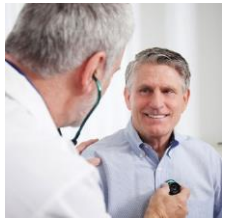
European Federation of Pharmaceutical Industries and Associations

EU pharmaceutical policy






Edith Frénoy, EFPIA Director
Market Access, HTA policy lead

College of Parma, 9 April 2019

INTRODUCTION

Declaration of interest – Edith Frénoy

I am a full-time employee of EFPIA

I declare having no direct/indirect financial interest in any life-science company

This slide deck includes EFPIA policy positions and analysis – not all slides are available in the public domain – they should therefore not be shared

When expressing personal opinions, I will clearly indicate so

Structure of presentation

1. About EFPIA
2. Key challenges (2019-2020)
3. Focus on P&R and HTA
4. Looking ahead

But first a question – question 1

What is your key take-away from this morning's session?

What's the role of the EU in healthcare/pharmaceutical policy?

Our network

2
specialised groups

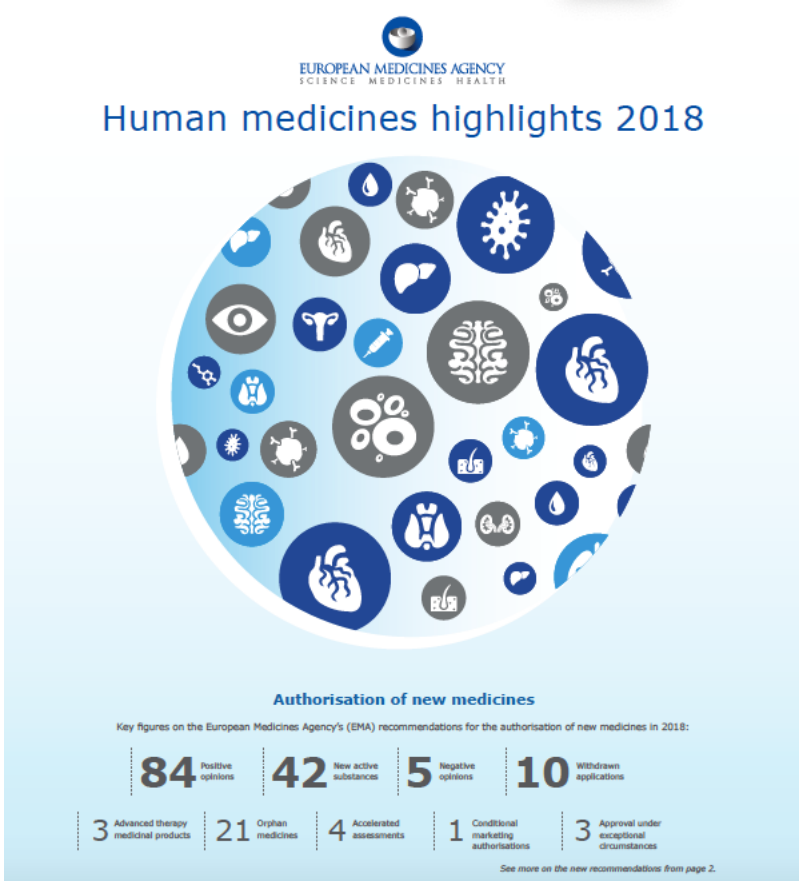
Our vision

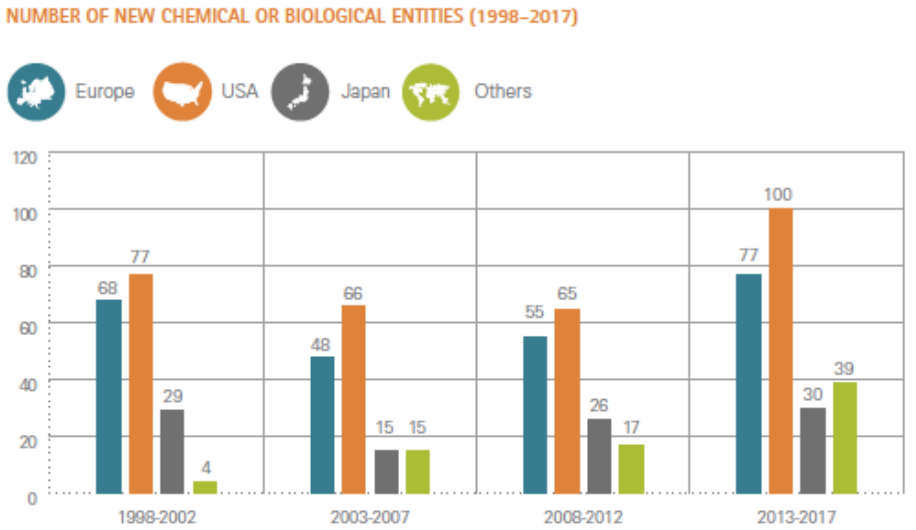
EFPIA's vision is for a healthier future for Europe. A future based on prevention, innovation, access to new treatments and better outcomes for patients.

Our mission

EFPIA's mission is to create a cooperative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy.

Delivering innovative medicines





Source: SCRIP – EFPIA calculations (according to nationality of mother company)

Contribution to the economy

INDUSTRY (EFPIA total)	2000	2010	2016	2017
Production	127,504	199,400	248,053	258,000 (e)
Exports (1) (2)	90,935	276,357	373,333	385,000 (e)
Imports	68,841	204,824	278,462	287,000 (e)
Trade balance	22,094	71,533	94,871	98,000 (e)
R&D expenditure	17,849	27,920	33,949	35,200 (e)
Employment (units)	554,186	670,088	747,607	750,000 (e)
R&D employment (units)	88,397	117,035	112,425	115,000 (e)
Total pharmaceutical market value at ex-factory prices	89,449	153,685	199,234	207,000 (e)
Payment for pharmaceuticals by statutory health insurance systems (ambulatory care only)	76,909	129,464	133,203	137,000 (e)

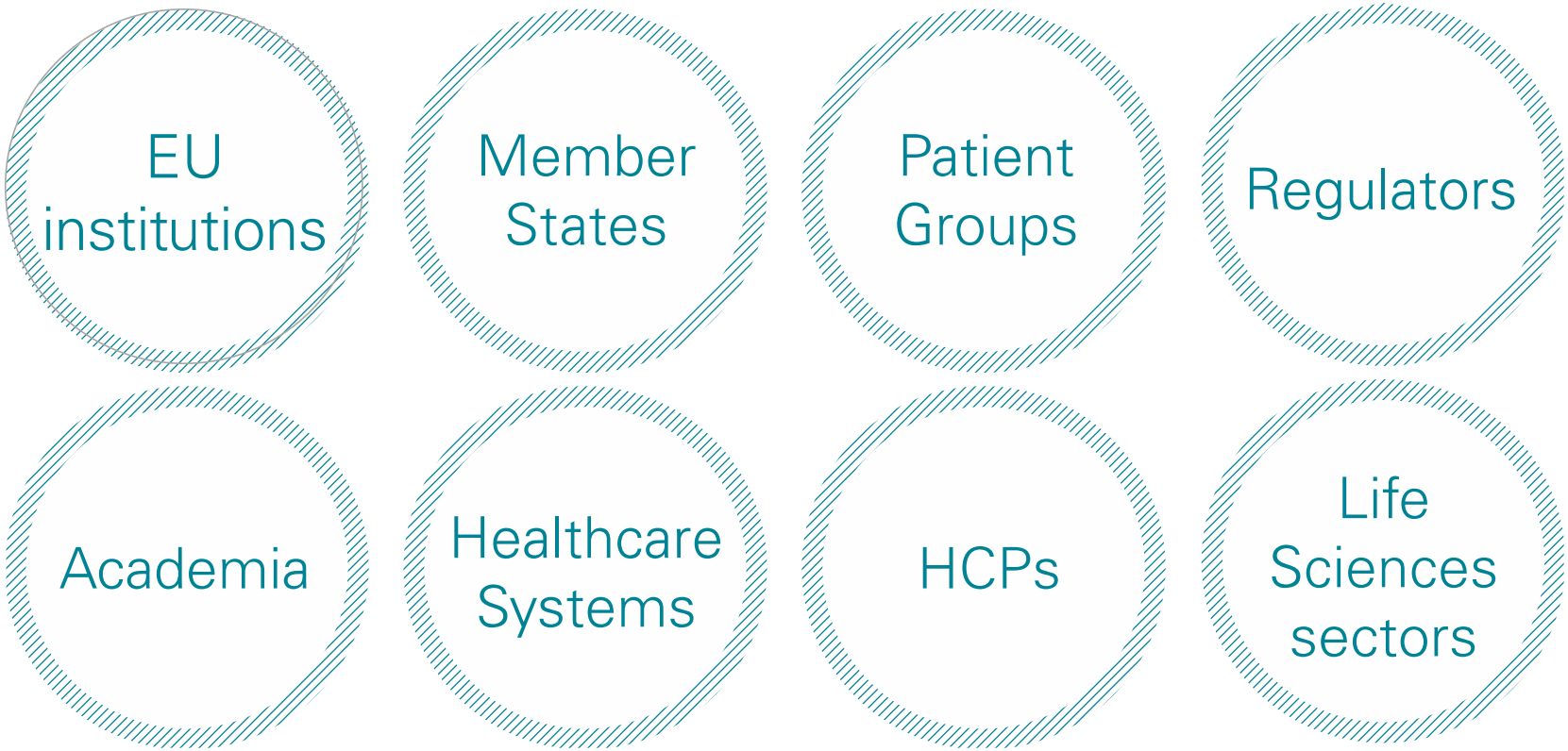
Values in € million unless otherwise stated
(1) Data relate to EU-27, Norway and Switzerland since 2005 (EU-15 before 2005); Croatia and Serbia included since 2010; Turkey included since 2011; Russia included since 2013
(2) Data relating to total exports and total imports include EU-28 intra-trade (double counting in some cases)
Source: EFPIA member associations (official figures) - (e): EFPIA estimate; Eurostat (EU-28 trade data 2000-2017)

Our areas of work

Shift the healthcare policy debate from a transactions focus to an outcomes focus

Patient Access	Innovation	International	Ethics & Compliance
Develop EU and national competitiveness policies for the pharma industry, focusing on patient access for new products	*Modernise the research, development and regulatory model to restore Europe's competitiveness and speed up access to medicines*	*Secure improved market access conditions, high regulatory and IP standards in international growth markets*	*Enhance ethical behaviour within a self-regulation (industry) framework to increase reputation and credibility of the pharmaceutical sector*

Our stakeholders

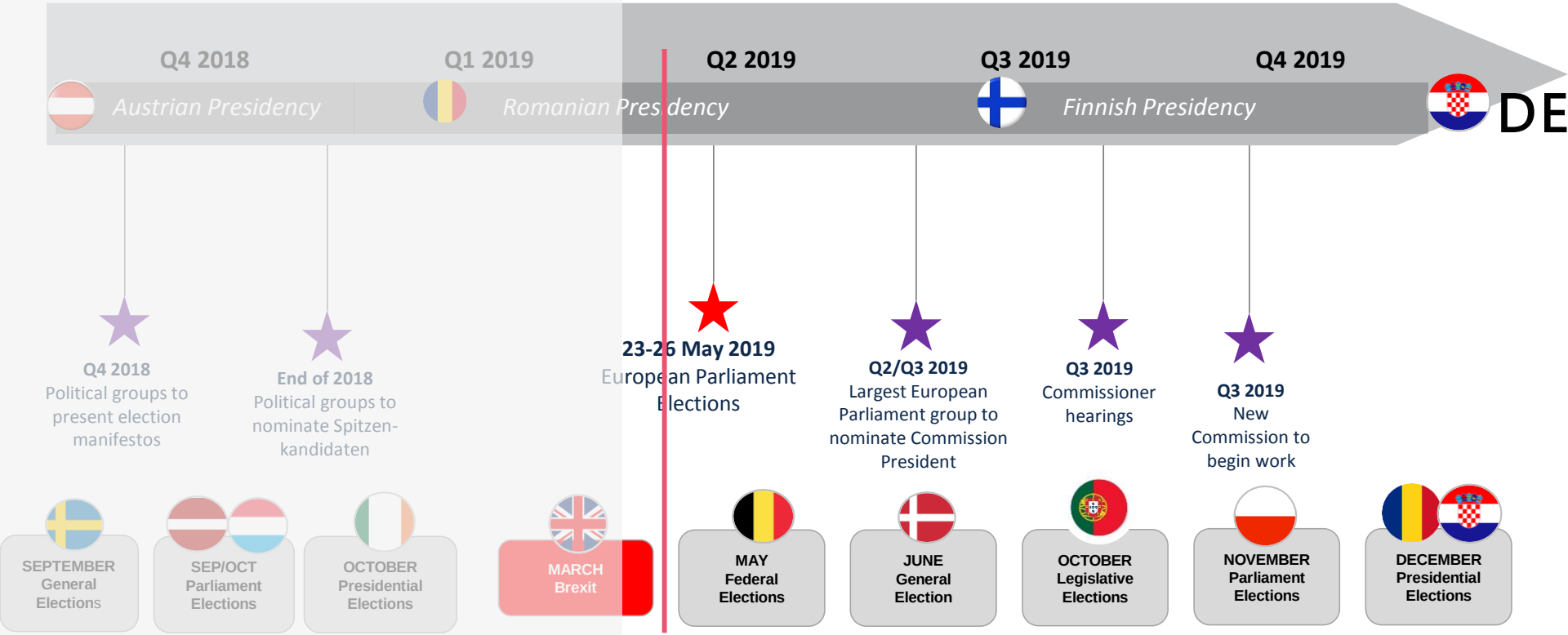


Question 2

How would you qualify EFPIA in one (or a few) word(s)?

KEY CHALLENGES AHEAD

Upcoming changes



KEY CHALLENGES AHEAD

2019 European elections

Centre-right European People's Party (EPP) predicted to remain the largest group

Rise of non-traditional, 'populist' and Eurosceptic parties

Battle between socialists and liberals (with En Marche) to become the second group

Increased fragmentation and instability might lead to uncertainty for policy-making in the next mandate

Concerns of policy makers

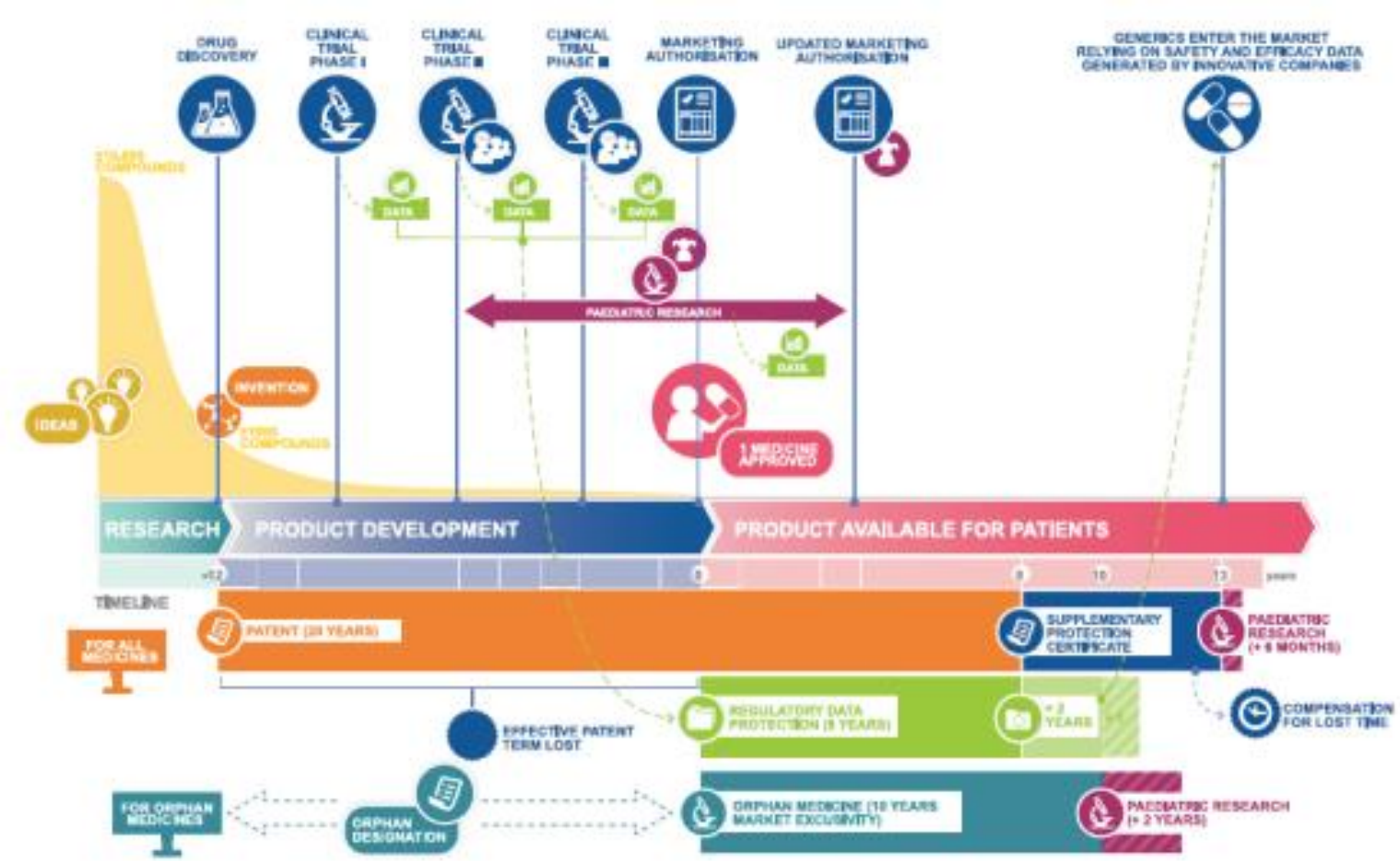
Austrian Presidency discussion paper on regulatory and supply policy challenges in EU drug approval (Sept 2018):

- "One of the reasons for a growing awareness of the problem is a significant increase in expenditure on some **high-priced medicines**, especially in the hospital sector.
- As a result, the **financing systems of the health sector** are coming under **increasing pressure** to continue to guarantee the high quality of care in Europe on a sustainable basis. There are **increasing differences in the availability of innovative drugs between member states**. In addition, evidence from recent studies shows that **many newly registered drugs do not bring any patient-relevant (additional) benefits**."

Prices / sustainability

Regulatory framework/incentives

Pharmaceutical incentives framework



Question 3

(How) do you think these issues can be tackled at the European level?

A national competence

In Europe the government/social system/healthcare system/ALL OF US VIA TAXES pay for medical care (doctors' visits, pharmaceuticals, hospital stay, surgery, etc etc)

Each country decides what they pay for and how much they pay for

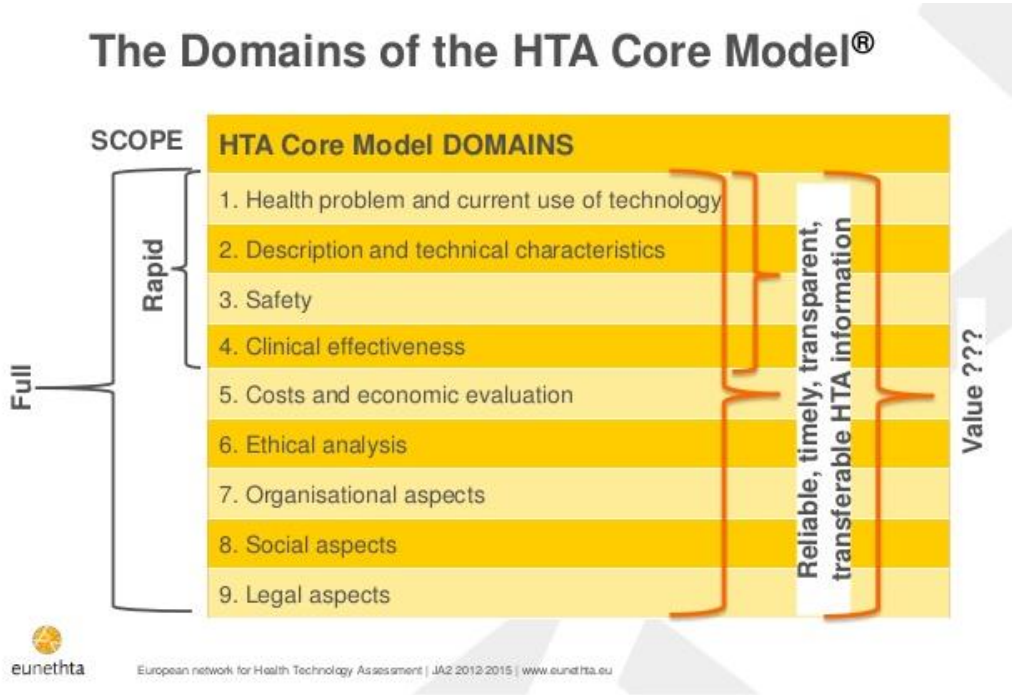
- Article 168.7 TFEU: "Union action shall **respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care**. .. **and the allocation of the resources assigned to them**. "
- Directive 89/105/EEC ('Transparency Directive') merely dictates that P&R must be based on **objective and verifiable criteria** and be finalized within a specified **timeframe** (90/180 days)

What is Health technology assessment?

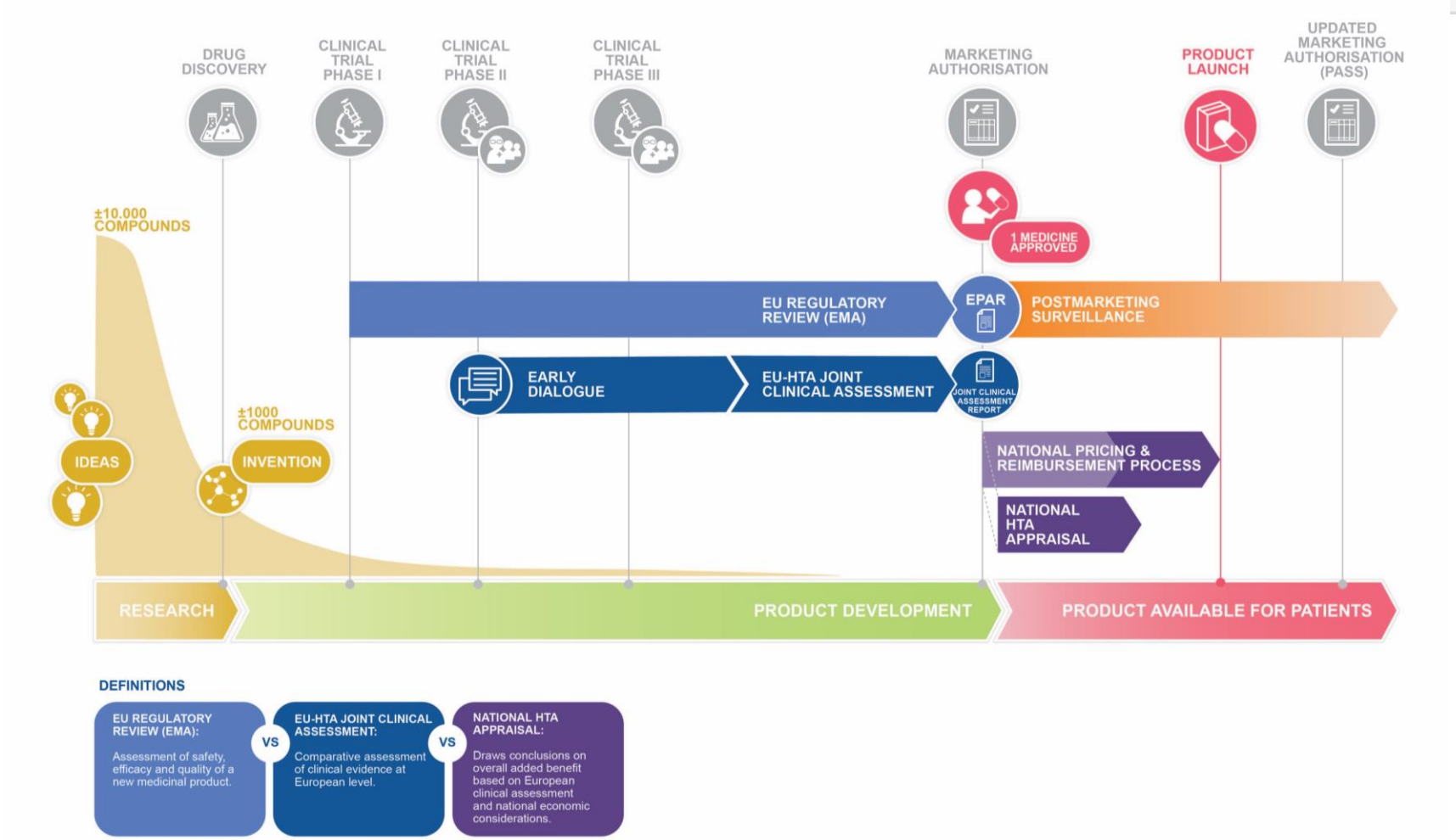
In a nutshell:

Looking at scientific and economic evidence to support pricing and reimbursement decisions (rather than eg looking at other countries, ie international reference pricing)

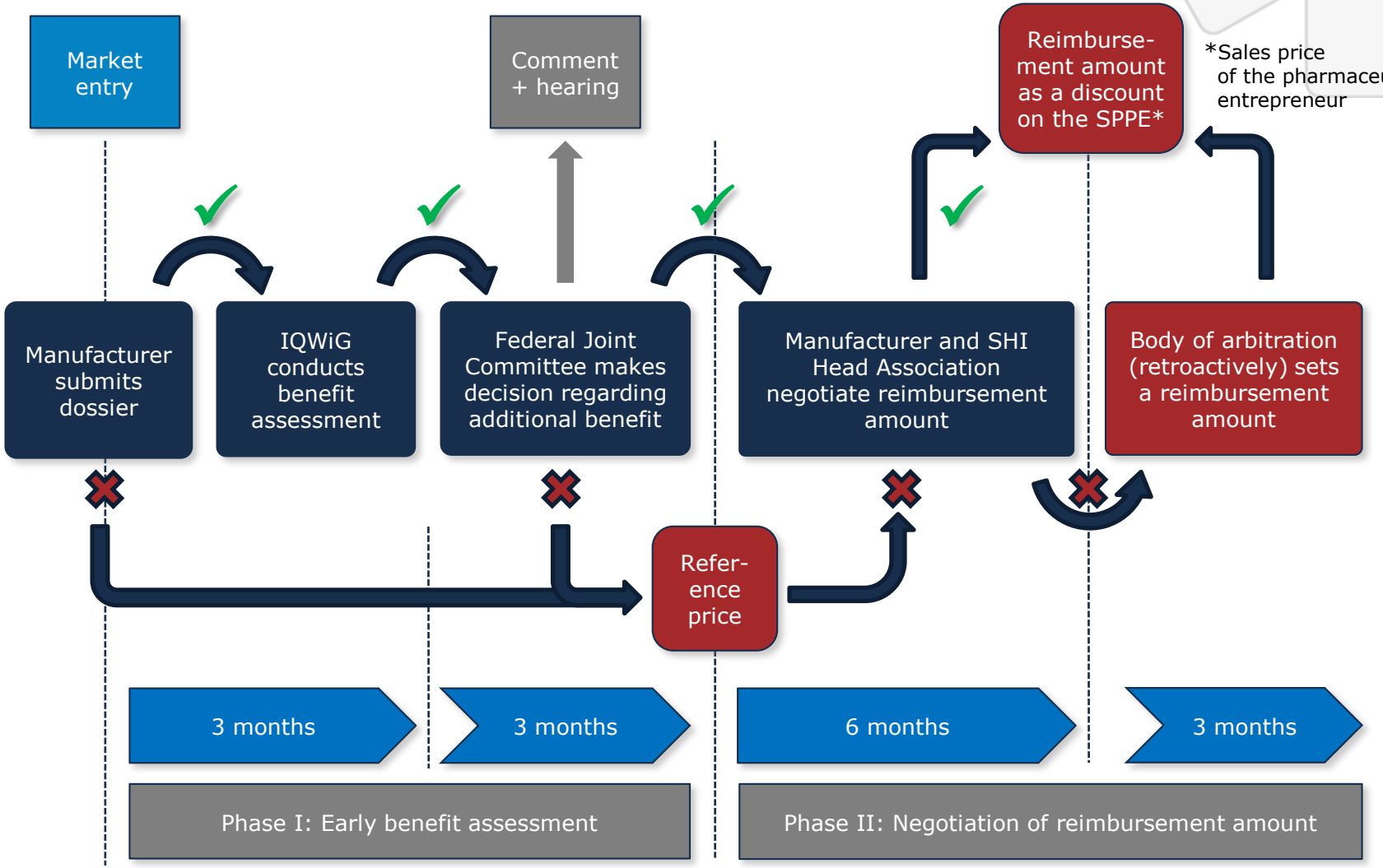
It is different from the regulatory approval because it informs a reimbursement decision: it's not about whether the medicine works (benefit/risk ratio) but whether it's worth its price given the existing alternatives



Bringing a product to market

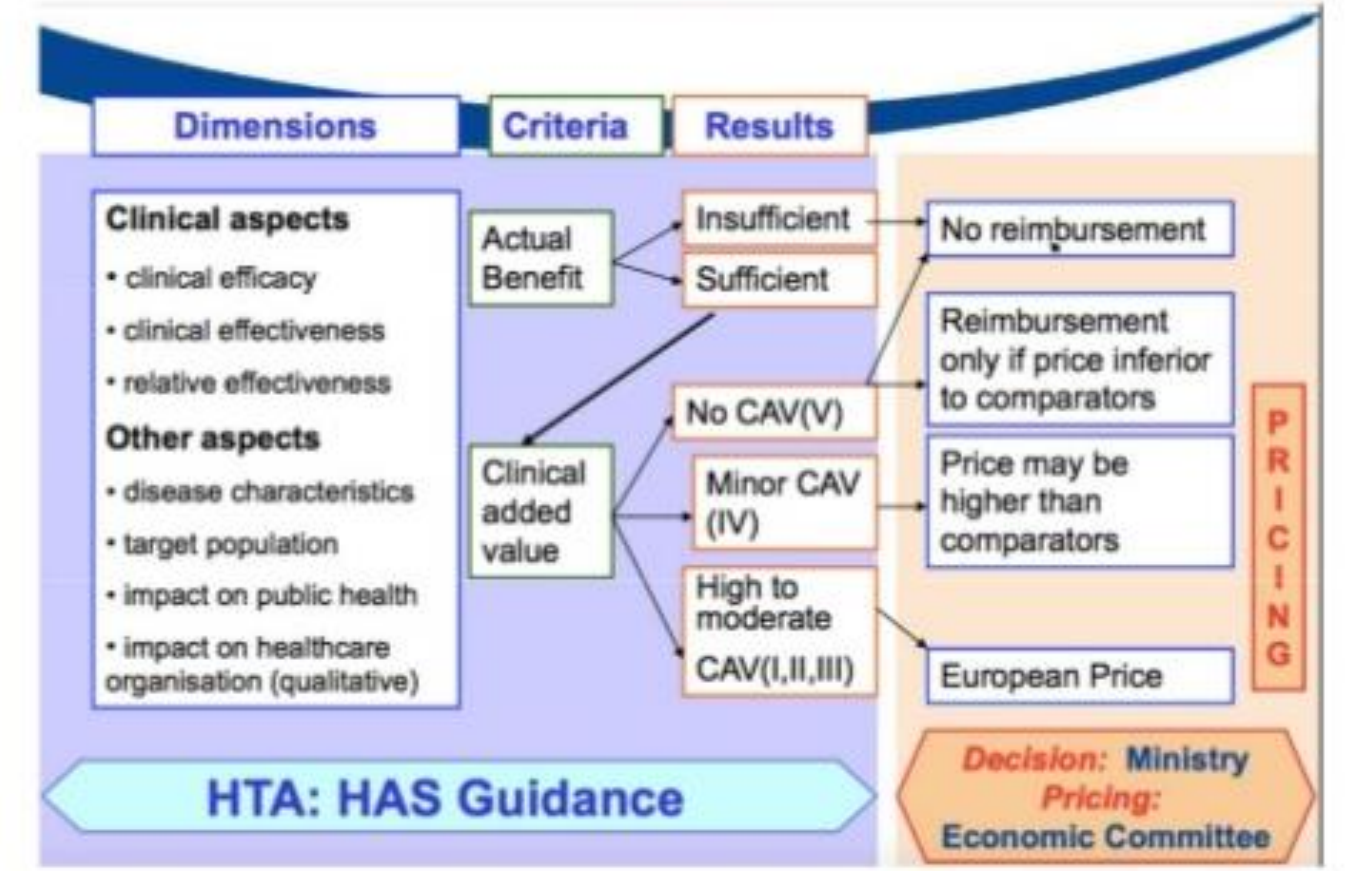


Germany's AMNOG

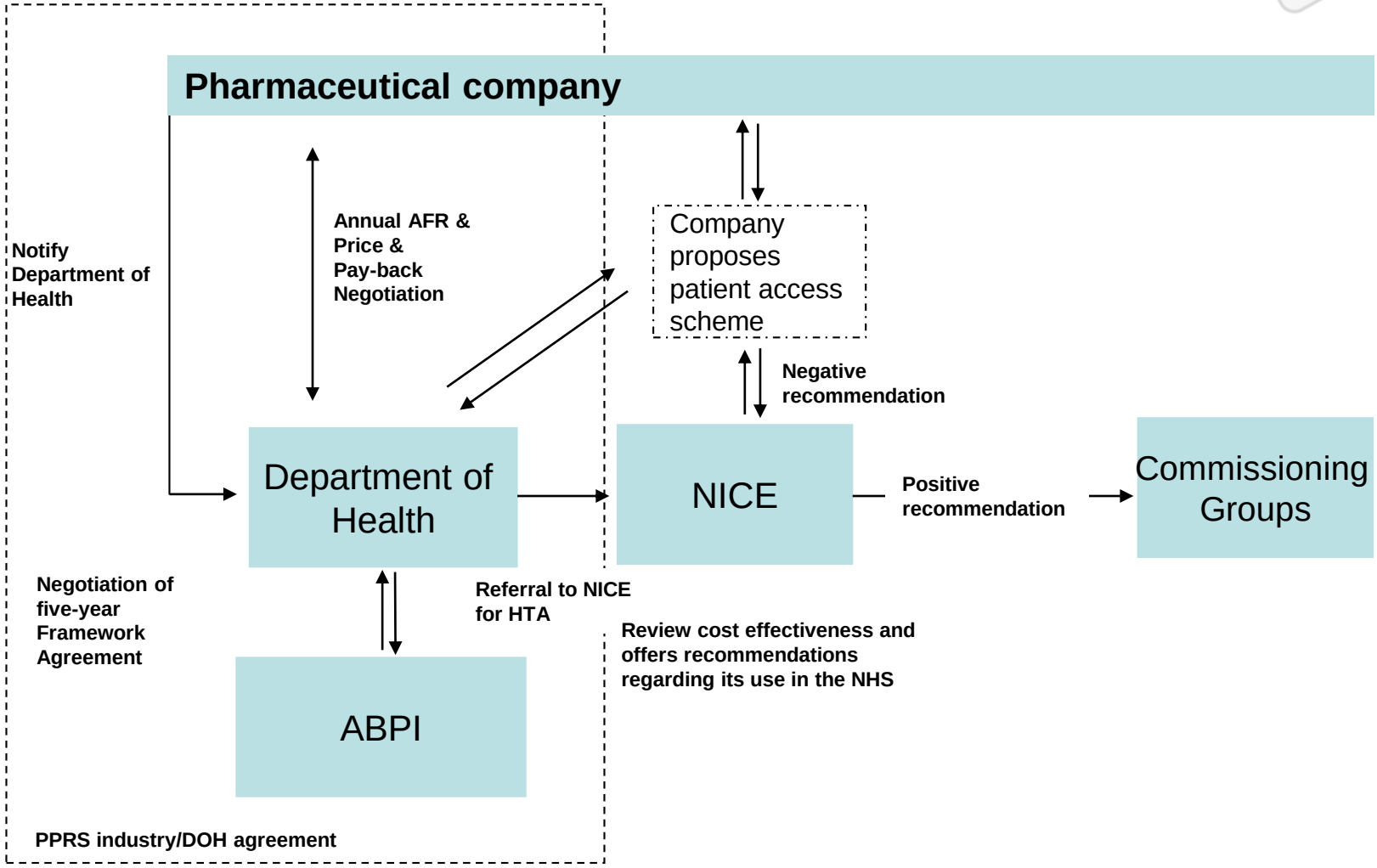


SOURCE: VFA

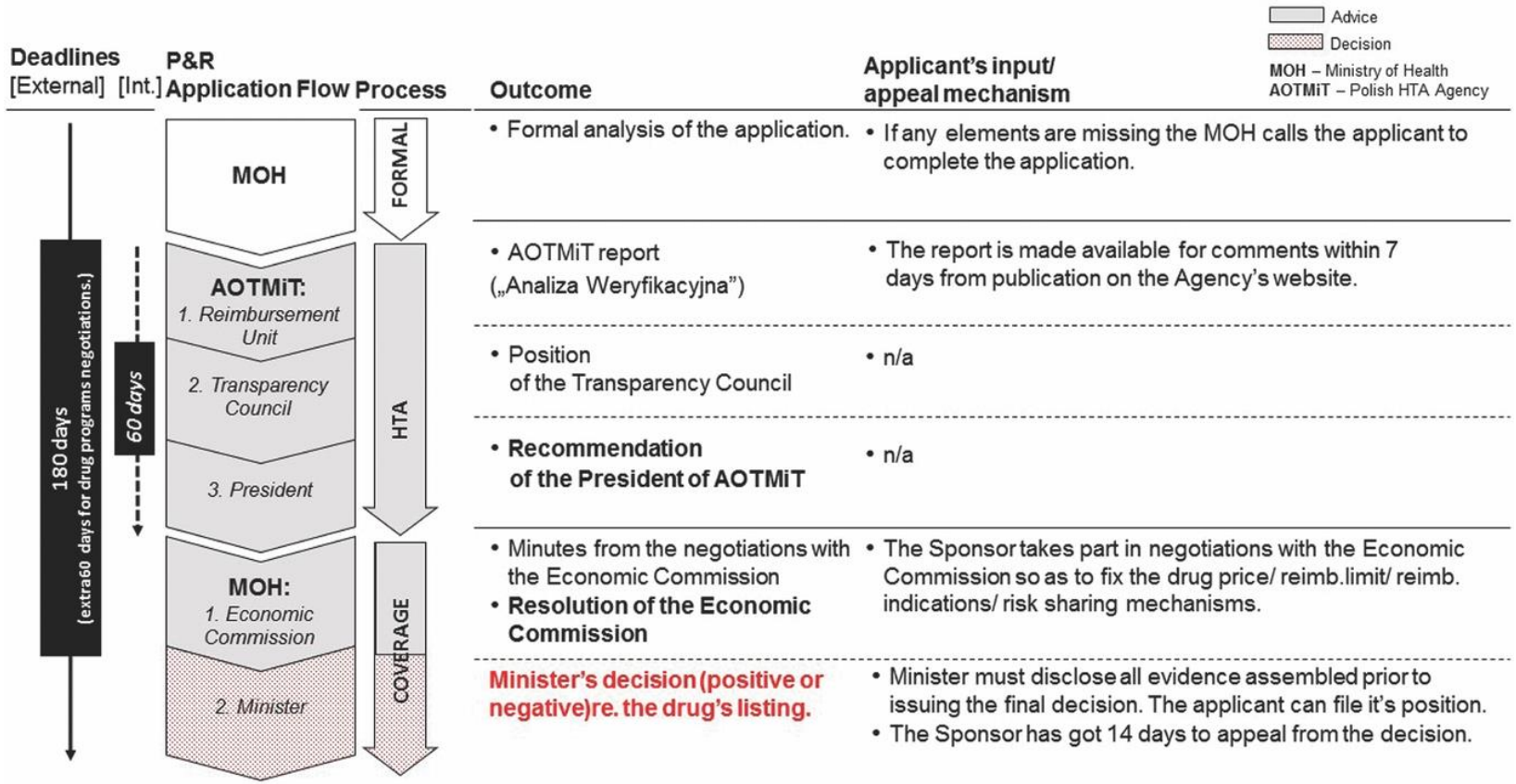
The French market access process



The English system



The Polish way

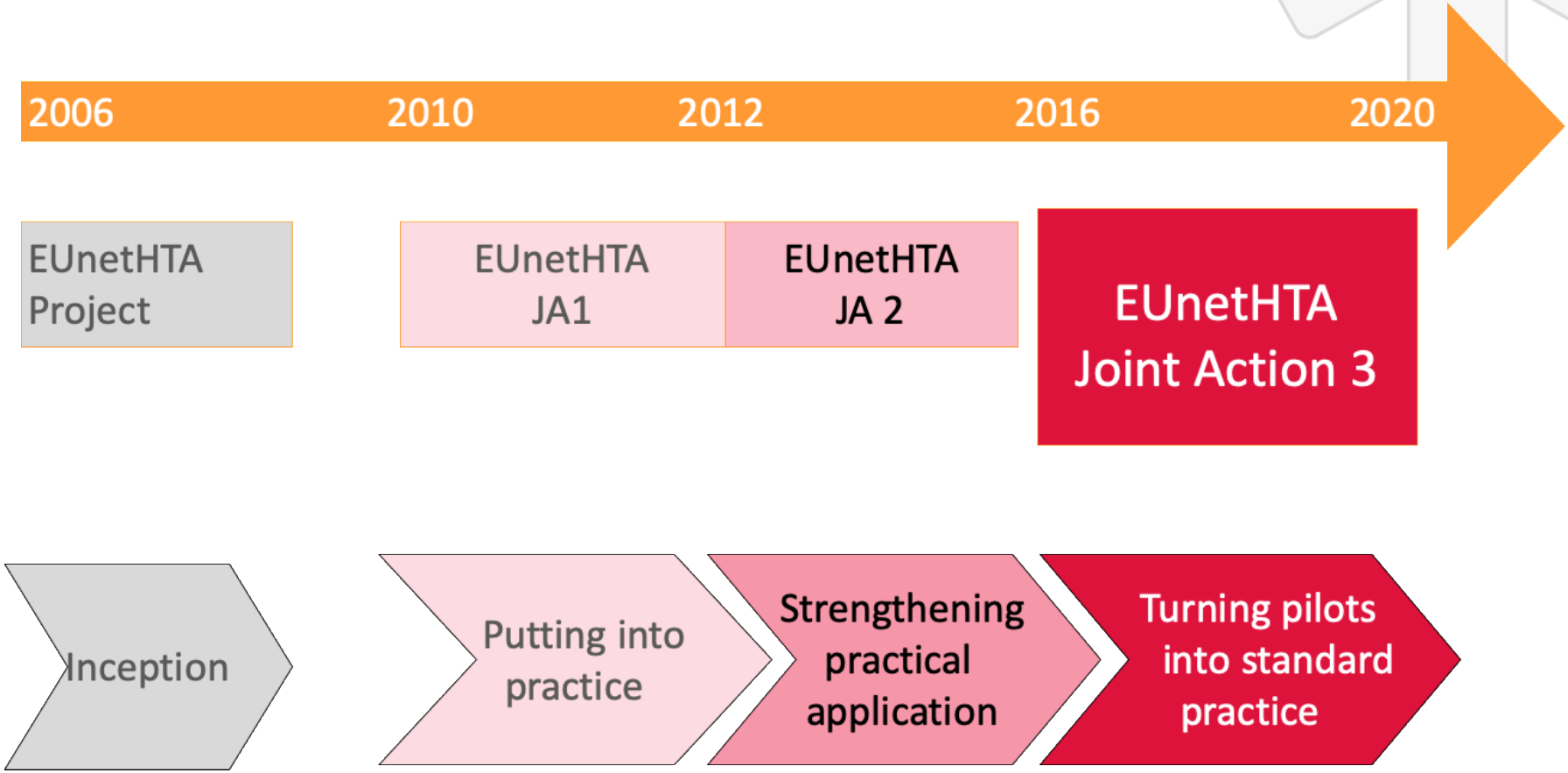


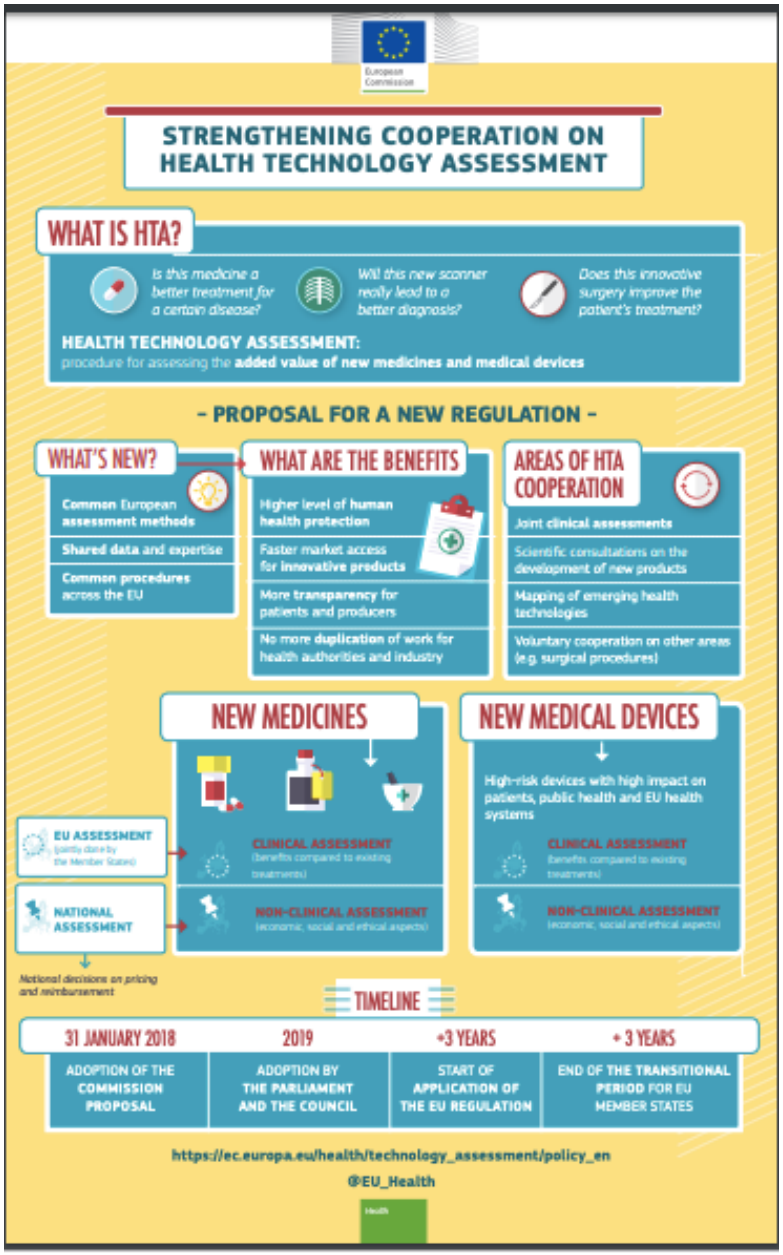
* drugs which do not have reimbursed equivalents for the given therapeutic indication (art.25 ust.8 of the Reimb. Law)
Sources: Reimbursement Law (esp. Art.12,18,24,25,35), Administrative Process Code (esp. Art. 10, 127, 129), Law on health care services financed out of public funds (esp. art. 31c), AOTMiT

Question 4

Do you see similarities between systems? Why is HTA needed AT ALL?

European cooperation on HTA

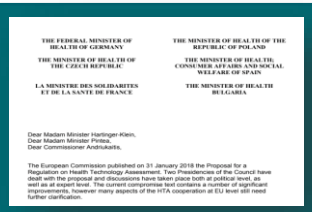



STRENGTHENING COOPERATION ON HEALTH TECHNOLOGY ASSESSMENT
WHAT IS HTA?
Is this medicine a better treatment for a certain disease?
Will this new scanner really lead to a better diagnosis?
Does this innovative surgery improve the patient's treatment?
HEALTH TECHNOLOGY ASSESSMENT:
procedure for assessing the added value of new medicines and medical devices
– PROPOSAL FOR A NEW REGULATION –
WHAT'S NEW?
Common European assessment methods
Shared data and expertise
Common procedures across the EU
WHAT ARE THE BENEFITS
Higher level of human health protection
Faster market access for innovative products
More transparency for patients and producers
No more duplication of work for health authorities and industry
AREAS OF HTA COOPERATION
Joint clinical assessments
Scientific consultations on the development of new products
Mapping of emerging health technologies
Voluntary cooperation on other areas (e.g. surgical procedures)
NEW MEDICINES
EU ASSESSMENT
CLINICAL ASSESSMENT
NATIONAL ASSESSMENT
NON-CLINICAL ASSESSMENT
National decisions on pricing and reimbursement
NEW MEDICAL DEVICES
High-risk devices with high impact on patients, public health and EU health systems
CLINICAL ASSESSMENT
NON-CLINICAL ASSESSMENT
TIMELINE
31 JANUARY 2018
ADOPTION OF THE COMMISSION PROPOSAL
2019
ADOPTION BY THE PARLIAMENT AND THE COUNCIL
+3 YEARS
START OF APPLICATION OF THE EU REGULATION
+ 3 YEARS
END OF THE TRANSITIONAL PERIOD FOR EU MEMBER STATES
https://ec.europa.eu/health/technology_assessment/policy_en
@EU_Health

Status of legislative process

2018 showed Member states are united on the overall objectives but split on the « how »

Use 2019 to advance on many « technical » aspects



THE FEDERAL MINISTER OF HEALTH OF GERMANY
THE MINISTER OF HEALTH OF THE REPUBLIC OF POLAND
THE MINISTER OF HEALTH OF THE CZECH REPUBLIC
THE MINISTER OF HEALTH, CONSUMER AFFAIRS AND SOCIAL WELFARE OF SPAIN
LA MINISTRE DES SOLIDARITES ET DE LA SANTE DE FRANCE
THE MINISTER OF HEALTH BULGARIA

Dear Madam Minister Hartinger-Klein,
Dear Madam Minister Pinteа,
Dear Commissioner Andriukaitis,

The European Commission published on 31 January 2018 the Proposal for a Regulation on Health Technology Assessment. Two Presidencies of the Council have dealt with the proposal and discussions have taken place both at political level, as well as at expert level. The current compromise text contains a number of significant improvements, however many aspects of the HTA cooperation at EU level still need further clarification.

Object to
Mandatory use
'status' of JCAs as a tool for decision-making
Role of COM as 'final decider'

Acceptance but on conditions
Complementary CAs
quality and timing
Role of member states

romania2019.eu

Achieve tangible progress on
Joint Scientific Consultations
'Horizon scanning'
support framework
role of the Coordination Group/European Commission
Timelines

New Commission

1H2019
Romanian Presidency

April/May: Council legal opinion

2H2019:
Finnish Presidency
Tbc: Process and methodology
Mandatory use
Transparency provisions

2020 ?
Croatian Presidency
German Presidency

efpia

Fate of the Commission Proposal on HTA

THERE ARE VARIOUS POSSIBLE OUTCOMES:

1. Council reaches 1st reading agreement, trialogue starts
   - Negotiations end: Regulation enters into force
   - Negotiations don't conclude, deadlock
2. Council does not reach 1st reading agreement - HTA PROPOSAL REMAINS ON THE COM WORKPLAN INDEFINITELY (and is eventually withdrawn after several years)
3. Council reaches 1st reading agreement, but it's unacceptable to Commission: COM WITHDRAWS THE PROPOSAL (which it can do at any time)

* *Agreeing to a 1st reading position is not bound by a time-limit in Parliament & Council*

Question 5

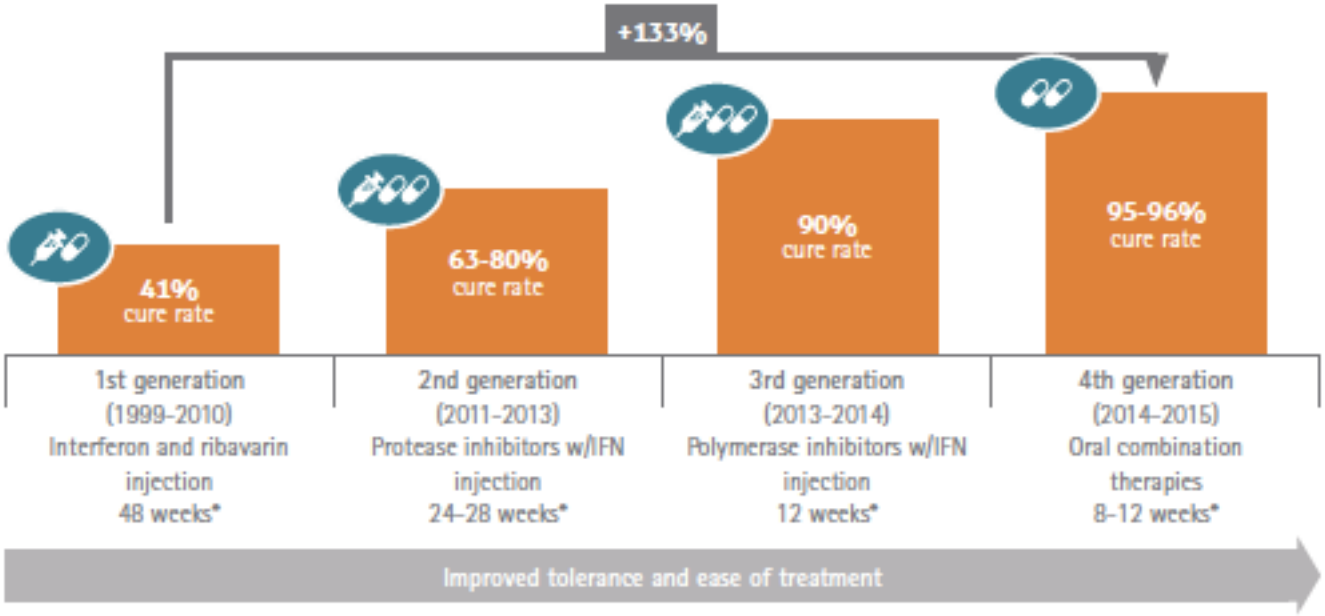
Any predictions given upcoming changes in EP, Commission, Countries?

LOOKING AHEAD

Innovative medicines' contribution to society – one example

CHRONOLOGY OF HEPATITIS C TREATMENT (1999–2015)

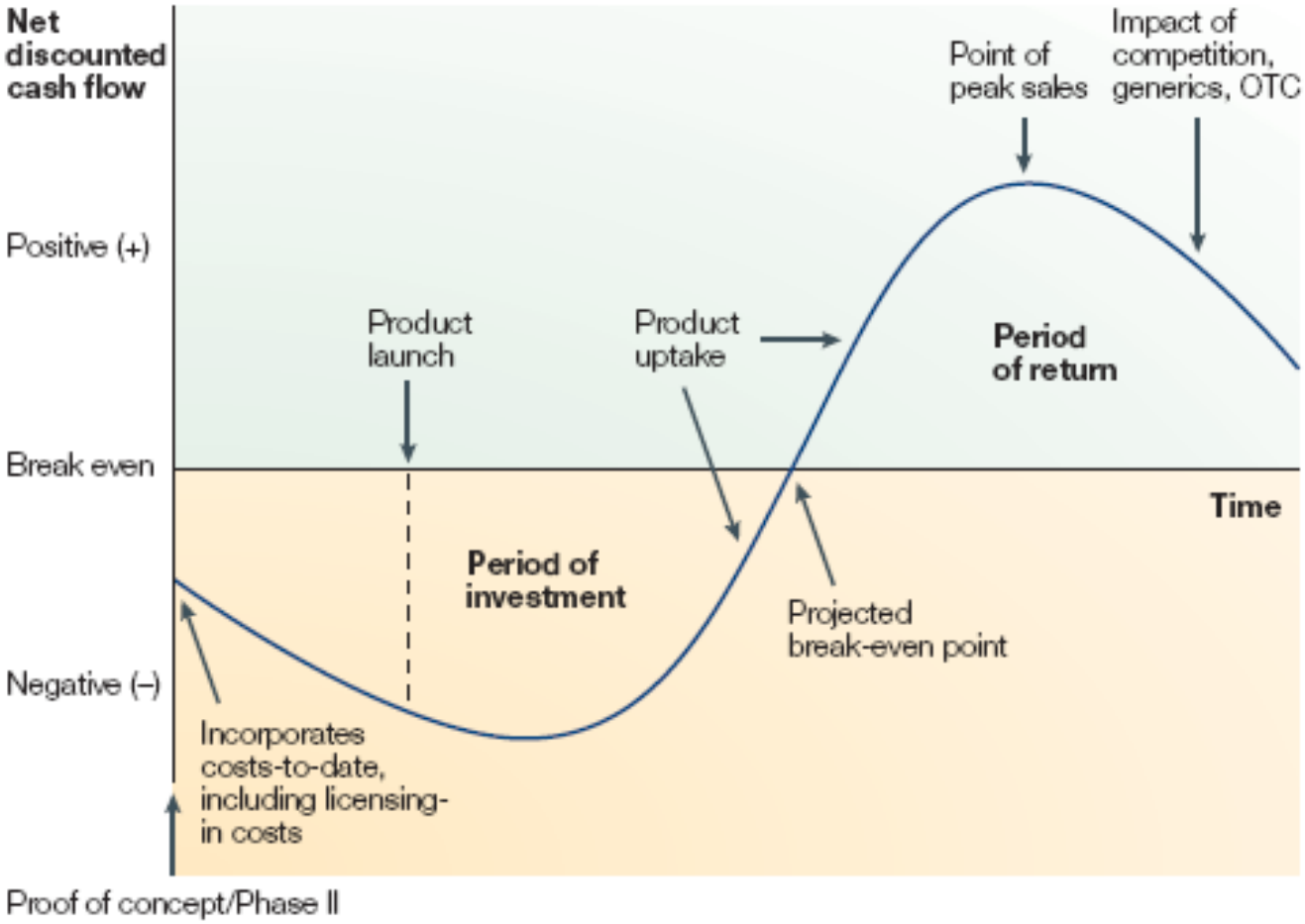
* Hepatitis C is the leading cause of liver transplants and the reason liver cancer is on the rise



** Treatment duration, INF=interferon;*

Source: PhRMA, 'Prescription Medicines: International Costs in Context' (2017)

Cash flow curve for a pharmaceutical product



SOURCE: GREGSON ET AL, NATURE REVIEWS 2005, (4) 121

LOOKING AHEAD

Protect the spark

Ideas need to be protected. They need time to grow, and a lot of help along the way.

Because an idea can lead to a breakthrough. Like vaccinations to help prevent the spread of infectious diseases…

Or therapies to help patients fight off Blood Cancer by arming their own cells. Or even new ways to slow down Alzheimer's Disease. And maybe one day, stop it for good.

Every new medicine was born from just the spark of an idea.

Ideas can go on to change lives. And if they are really special, save them.

Don't let medical innovation burn out in Europe.

For tomorrow's patients.

Protect the spark.

LOOKING AHEAD

Need for flexible pricing models

Value based pricing

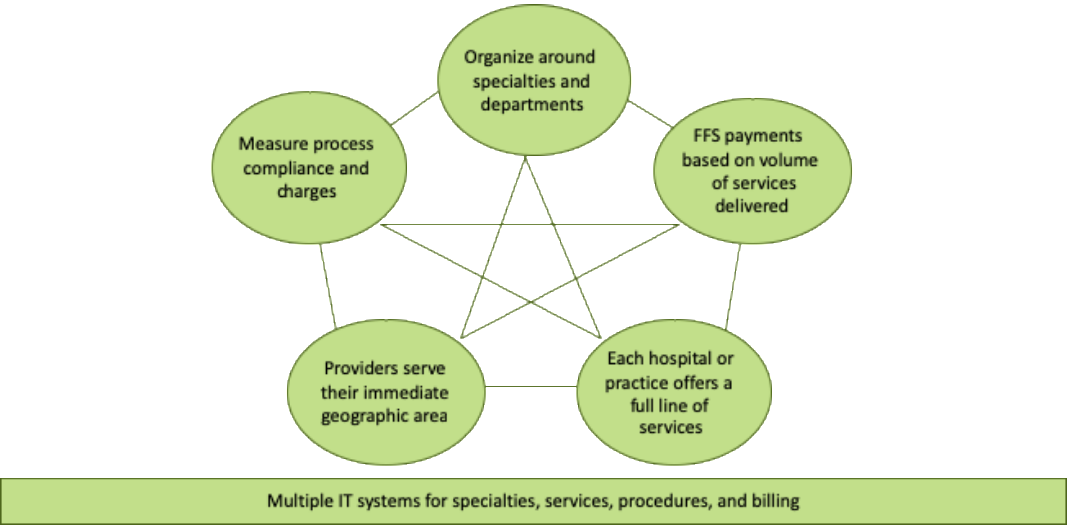
Breakthrough Innovations/ Adaptive Licensing	Multiindication Products	Combination Products	ATMPs	Personalized Therapies
«preliminary» value (evidence)/ dealing with uncertainty (risk sharing agreements)	Net price reflecting value of indication or value sharing (weighted average net price)	Value sharing/ price split	Multi – annual outcomes based payments	aligned payment of companion diagnostics and medicines based on outcomes measures and patient treatment pathways

Increasing complexity

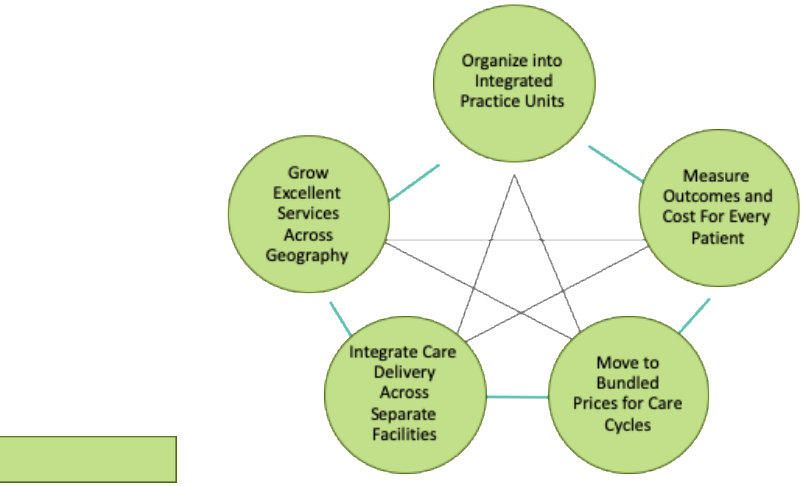
SOURCE: INTERNAL PRESENTATION INTERPHARMA

LOOKING AHEAD

Moving to value-based healthcare



TODAY



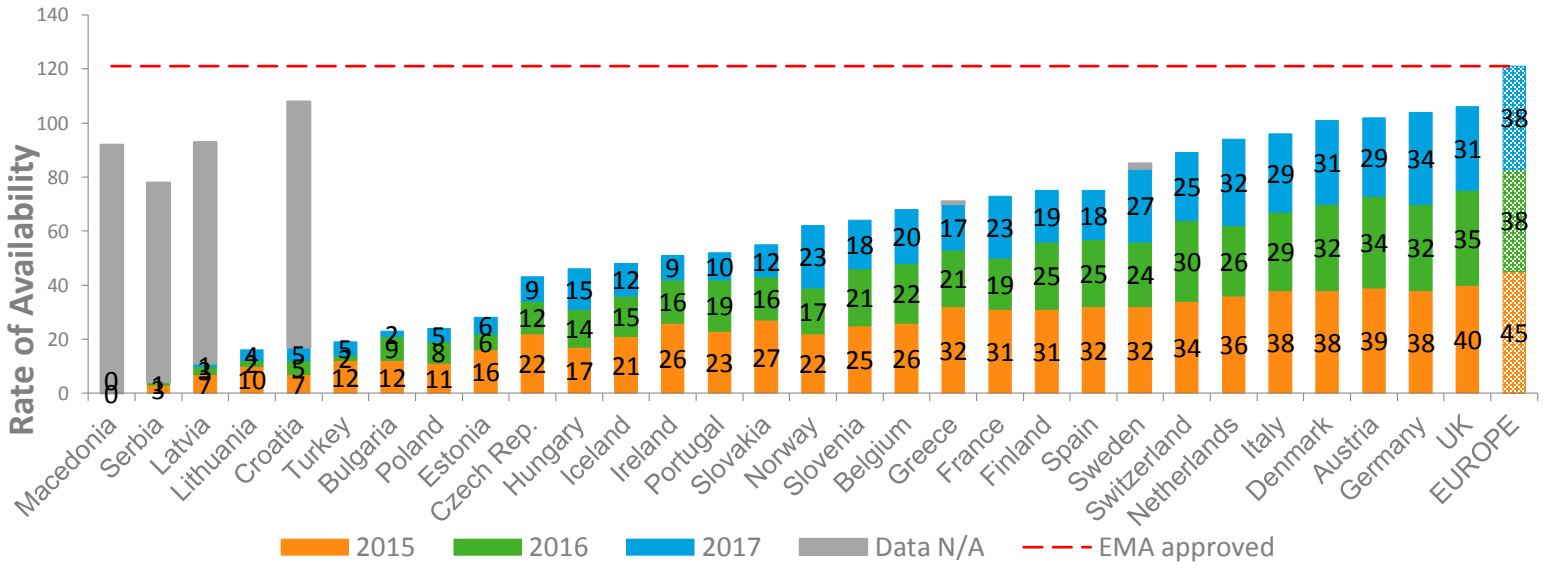
TOMORROW


Q
A

EFPIA WAIT INDICATOR

Rate of availability

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 2018: for most countries this is the point at which the product gains access to the reimbursement list*.



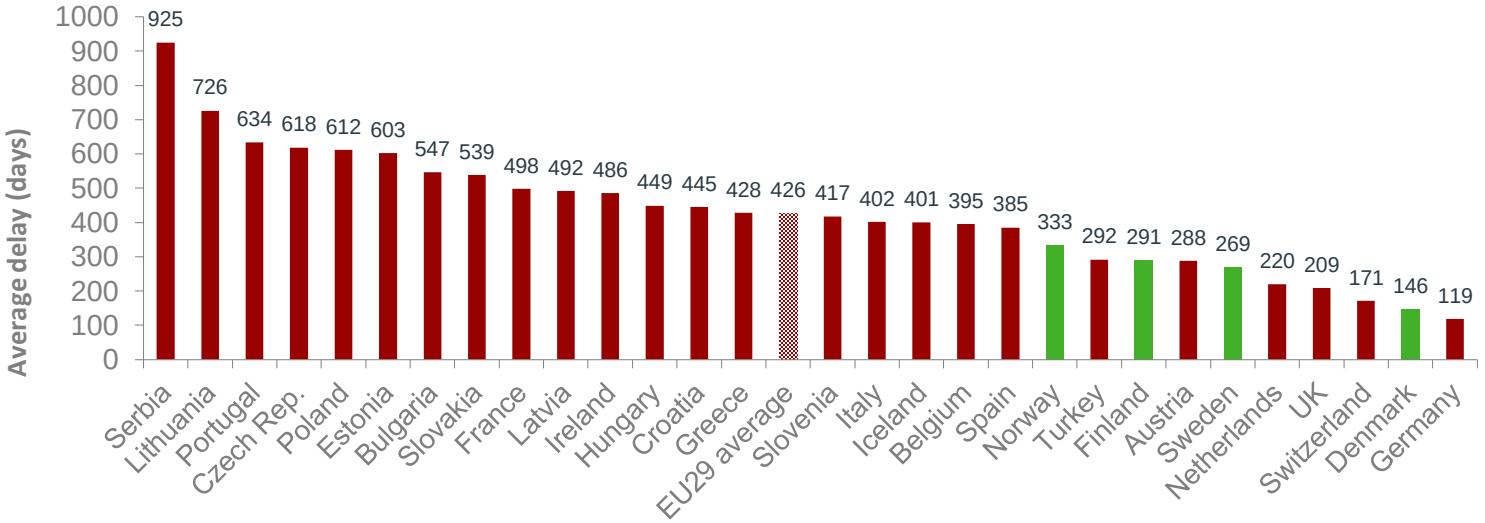
Data N/A- data is not provided by associations (companies have not sent data or are not members of the association)

*See next slide for country specific definitions

EFPIA WAIT INDICATOR

Length of market access delays (average)

The **average time between marketing authorisation and patient access** - the number of days elapsing from the date of EU marketing authorisation (or effective marketing authorisation in non-EEA countries) to the day of completion of post-marketing authorisation administrative processes



In most countries patient access equates to granting of access to the reimbursement list, except for hospital products in DK, FI, NO, SE where some products are not covered by the general reimbursement scheme and so this shorter delay is artificially declining the median and average.

- In France, some innovative products without competitors can be made available prior to market authorisation under the system of Temporary Authorisations. As these are not taken into account in the analysis, the average for France is higher than in reality.
- Average of 29 European countries in the analysis (excludes Macedonia)

OUR VISION AND CALLS TO ACTION

Manifesto for a healthier future for Europe

VISION #1 - HEALTH FOR ALL:

Bringing Innovative Health Solutions to all patients

What Europe can do

- Drive the evolution towards patient-centred and outcomes-based healthcare systems
- Improve patient access in Europe by setting up a future European clinical assessment system
- Convene a coalition for vaccination could bring together European associations of healthcare workers to commit to increasing vaccination coverage in Europe.

VISION #2 - EUROPEAN EXCELLENCE:

Making Europe a world leader in medical R&D

What Europe can do

- Improve the position of Europe in fast-tracking breakthrough therapies which meet unmet health needs for patients
- Defend Europe's world-class intellectual property (IP) system
- Advance Europe's smart trade agenda to promote investment

VISION #3 - STRONGER TOGETHER:

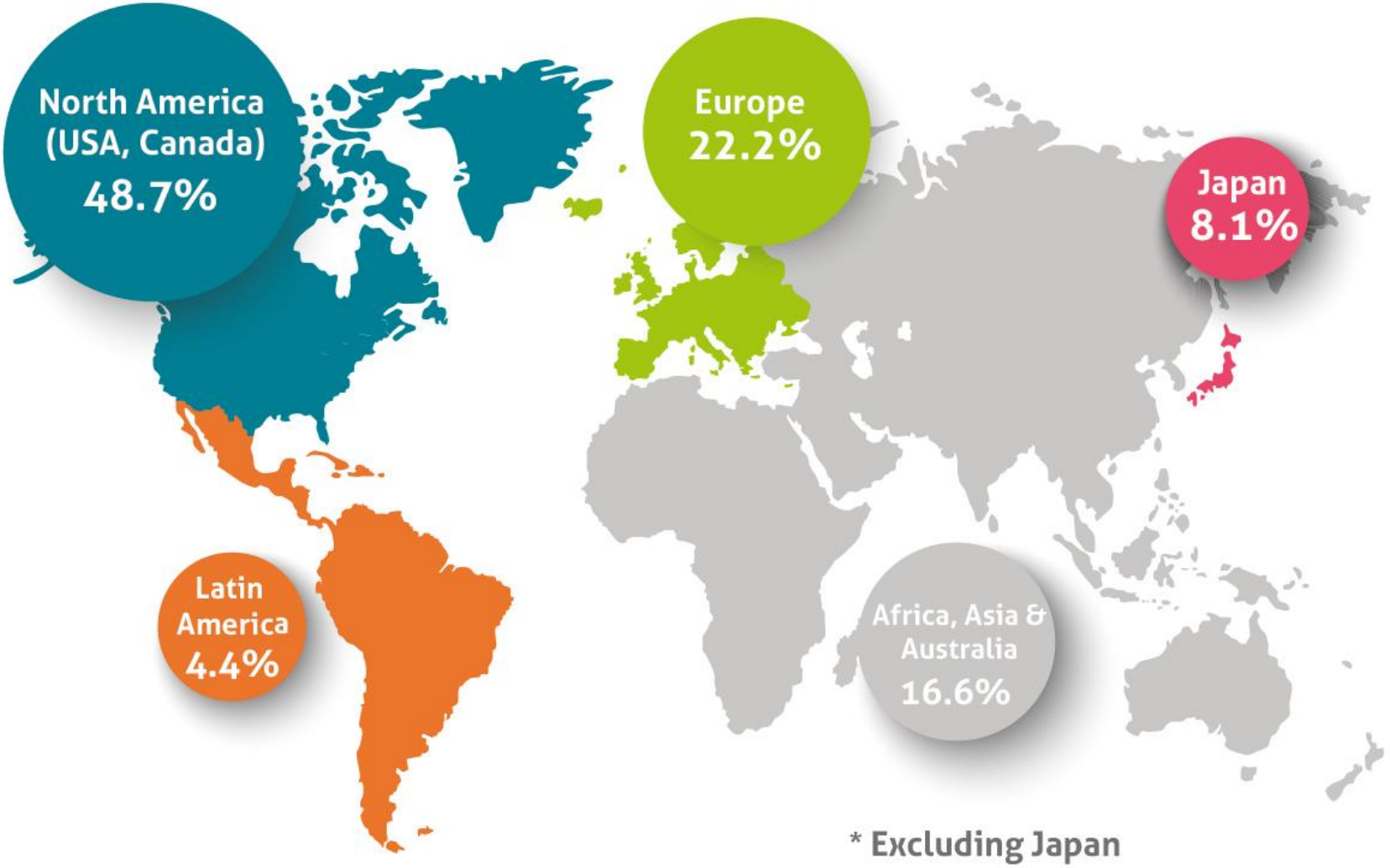
Joining forces to fast-track results

What Europe can do

- Make Europe a world leader in clinical research by fostering the adoption of new trial designs supported by digital tools
- Support a flexible legal framework for a Public Private Partnership in health
- Launch a new strategic dialogue for the EU healthcare and life sciences sectors

BREAKDOWN OF THE WORLD PHARMACEUTICAL MARKET – 2015 sales

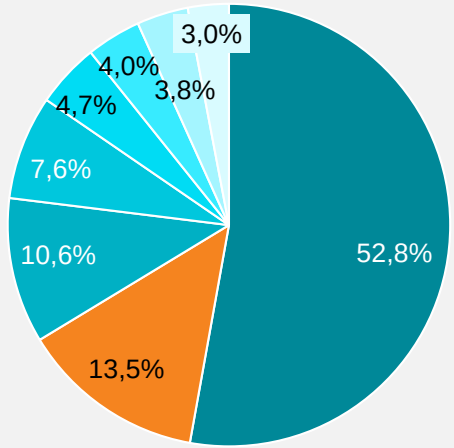
May 2016 (data related to the 2015 audited global retail and hospital pharmaceutical market at ex-factory prices



Europe includes Turkey, Russia and Ukraine
Source: IMS Health (MIDAS); in EFPIA in Figures, www.efpia.eu

Overall medicines across Europe represent less than 15 % of total expenditure although variances exist between therapy areas

Total healthcare expenditure by function (2010, pop.-weighted, current prices, PPP, $)*



- Curative and rehabilitative care
- Long-term nursing care
- Ancillary services
- Other
- Medicines
- Other Medical Goods
- Health administration and health insurance
- Prevention and public health services

Medicines contribution to disease cost (2011, various diseases)

Cost factor	COPD†	Diabetes†	CHF†	Alzhei-mers△	Prostate Cancer#
Care	21%	8%	6%	9%	34%
Hospitali-sation	30%	22%	64%	11%	31%
Indirect Cost	22%	35%	18%	76%	N/A
Other Cost	14%	20%	6%	1%	2%
Medication	14%	15%	5%	3%	34%

Source: * OECD Health Statistics Database (accessed 2013); † A.T. Kearney analysis (2012); △ Schwarzkop et al. (2010); # Damm el al. (2012)

BREAKDOWN OF THE RETAIL PRICE OF A MEDICINE

Non-weighted average for Europe

Based on average estimate for 22 countries.
Source: EFPIA Member Associations; in EFPIA in Figures, www.efpia.eu