PHARMAprocess

Innovation Forum in Pharmaceutical Process

Market Acces integration in QbD strategy

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Fira Barcelona

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WHAT IS MARKET ACCESS?

FOR ME:

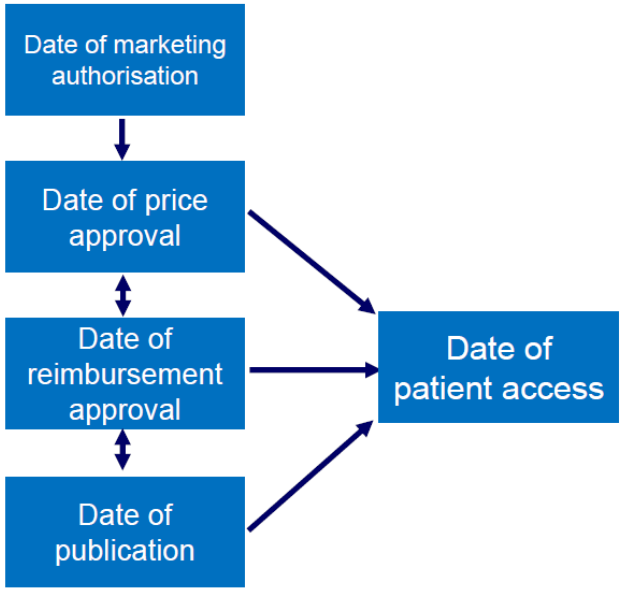
Ensure that the most appropriate treatments are available to patients as soon as possible

HOW:

By developing and communicating evidence that will convince

- Regulators to approve a new treatment
- **Evaluators to recomment it**
- **Payers to finance it**
- Physicians to prescribe it
- Pharmacists to dispense it
- Patients to use it

In a way that it is profitable and sustainable for our business



Content: Objectives of this presentation

1. Review EU payers' environment
2. Identify impact on drug developers
3. Discuss how QbD is considering Market Access

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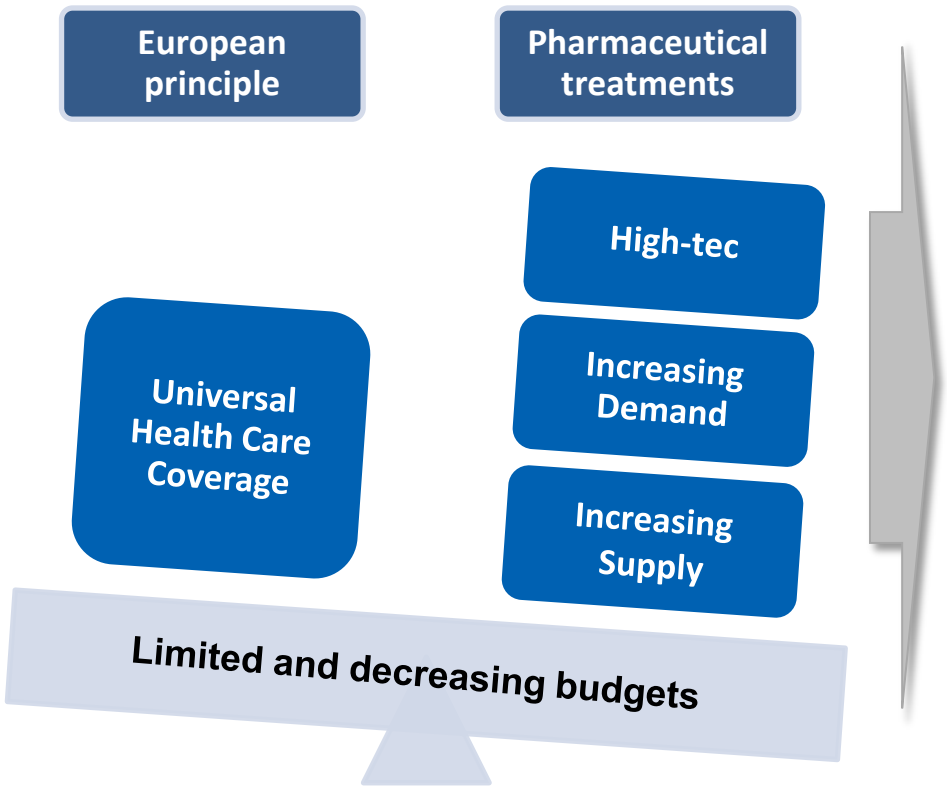
What are EU payers´concerns?

Low Economic Growth & High Public Debt



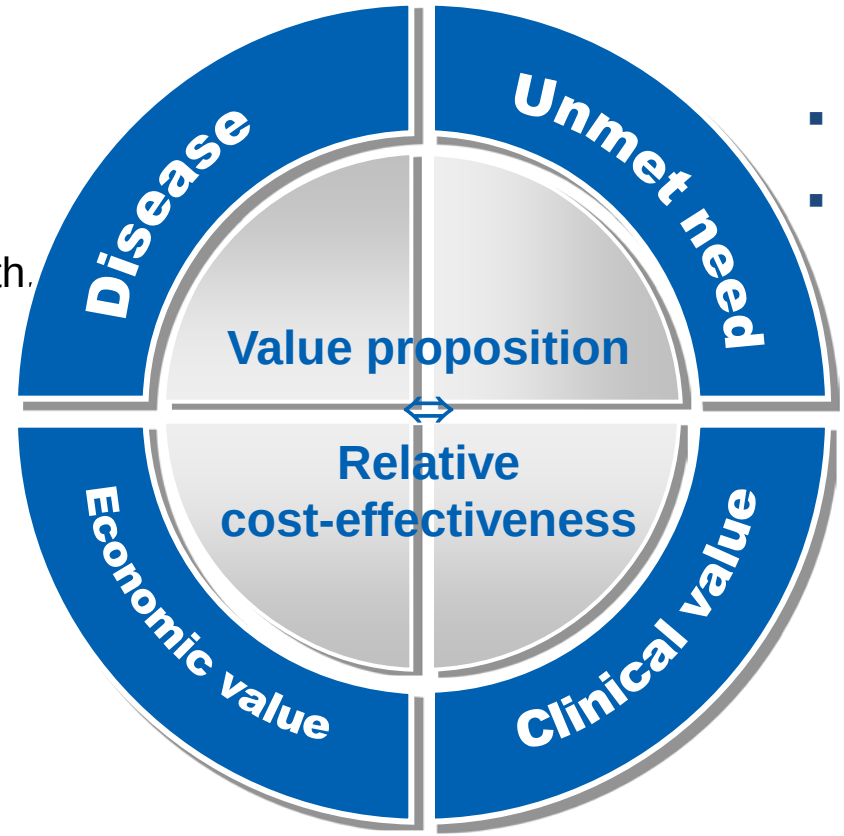
EU Payers´ Questions

- What healthcare technologies are we **willing to finance**?
- What can we afford? How do we **prioritise and assign limited resources**?
- **What measures** can we put in place to decrease pharma expenditure?

EU payers are willing to finance treatments that offer good value for money

- Life threatening, degenerative vs functional, life style
- Acute vs chronic
- Burden of Illness
- Impact on public health or prevention

- Number and evidence of competitors
- Symptomatic vs curative
- Satisfaction with current treatments



- Use of resources
- Budget impact

- Survival
- Patient Reported Outcomes

What does Value for Money mean?

VALUE FOR **MONEY**

How do we measure value?

- UK/Nordics: QALY
- FR/DE: Additional clinical benefit
- ES/IT: Budget impact

$$\frac{\text{Cost}_{\text{New}} - \text{Cost}_{\text{SoC}}}{\text{Benefit}_{\text{New}} - \text{Benefit}_{\text{SoC}}}$$

How do we estimate costs?

- Total pharmaceutical costs
- Direct health care costs
- Societal costs

IMPACT FOR DRUG DEVELOPERS

- What **evidence** do we need to generate to satisfy all these requirements?
- What **pricing and reimbursement** should I expect with what we have?

QALY: Quality Adjusted Life Years SoC: Standard of Care FR: France, DE: Germany, ES: Spain, IT: Italy

Cost containment measures are used to control pharma expenditure

Cost containment measures

ILLUSTRATIVE
Not exhaustive

Prescription Behaviour	• Specialist prescriptions • Pre-authorisation
Price Reviews	• Mandatory • Re-evaluations conditional to long-term evidence
Pricing Benchmarks	• Pressure to have a comparator • External reference price
Discounts & Paybacks	• Applicable to all products or negotiated • Risk-sharing
Patient Co-payments	• By type of treatment • By patient´s ability to pay
Expenditure Caps	• ICER* (20k to 30k GBP/QALY*) • Volume caps • Annual maximum expenditure

*ICER: Incremental cost-effectiveness ratio; QALY: Quality Adjusted Life Years

GBP: British Pound

EU payer environment trends (I)

AMNOG in Germany [1]

- New legislation as from 2011; from free to negotiated prices
- Need to demonstrate additional benefit of innovation
- After 5 years, some products no longer available in Germany
- Lowest prices in Europe

Decentralisation

- Budgets and decision making delegated to local authorities
- Use of different evaluation criteria according to preferences
- Fragmentation, geographic differences

Decreasing Willingness to Fund

- De-reimbursement
- Focus on areas of higher unmet need
- Lower interest for minor public health problems

1. AMNOG: The Act on the Reform of the Market for Medical Products

EU payer environment trends (II)

Greater Collaboration

- EUnetHTA
- Offer for early and joint EMA advice
- Need for sharing the risk
- Adaptative licensing

Patient Centricity

- Need to understand patient segments, behaviours
- Patient reported outcomes (PRO) required
- Patient feedback included in HTAs

Real World Evidence

- Increasing interest in Real Life (comparative effectiveness and safety)
- As a way to overcome study limitations

1 EUnetHTA: European network of Health Technology Assessments

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Different recommendations for the same product
New Fixed Dose Combination in COPD - HTA assessment

Country	Recommendation *ILLUSTRATIVE*
 Germany	Additional benefit in **moderate and severe COPD with ≤ 2 exacerbations per year**
 Sweden	Patients who **do not respond adequately to LAMA or LABA monotherapy treatments**
 France	Moderate to severe COPD patients from whom **symptoms are already controlled by molecule X and molecule Y taken separately**
 Czech	Symptomatic patients with the diagnosis of **COPD category C**, **FEV_1 less then 50% predicted**
 Austria	**GOLD B COPD patients**, first prescription by pneumologist
 Switzerland	Patients who **do not respond adequately to LAMA or LABA monotherapy** treatments
Not restricted in UK, Ireland, Spain, Finland, Netherlands, Denmark, Norway, Portugal	

Impact on drug developers (I)

AMNOG in Germany[1]

- Plan for early scientific advice
- Re-consider trial design, including comparators and clinical local practice
- Get advice for dossier development, sub-group analysis
- Consider impact on other countries

Decentralisation

- Anticipate need to meet more and more diverse requirements
- Restrictions on label (after failure of other lines)
- Additional arguments and tools required, e.g. APN* (UK), Horizon Scanning (UK, Sweden), regional BIM* (Italy, Spain)

Decreasing Willingness to Fund

- Focus on high unmet need and burden of illness
- Sub-grouping strategy and stopping rules (combine with risk-sharing, e.g. rebate for non-responders)
- Acceptance of prescription limitations (reimbursement restrictions, controlled centres, hospital only use)

1. AMNOG: The Act on the Reform of the Market for Medical Products

*CCG: Clinical Commissioning Groups, APN: Advanced Product Notification, BIM: Budget Impact Model

Impact on drug developers (II)

Greater Collaboration

- Anticipate payers´ interests and concerns
- Need to build relationships with payers
- Not only the brand but the “package”
- Adaptive license

Patient Centricity

- Early engagement with patients associations and groups
- Health outcomes research focus on patients needs
- Focus on patient relevant benefits

Real World Evidence

- Opportunity to develop more evidence
- Deep dive on available patients registries
- Generation long-term evidence, including collection of economic evidence (e.g. open-label follow up, registries)

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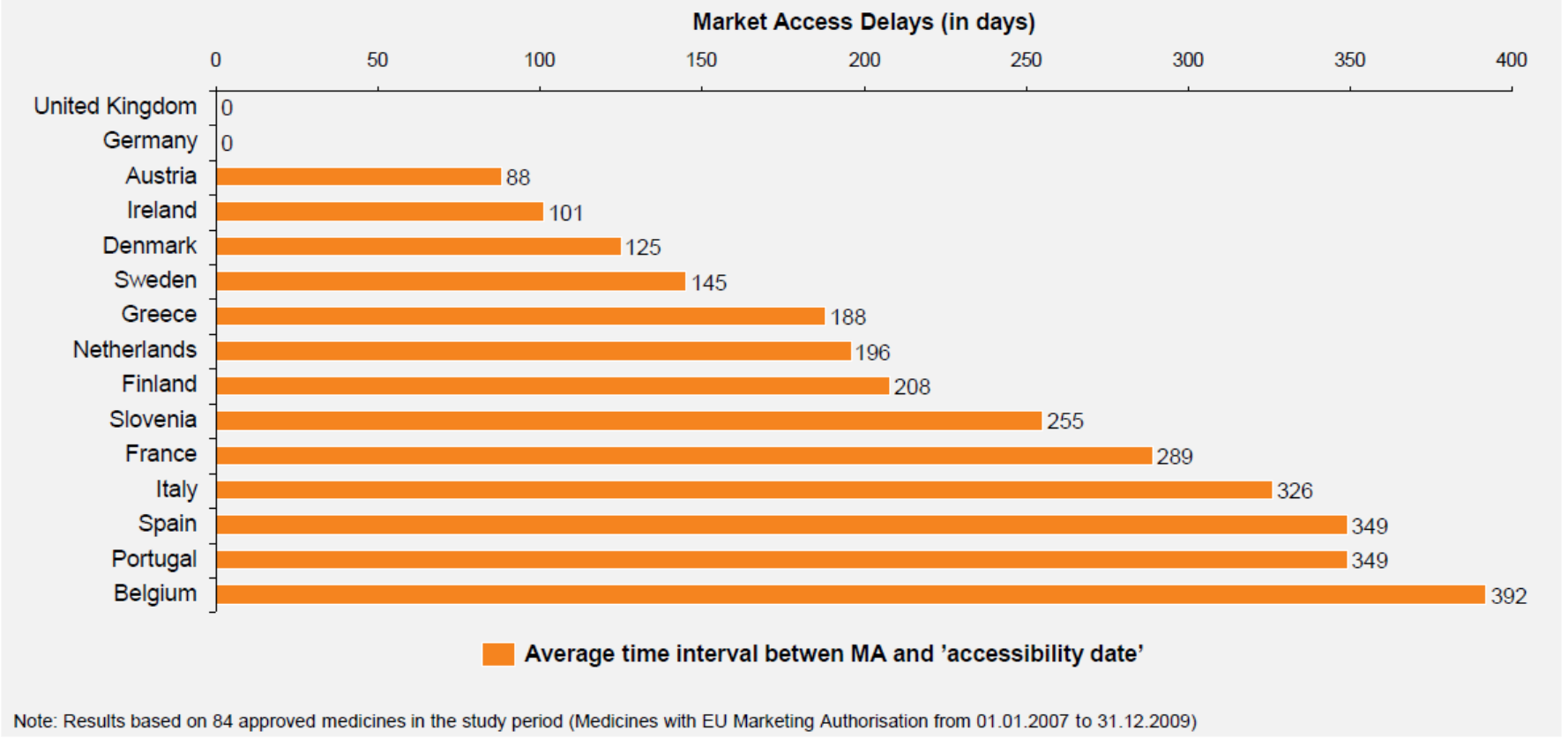
As a summary:

- Across Europe payers have different ways to assess “value for money” of new health solutions (relative effectiveness, cost-effectiveness, budget impact)
- Payers are becoming even more demanding; evidence is required to demonstrate the clinical and economic value of new drugs
- There is no Guidance on how to plan for Market Access as it is for Regulatory
- We need to learn new ways of working collaboratively with payers, understand their concerns about value uncertainty and be creative

There is room for improvement if we want to increase patients´access to new medicines

Average time between MA and 'accessibility date' for medicines with EU MA between 2007 - 2009



Note: Results based on 84 approved medicines in the study period (Medicines with EU Marketing Authorisation from 01.01.2007 to 31.12.2009)

Source: Efpia

How are we integrating Market Access in QbD?

- At what time would you consider incorporating **Market Access** requirements in the **product development**?

- What about **production costs**, at what time would you consider incorporating them in the product development process?

- Could you provide some examples on how **Regulatory or Market Access commitments** have impacted you in your drug production process?

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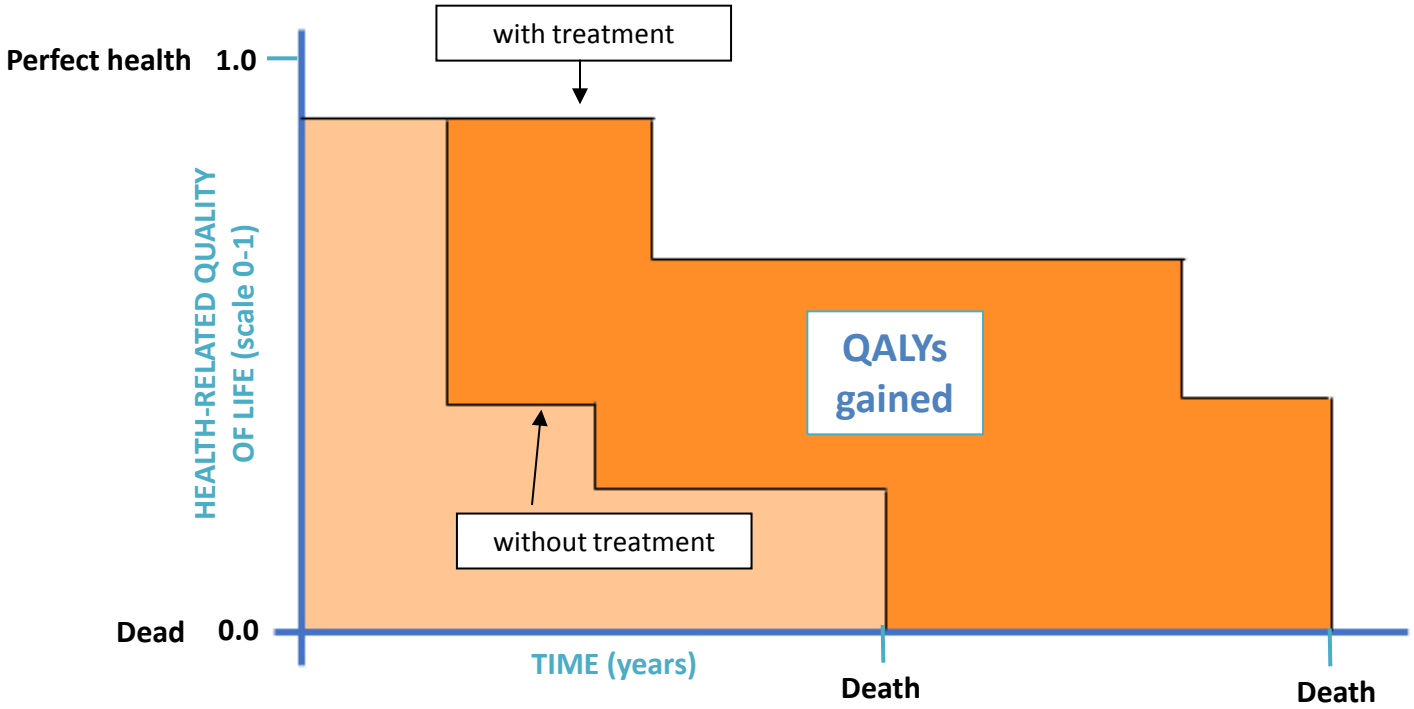
Thank You!

Back Up Slides

QALY: Quality Adjusted Life Year



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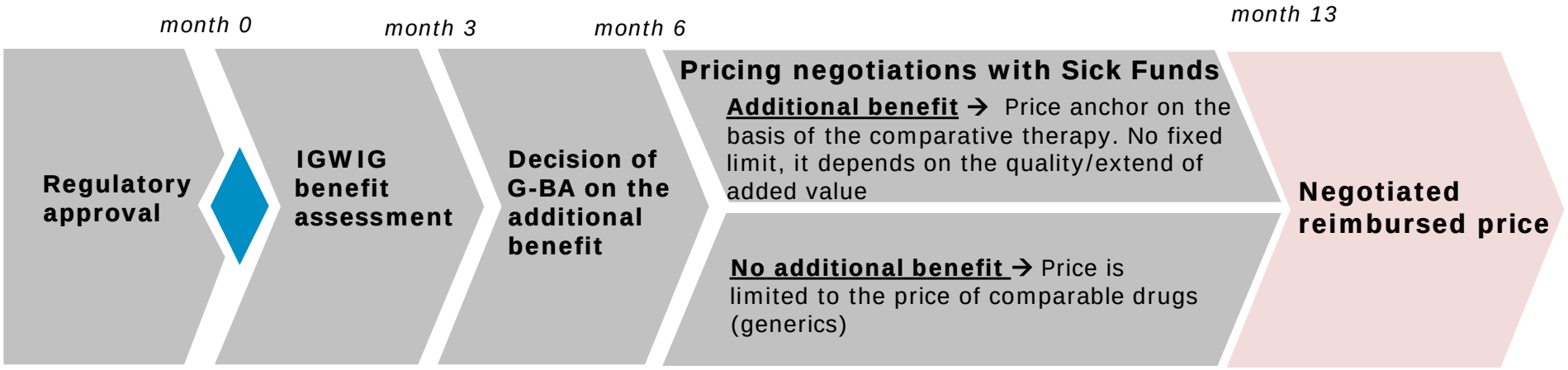
AMNOG Process in Germany



Additional Benefit demonstrated

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HTA – Some well known agencies

NICE National Institute for Health and Care Excellence

IQWiG Institute for Quality and Efficiency in Health Care

HAS HAUTE AUTORITÉ DE SANTÉ

Scottish Medicines Consortium

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