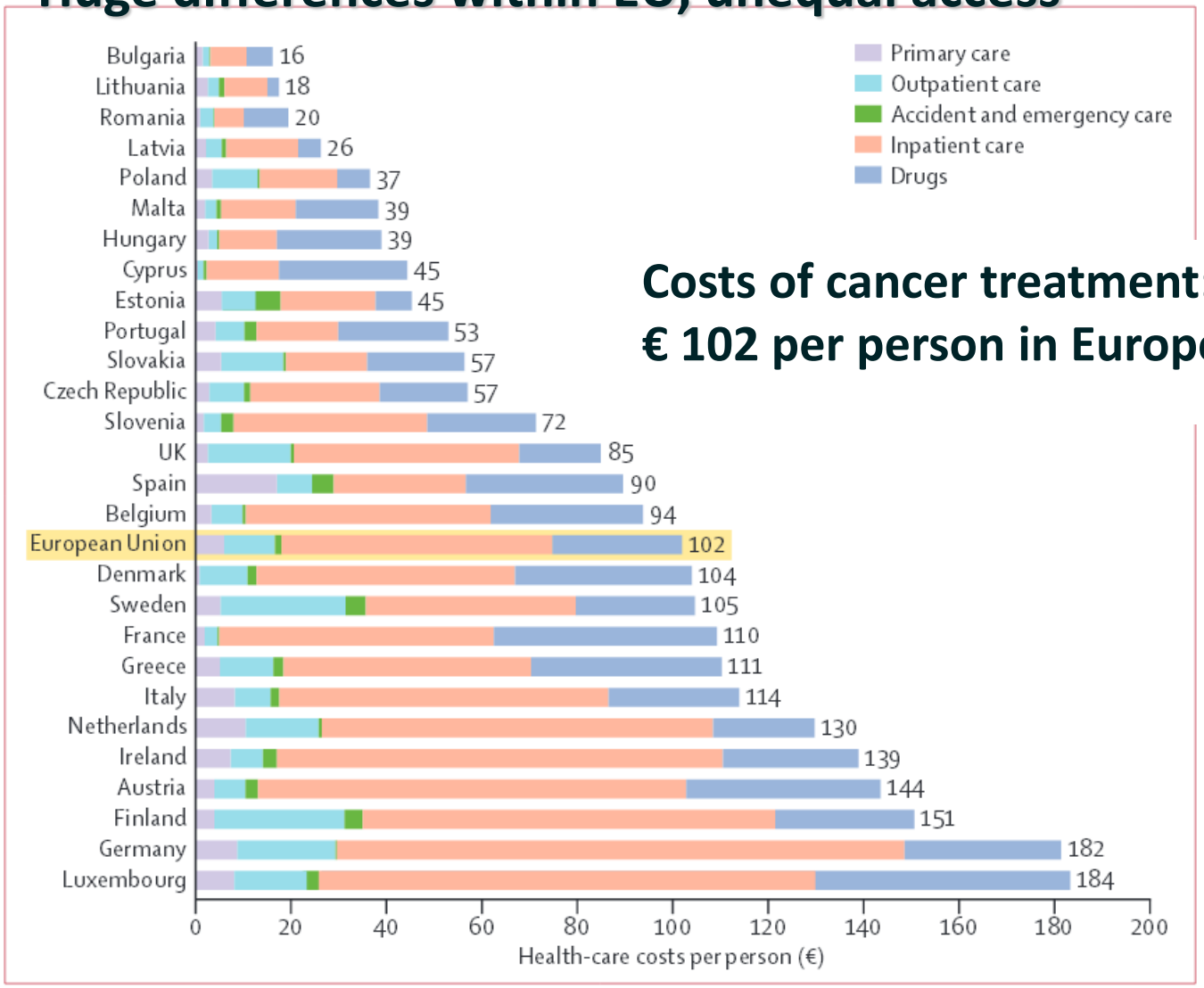
The bad news (1):

Rise in health expenditures 2000-2015 as share Gross Domestic Product (GDP)

Country	**2000**	**2005**	**2010**	**2015**
Austria	9.2	9.6	10.1	10.4
Czech Republic	5.7	6.4	6.9	7.5
Denmark	8.1	9.1	10.4	10.6
France	9.5	10.2	10.7	11.0
Germany	9.8	10.2	11.0	11.1
Ireland	5.9	7.7	10.6	9.4
Netherlands	7.1	9.4	10.4	10.8
Norway	7.7	8.3	8.9	9.9
Poland	5.3	5.8	6.4	6.3
Spain	6.8	7.7	9.0	9.0
United Kingdom	6.3	7.4	8.5	9.8
Average EU	**7.3**	**8.2**	**8.9**	**9.0**

The bad news (2):

Huge differences within EU, unequal access



Costs of cancer treatment:
€ 102 per person in Europe

Figure 1: **Health-care costs of cancer per person in European Union countries in 2009, by health-care service category**
Data not adjusted for price differentials.

Luengo-Fernandez et al. Lancet Oncology 2013;14:1165-1174

Result budget problems

The Netherlands (2014): € 530 million spent on new cancer drugs
Maximum growth budget per year: 1.2%

New cancer drugs 2016	Estimated costs per	ICER	Estimated budget impact
Nivolum			200 mln
Pertuzumab	€ 78.000	€ 150.000	€ 40 mln
Ibrutinib	€ 70.000	Unknown	€ 100 mln
Palbociclib	Unknown	Unknown	€100 mln
CAR-T cells	€300-400.000	Unknown	Unknown

Opportunity cost

Affordable (expensive) therapies

Thanks to Matthijs Versteegh

etherlands

3,000 patients

AD

€80,000 per patient

AD

Survival gain of 3 months (median)

AD

Too expensive?

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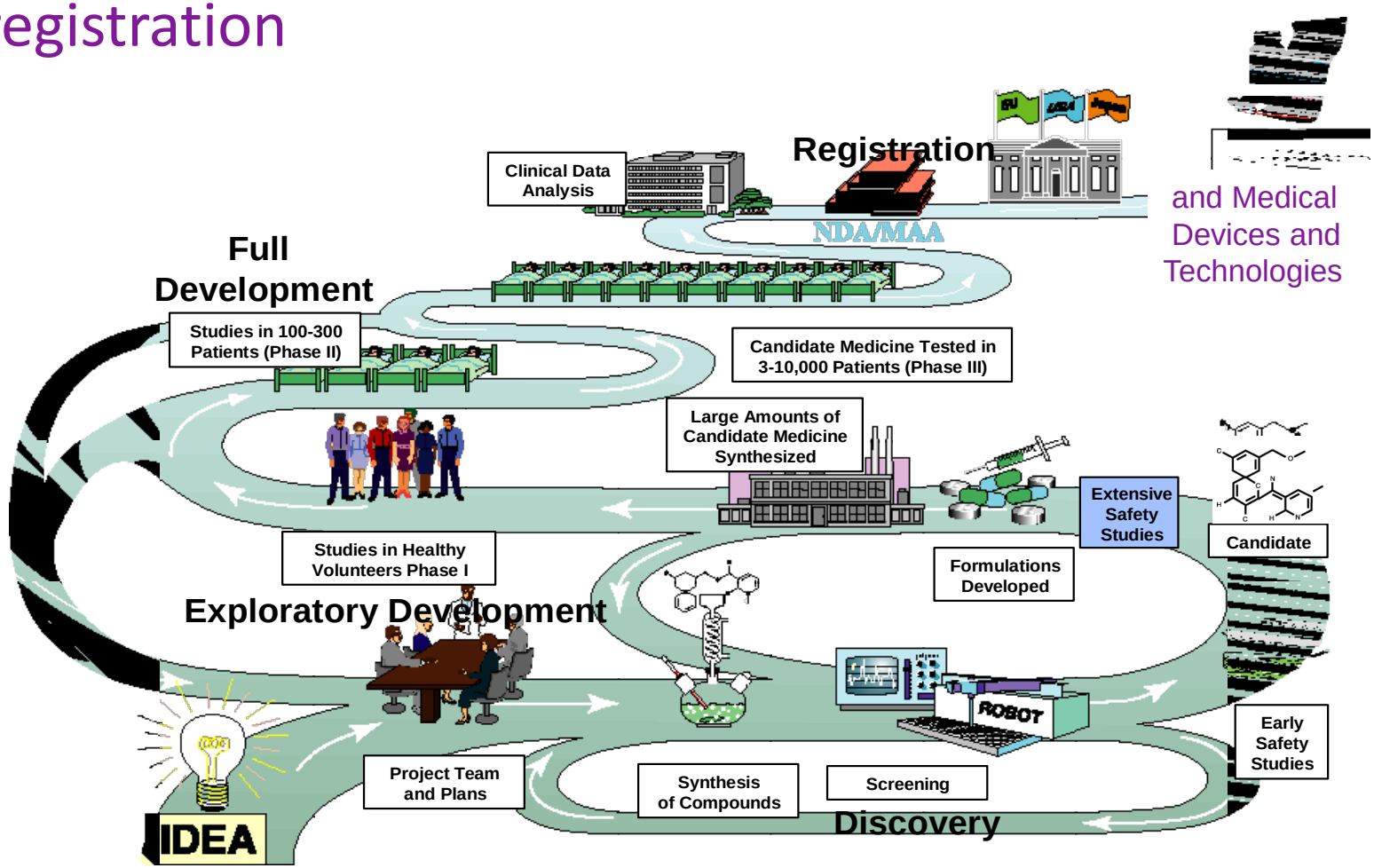
Opportunity costs

What we give to patient A, we cannot give to patient B.

Given a **limited health care budget** (or a limited willing to pay a higher premium) it is **unethical** not to make a societal decision.

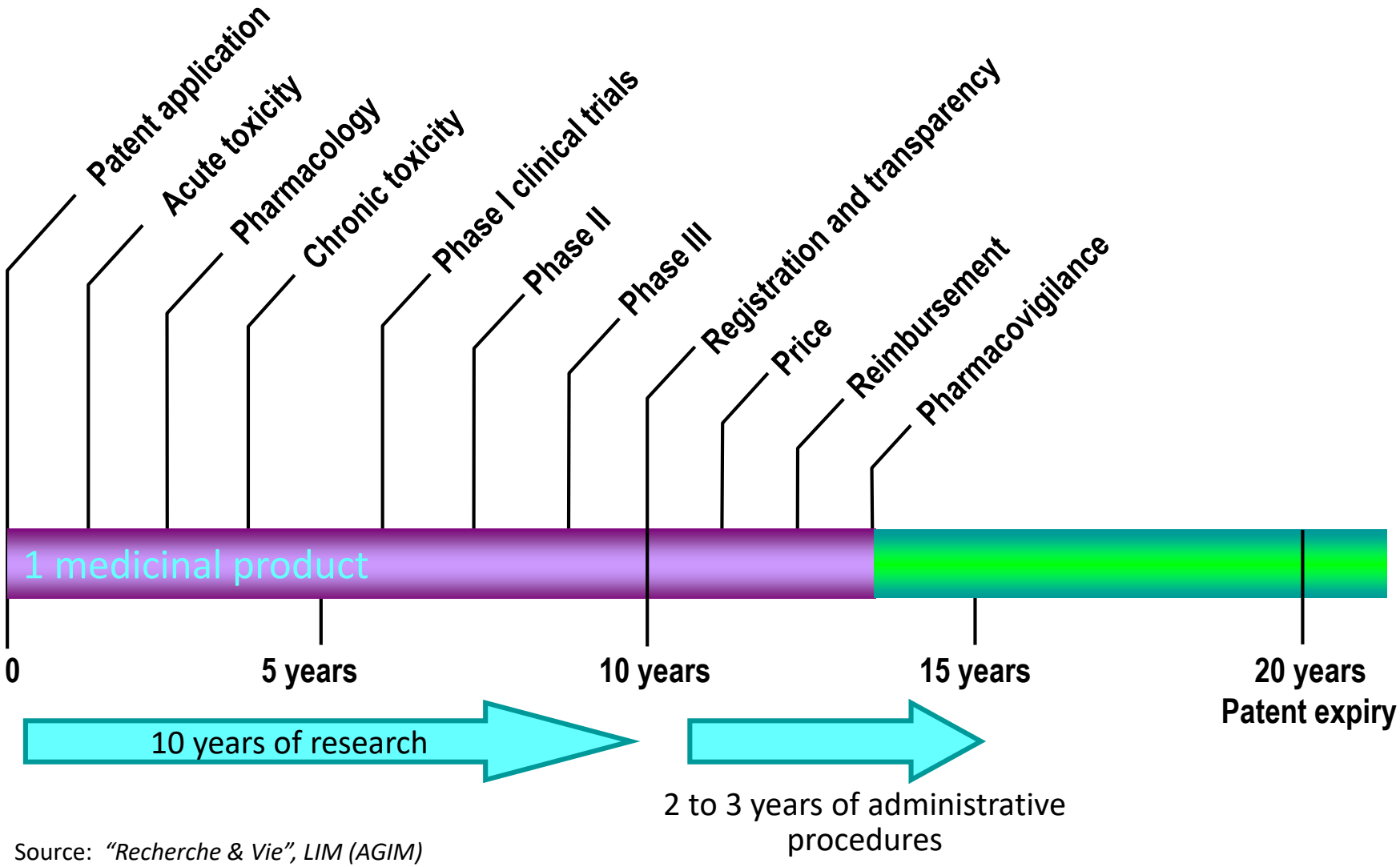
Problem is a EU / worldwide problem

Why is it expensive?
Development phase: a long and winding road to registration



Pfizer -- http://www.pfizer.co.uk/pfizer_uk/navigation/research_frame.htm

Development phase
From discovery to patient



Source: *"Recherche & Vie", LIM (AGIM)*

Costs of development new drug

Cost factors:

- R&D (including failures)
- Manufacturing
- Marketing and promotion

- Estimation: 300 million -2.6 billion dollars

Worldwide total revenues of leading pharmaceutical companies in 2014 (in billion dollars)

Company		Total revenue ($)	R&D costs ($)	Sales and Marketing costs ($)	Other activitiescosts* ($)	Profit ($)	Profit Margin (%)
1.	Johnson & Johnson	71.3	8.2	17.5	31.8	13.8	19
2.	Novartis	58.8	9.9	14.6	25.1	9.2	16
3.	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	3
4.	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	4
5.	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	1
6.	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	0
7.	GSK	41.4	5.3	9.9	17.7	8.5	21
8.	AstraZeneca	25.7	4.3	7.3	11.5	2.6	10
9.	Eli Lilly	23.1	5.5	5.7	7.2	4.7	20
10.	AbbVie	18.8	2.9	4.3	7.5	4.1	22
Total Top 10 global companies Percentage of total revenue – profit		429.4	65.8 (19%)	98.3 (29%)	175.5 (52%)	89.8	20.9

Pharma highest profit: 20%, followed by banks 10%

*Other activities' costs = Total revenue – R&D costs – Sales and marketing costs. Overhead costs are included in R&D, sales and marketing and other activities.

Systems are not sustainable so:

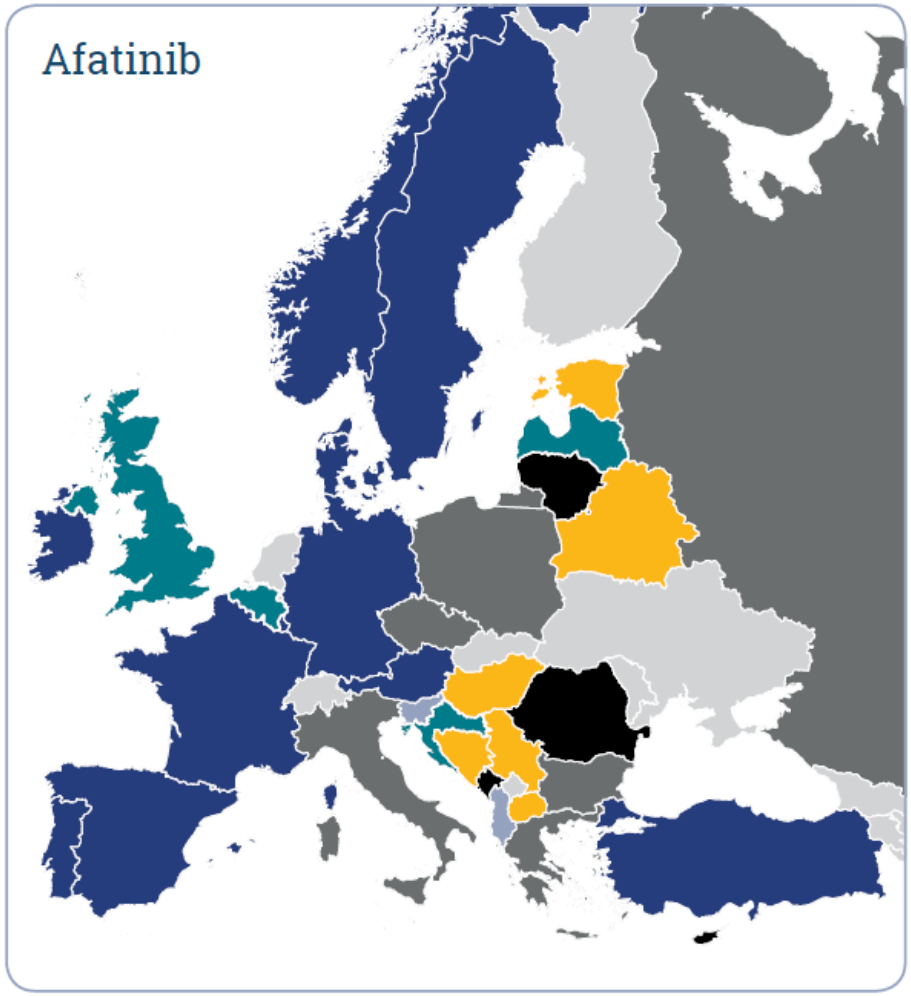
How to reduce spending?

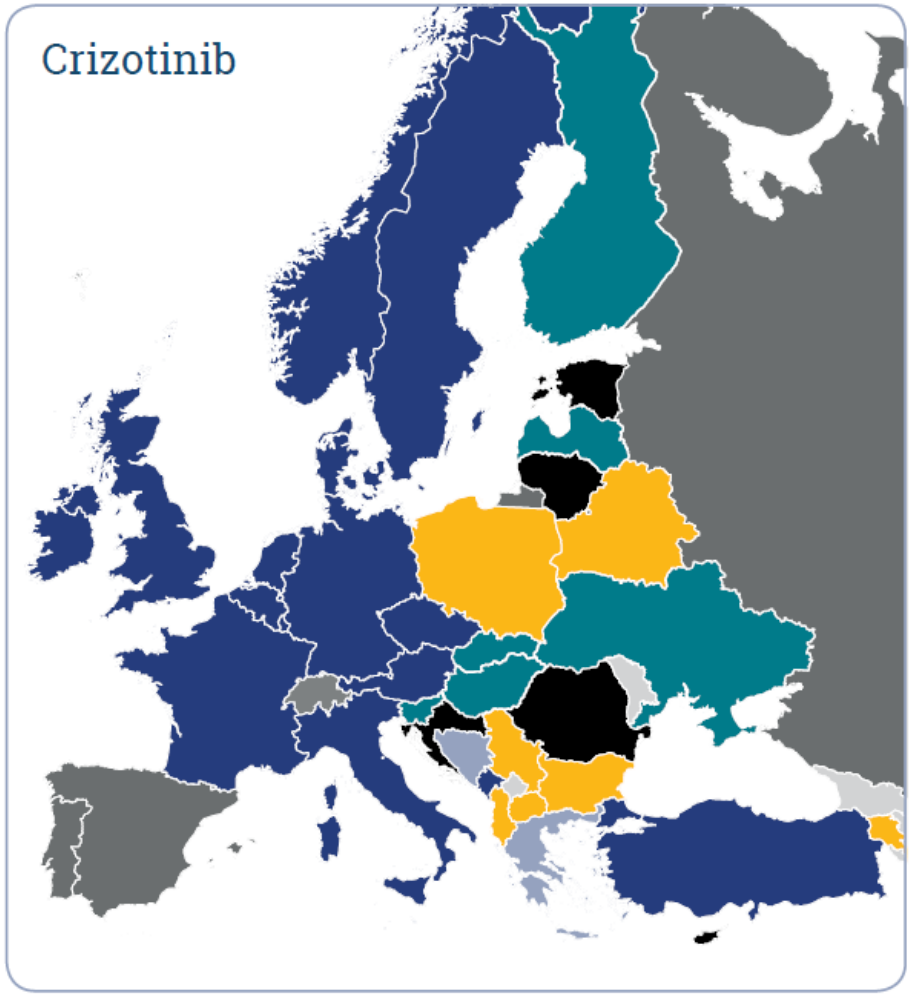
- Shift from expensive to cheap technologies
- Make patients or the insurance pay a larger part
- Reduce the **prices of drugs**
- Reduce the total use of drugs

- Focus on reduction of prices
- However, also issue of **unequal access across Europe**

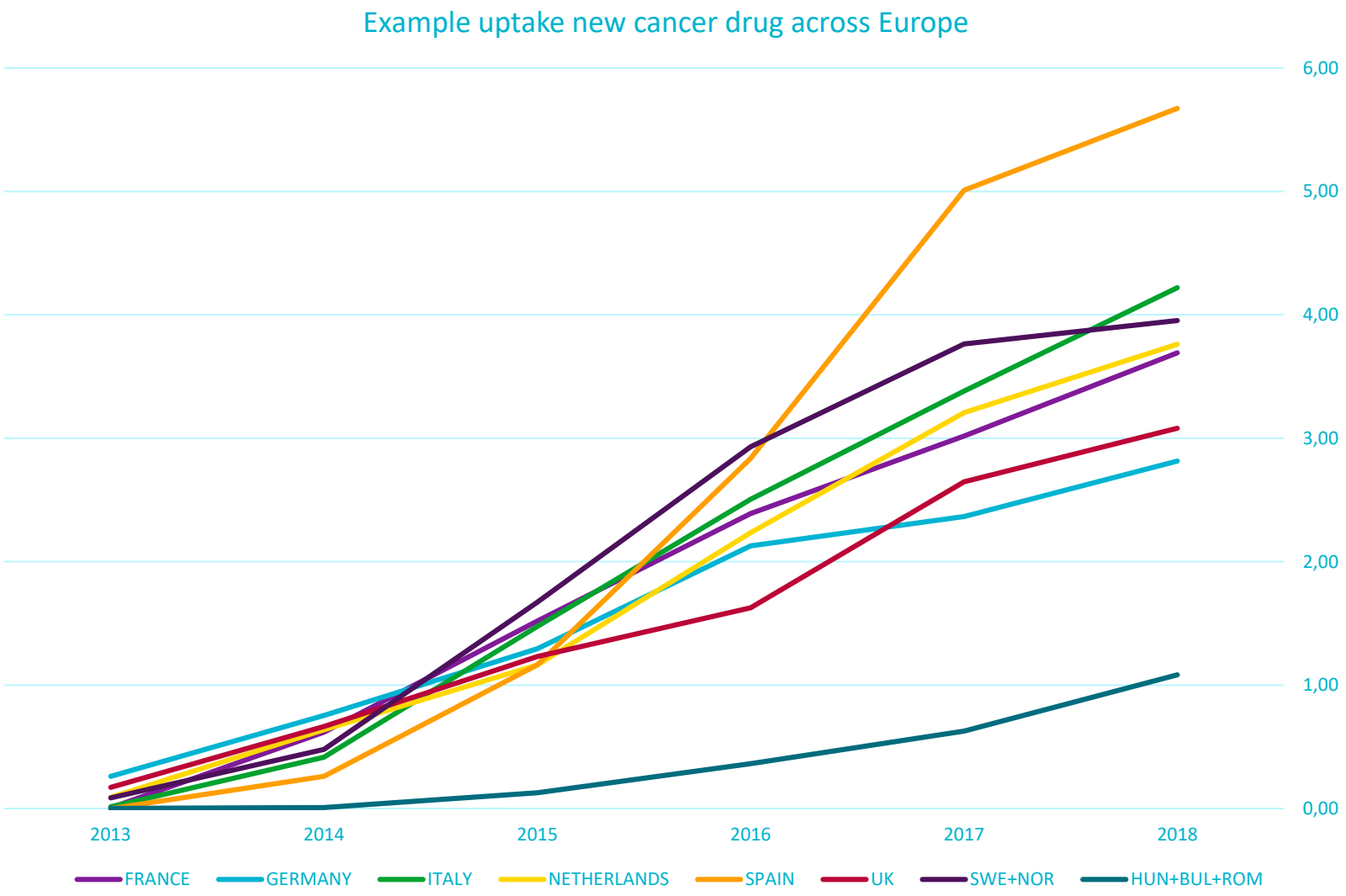
Availability of 2 cancer drugs

Source: ECL report, October 2018

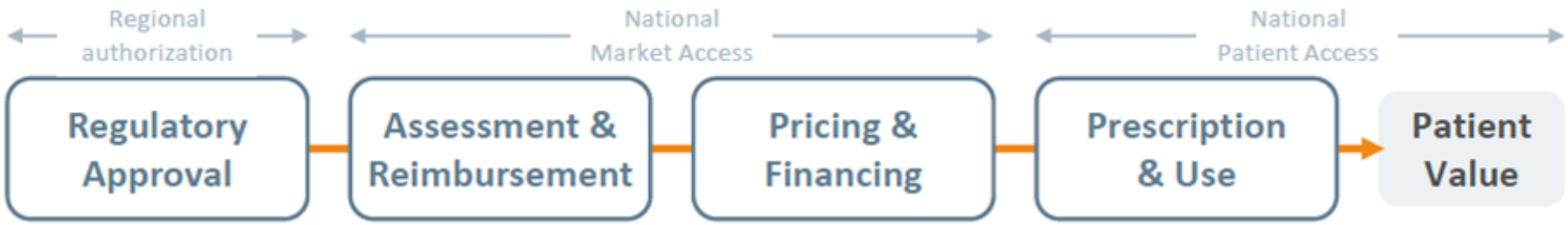




Always | Usually | Half of the time | Occasionally | Never | Not Available | No Data


Example uptake new cancer drug across Europe
6,00
5,00
4,00
3,00
2,00
1,00
0,00
2013
2014
2015
2016
2017
2018
FRANCE
GERMANY
ITALY
NETHERLANDS
SPAIN
UK
SWE+NOR
HUN+BUL+ROM

PATIENT ACCESS PATHWAY



Value based pricing

Incremental cost-effectiveness ratios: Cost per QALY gained

Thresholds

- NICE: £ 30.000, US: US$ 50-100.000
- WHO threshold: depend on WHO region and Gross Domestic Product (GDP)

Still budget impact problem.

Pay for performance (P4)

- Reimbursement dependent on treatment success

Volume-price arrangements

- sales < Y price P1; sales > Y lower price P2

Rationale for adapting the business model of (cancer) drug pricing

Issues:

1. A free market does not work for innovative (cancer) drugs
    - *Informational imbalance*
    - *Failure of competition*
2. Current cancer drug prices not justified by Research and Development (R&D)
3. Country specific solutions did not solve the problem
    - EUNeHTA
4. Restricted access to innovative drugs

New pricing model innovative (cancer) drugs:

https://www.youtube.com/watch?v=znTgYPRWyrA

News and Views | 7 May 2018

Sustainability and affordability of cancer drugs: a novel pricing model

Carin A. Uyl-de Groot & Bob Löwenberg

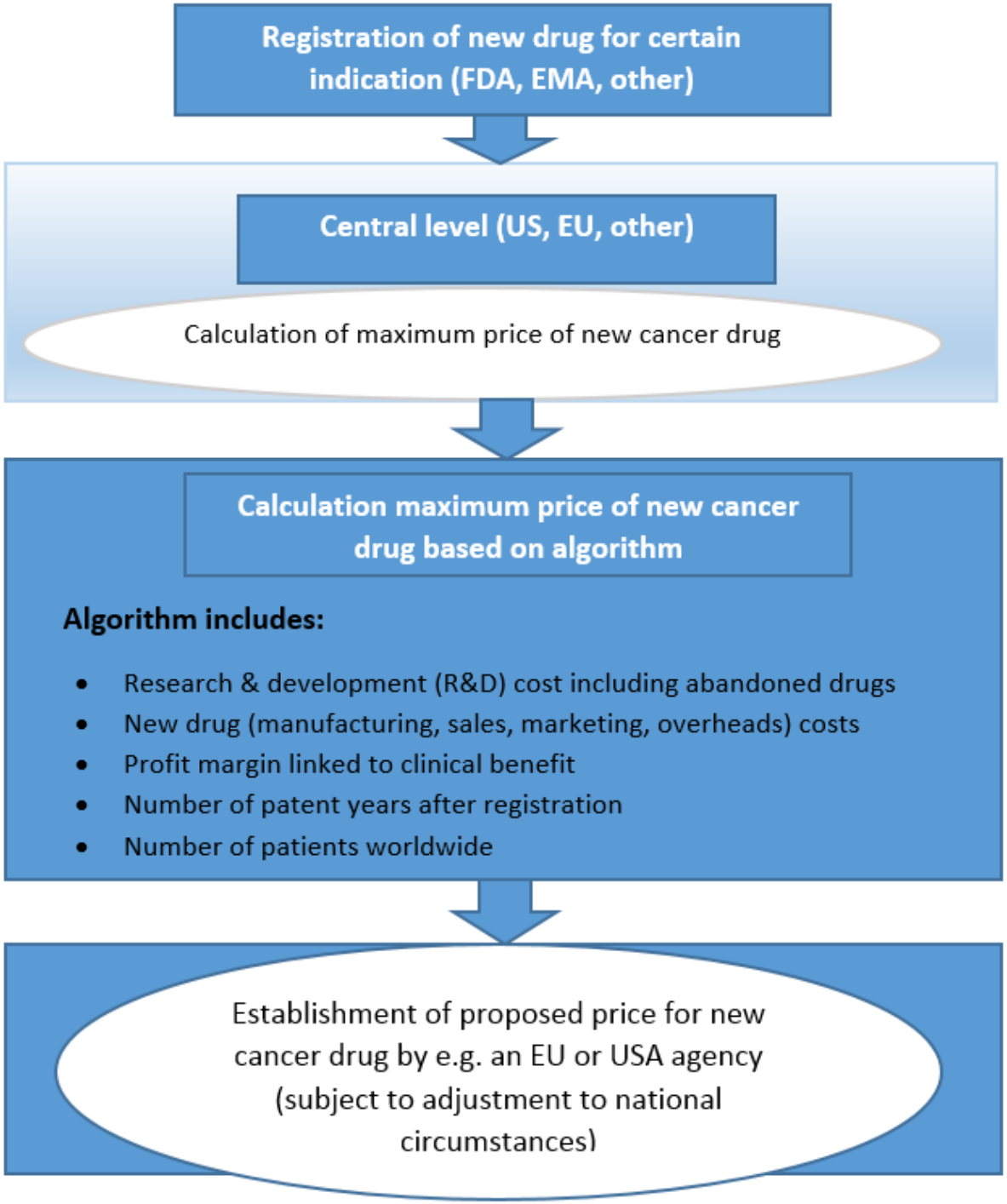
Nature Reviews Clinical Oncology **15** , 405–406

The algorithm

$$\text{Fair Cost of New Medicine} = \left[\frac{\text{R\&D costs}}{\text{nr. of patients} \times \text{years of patent left}} + \text{production costs per patient per year} \right] \times (1 + \text{profit margin})$$

Carin A. Uyl-de Groot and Bob Löwenberg, Sustainability and affordability of cancer drugs: a novel pricing model. *Nature Reviews,* July 2018. [link]

Outline adapted business model of (cancer) drug pricing



Ongoing debate and progress

Meetings with the European Parliament

- Resolution: transparency R&D costs, discounts (2017)
- White paper access to medicines (October 2018)

Dutch Ministry of Health: BeNeLuxAI
ESMO: access to medicine hot topic
EHA: task force fair prices

Patient organizations: e.g. Inspire2Live

Pharmaceutical companies (improving access/uptake)

Collaboration with other organizations:

- Fair Medicine

Measures needed at different levels (national, European), but barriers and limitations

Access issue is broader than discussion about drug prices

Change health systems/legislation: will take years

- Patient's right to health – right to have access to optimal quality of cancer care
- Collaboration between all stakeholders, including pharmaceutical companies
- Encourage joint negotiations

Health systems:

Take home message

- Faster access to new (cancer) therapies
- Better access to new (cancer) therapies
- Lower prices for new (cancer) therapies

It is not a utopia.

THANK YOU