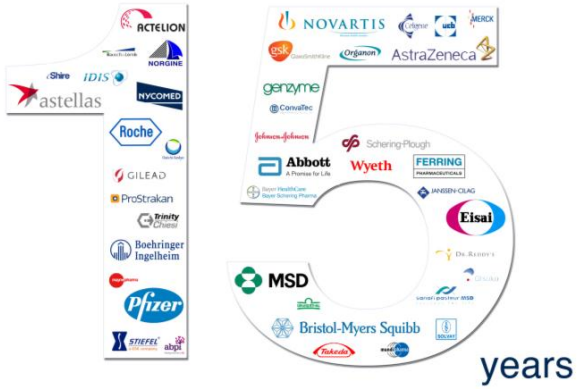


GALBRAITH WIGHT Re:thinking

Learning from best (& worst) practice: pioneering new ways to make Market Access work for healthcare companies

Colin Wight
Chief Executive, GalbraithWight

22nd March 2012

Pharma Pricing & Market Access Outlook EUROPE

Contents

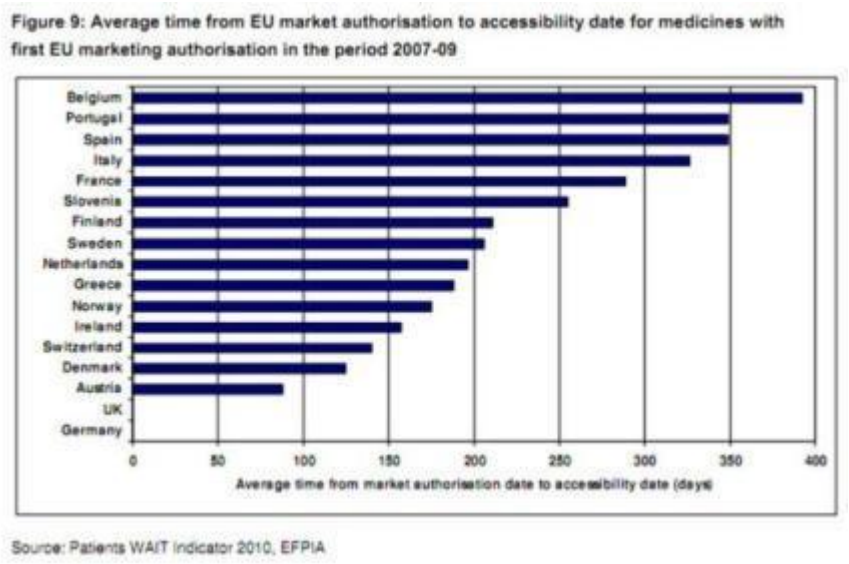
1. **The good news - what's working well**

2. The bad news - barriers, hurdles & obstacles to operational success

Pharma industry now takes Market Access seriously

GALBRAITH WIGHT Re:thinking Market Access

We actively **measure** it



We talk & **listen to Payer** customers

"Perception of value drives the willingness to pay, and those perceptions vary from country to country," "We need to do a much better job communicating value to payers" *Adam Woodrow, Vice President , Specialty Business Unit, Pfizer September 2011*

We've created **Market Access teams** & hired HEOR experts – in house & agencies

There are good examples of **best practice**

Herceptin trastuzumab

Contents

1. The good news - what's working well

2. **The bad news - barriers, hurdles & obstacles to operational success**

Insight & understanding on both sides comes directly from engaging with Payer Customers & Influencers

GALBRAITH WIGHT Re:thinking Market Access

Pharma industry still making too many unforced errors

Most market access work starts **much too late**

Market access **capabilities** are **siloed** and **too limited**

Most market access **value propositions** fail to address the issue of **'ability to pay'** in existing economic conditions

R&D focus is still **marketing authorisation**, not reimbursement

Market access is **fragmented** & **not integrated** with other mainstream company processes

So far industry has failed to **shape the way 'value' is measured** by governments & insurers

Our **pricing** strategies are **stuck in the dark ages** when we used to be chemical manufacturers

Pharma industry still making too many unforced errors

Most market access work starts **much too late**

One reason market access starts too late is a poor & inconsistent understanding of Market Access among senior management – Senior Executive research 2010*

1. A minority had little or no understanding of the term
   - "I have no idea what it means" "I don't have a definition"

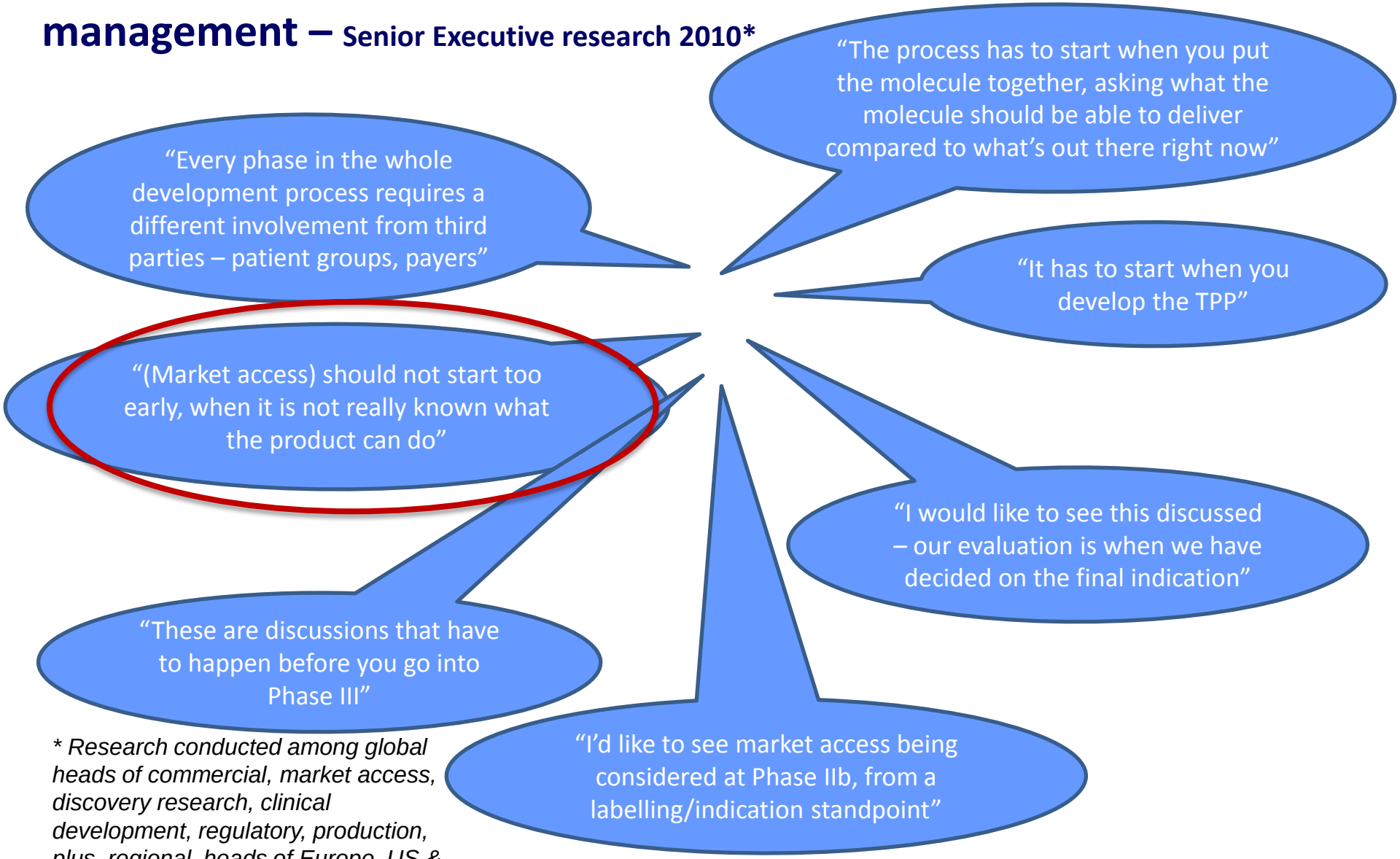
2. The majority associated regulatory approval with market access
   - Also some confusion between market access and marketing (sales reps, advertising, key claims in promotion)

3. Generally, there was a very wide variation in understanding with very differing views
   - No consistent view of market access
   - Definitions encompassed elements of regulatory approval, effective positioning and usage, target audience selection, price negotiation and reimbursement

4. Some linked the term to 'value' or 'benefits to the payer'

** Research conducted among global heads of commercial, market access, discovery research, clinical development, regulatory, production, plus regional heads of Europe, US & Asia Pacific*

One reason market access starts too late is a poor & inconsistent understanding of Market Access among senior management – Senior Executive research 2010*



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The R&D Process – a series of 'Decision Gates'

GALBRAITH WIGHT Re:thinking Market Access

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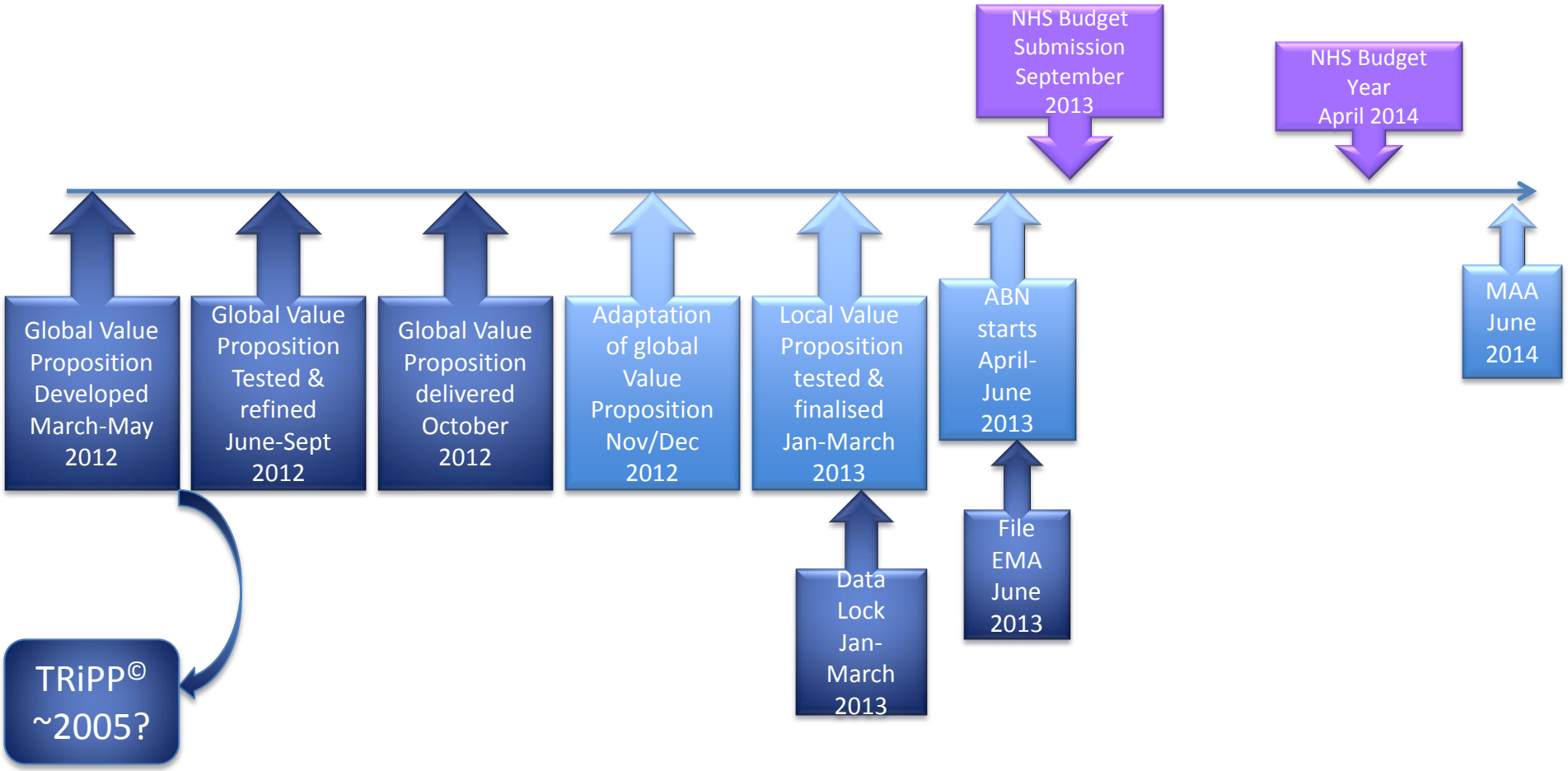
Market Access Starts Here!

…and continues throughout!

If you think Market Access expenditure is expensive, try "no access".
We spend ~$1.2 billion in R&D to bring a new drug to market*

* http://onlinelibrary.wiley.com/doi/10.1002/hec.1454/abstract

Understanding Market Access timelines & resource implications globally & locally



Launch sequence/Market Access benchmarking shows a big difference in speed of access

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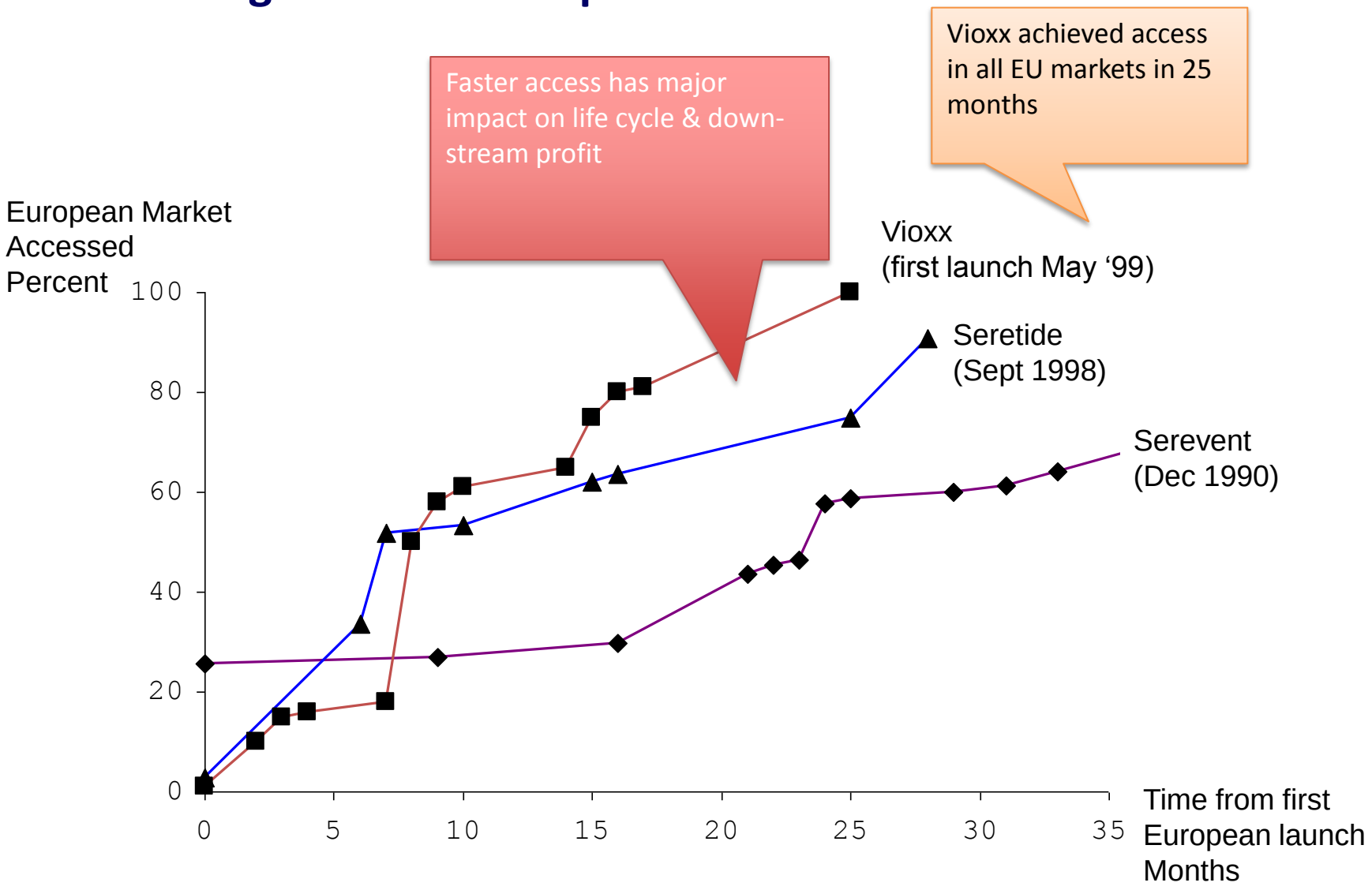

Creating dialogue - global & local

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Customer Decisions

Horizon Scanning
3yr prior to launch / start PhIII
PharmaScan / SMC / NHSC

Advance Budget Notification
18m before launch – Oncology earlier 3 y

NICE Topic selection
(Referral or Deferral)

NICE Appraisal

ACD

STA / MTA

Decision Gate

Decision Gate 5	Decision Gate 6	Decision Gate 7	Decision Gate 8	Decision Gate 9	Decision Gate 10	Decision Gate 11	Decision Gate 12
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DG Input/Output

Commercial Attractiveness Evaluation (including market access)

Rating Red/Amber/Green

Proposed Action Plan & Budget (Amber & Green only) by Shape Market, Shape Product, Shape Company

Approved Action Plan & Budget (Amber & Green only) implemented

Communication to Region & Global

Commercial Evaluation with funding agreed **at each Decision Gate** enables companies to **stage investment** for market access, market shaping & launch excellence in accordance with the **potential value** of the asset in **uncertainty**

Senior Management Education & Engagement is vital to help them understand market access timing & investment

Senior Management **knowledge**, **understanding**, **buy-in**, & **commitment** to market access culture, processes & capabilities are a fundamental & **business critical** organisational requirement for future success – without this, you're sunk!

Engage with Senior Management to **educate** & help them understand fully what Market Access means & understand their concerns about the risks

1. When it starts
2. What to do when
3. How much investment

Pharma industry still making too many unforced errors

Market access **capabilities** are **siloed** and **too limited**

We need to change the perverse internal incentives around market access

We've tended to build functional or therapeutic **silos** in Pharma, & market access is the latest version. **Take the test....**

There is a **complicity** between many Marketers that market access is **'too complicated'** with Market Access technical experts happy to agree with them to protect their own value to the company.

The result? No joined up thinking, planning & action across the brand teams at global, region & country level – so **no overall company capability** in market access

All functions need to closely align to work together to effectively satisfy the requirements of all Market Access stakeholders

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Market Access needs to be a **company-wide capability**

No functional group on their own has the answer!

Pharma industry still making too many unforced errors

Most market access **value propositions** fail to address the issue of **'ability to pay'** in existing economic conditions

We cannot be 'blind' to the economic realities which pay for healthcare....we must be part of the solution..

GALBRAITH WIGHT Re:thinking Market Access


Market jitters as Spain credit downgraded

By Victor Mallet in Madrid, David Oakley in London and Quentin Peel in Berlin
Published: March 10 2011 05:18 | Last updated: March 10 2011 22:07

The euro fell against the dollar and stock markets slid on Thursday after Moody's downgraded Spain's sovereign credit rating and revived investor fears about weaker eurozone economies.

Spain, which held triple A ratings from all the main rating agencies before the global financial crisis, had its Moody's rating cut by one notch to Aa2 – two notches below the top level and the same as that from Standard & Poor's.

The euro tumbled further against the dollar to one-week lows and was down 0.7 per cent to $1.3502 at the end of the London trading day. Spanish government bond prices fell, and at one point the yield on its 10-year debt rose to 5.55 per cent, the highest since January 11.

European Union officials said they did not expect heads of government to take any special steps at an emergency eurozone summit on Friday in Brussels in spite of the renewed market jitters.

The slow pace of European decision-making has caused hand-wringing among some EU economic policymakers. They fear EU leaders are again misjudging the patience of the financial markets.

Germany is adamant that no detailed decisions on rescue measures will be taken at the summit. In Berlin, a senior government official ruled out use of European rescue funds to finance the buying of government bonds, describing such a move as "inconceivable."

The official said that Angela Merkel, German chancellor, will make it clear that use of the permanent European Stability Mechanism, which

EDITOR'S CHOICE

Spain's banks suffer from heavy selling - Mar 10

Gavyn Davies: Warning shot to EU leaders - Mar 11

Lex: Spain - Mar 10

FT Alphaville: Spain shoots the messenger - Mar 10

Eurozone leaders to meet on stabilisation pact - Mar 10

Opinion: Europe's first step to recovery - Mar 10

Click for full graphic

Spain credit rating downgraded

10th March 2011


U.S. Loses AAA Credit Rating as S&P Slams Debt Levels, Political Process

Standard & Poor's downgraded the U.S.'s AAA credit rating for the first time, slamming the nation's political process and criticizing lawmakers for failing to cut spending or raise revenue enough to reduce record budget deficits.

S&P lowered the U.S. one level to AA+ while keeping the outlook at "negative" as it becomes less confident Congress will end Bush-era tax cuts or tackle entitlements. The rating may be cut to AA within two years if spending reductions are lower than agreed to, interest rates rise or "new fiscal pressures" result in higher general government debt, the New York-based firm said yesterday.

"The downgrade reflects our opinion that the fiscal consolidation plan that Congress and the Administration recently agreed to falls short of what, in our view, would be necessary to stabilize the government's medium-term debt dynamics," S&P said in a statement late yesterday after markets closed.

Lawmakers agreed on Aug. 2 to raise the nation's $14.3 trillion debt

US credit rating cut by S&P from AAA to AA+

6th August 2011

Italy credit rating slashed by Moody's from Aa2 to A2

4th October 2011

Payer Customer Value Proposition Template

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The 'unmet need' as perceived by the Payer is that…	
The patient population in which this unmet need exists is…….	
The Clinical justification for using (brand) versus SOC in these patients is.	
The Economic justification for using (brand) in these patients versus SOC is…	
Summary Value Proposition for Payer (sum of the parts above)…	

Pharma industry still making too many unforced errors

R&D focus is still **marketing authorisation**, not reimbursement

The R&D Process – a series of 'Decision Gates'

(extended to incorporate commercialisation decisions)

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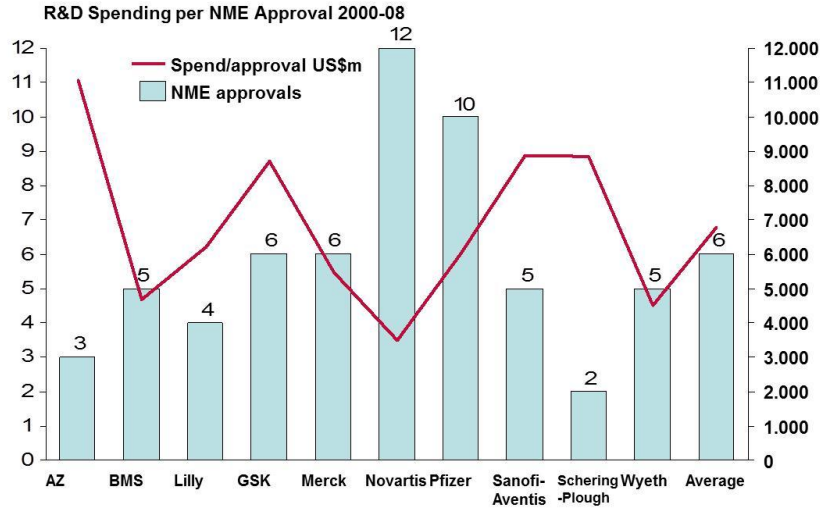


Source: FDA, public company filings

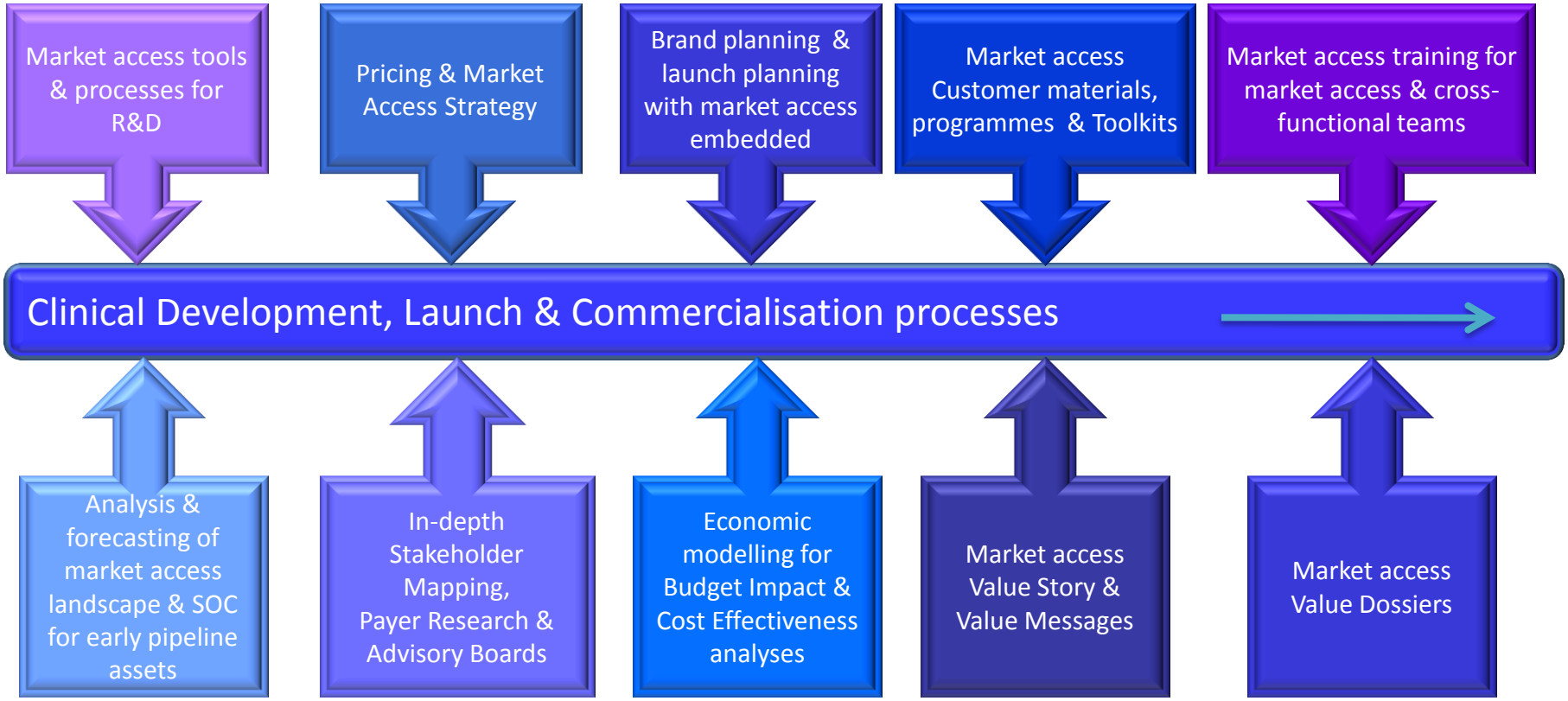
1. R&D focus on explicit needs from FDA & EMA to achieve **marketing authorisation** - best chance of regulatory approval is 'cut & paste' what got approved before

2. Traditionally, commercial involvement starts at Phase III – **too late** to shape the brand

3. Not much focus on **tools & processes** for market access early on in development

4. **Push back** from R&D on **fragmentation** of Payer opinions (e.g. NICE vs GB-A) & '**durability**' of Payer decisions relative to FDA/EMA

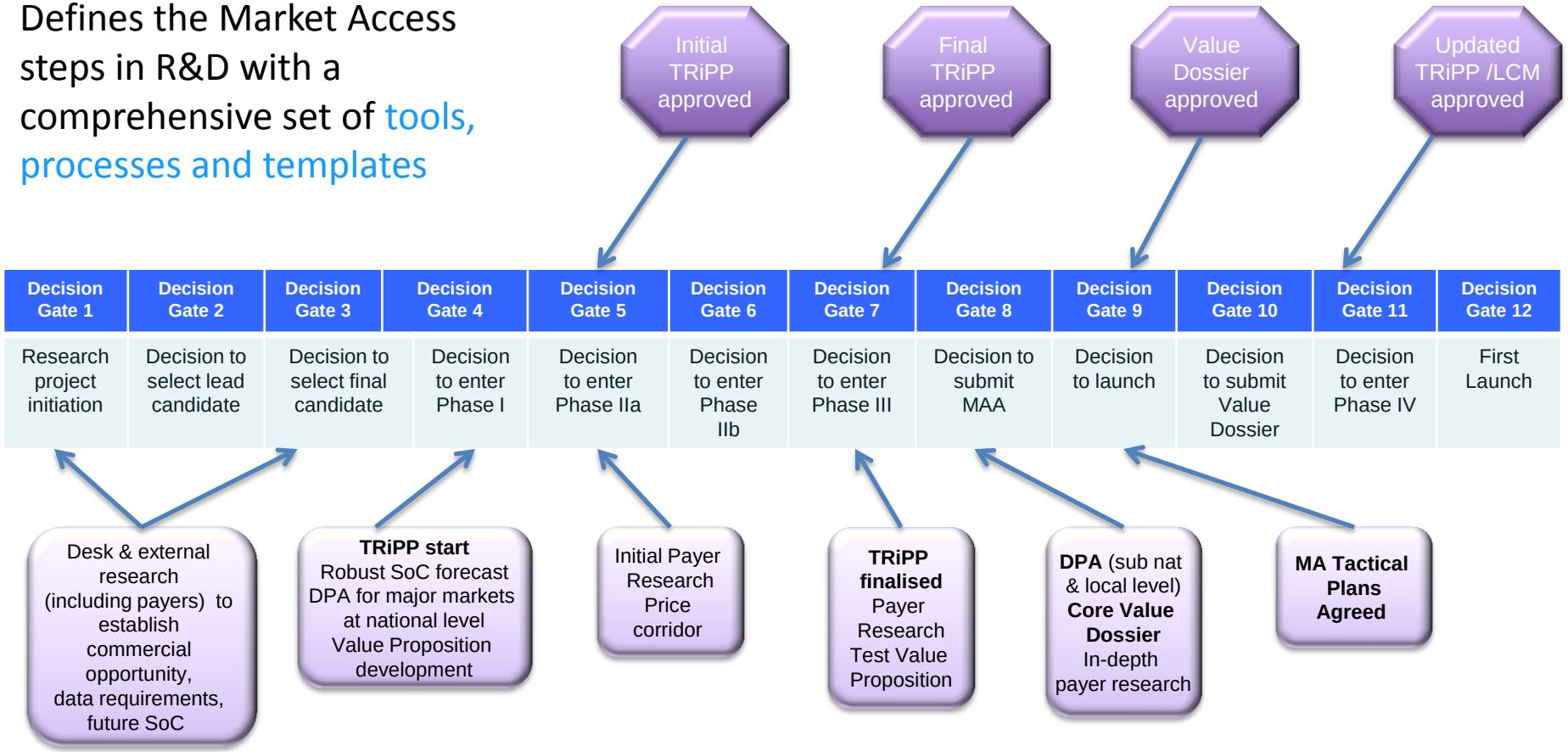
Market Access planning for clinical development & commercialisation



R&D market access planning for pipeline assets

GALBRAITH WIGHT Re:thinking Market Access

Defines the Market Access steps in R&D with a comprehensive set of tools, processes and templates



TRiPP© – Target Reimbursable Product Profile

Customer Value Identification

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Launch Excellence

1. Preparing the brand for the market
2. Preparing the market for the brand
3. Preparing the company for the brand

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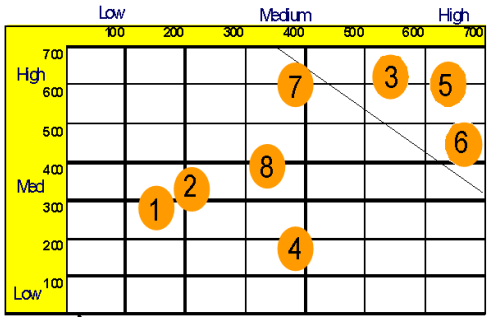
Customer Value Identification

- Commercial appraisal & Business Opportunity analysis
- Identify and evaluate commercialisation scenarios
- Identify patient population with most value, determine future market landscape, current SoC, generic launches etc.
- Preliminary TRiPP©
- Preliminary pricing based on SoC landscape research
- Phase II Payer research to identify value drivers to help design phase III trials
- Conducted in collaboration with Project Teams



Customer Value Creation

GALBRAITH WIGHT Re:thinking Market Access

Launch Excellence

1. Preparing the brand for the market
2. Preparing the market for the brand
3. Preparing the company for the brand

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Customer Value Creation

- Refined Business Opportunity, Brand Vision & Commercial Appraisal
- Refine TRiPP© based on clinical data
- Payer research to test value proposition, preliminary PE model design and data requirements
- Preliminary pricing input to Region & Global based on product proposed value
- Pricing corridor dialogue with Region & Countries
- Go-to-market commercialisation scenario planning
- Conducted with Project Teams

Customer Value Communication

GALBRAITH WIGHT Re:thinking Market Access

Launch Excellence

1. Preparing the brand for the market
2. Preparing the market for the brand
3. Preparing the company for the brand

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Customer Value Communication

- Final Brand Vision & Commercial Opportunity analysis.
- Market access tactical plans & Launch sequence agreed Global, Region & Country
- Commercialisation Go-To-Market model agreed
- Local market access strategic plans in place
- Local decision point analysis confirmed
- Core value dossier developed
- In-depth payer research to finalise pricing
- PE & BIM model development
- Conducted with Project Teams

Pharma industry still making too many unforced errors

Market access is **fragmented** & **not integrated** with other mainstream company processes

Great! Another new corporate initiative!

GALBRAITH WIGHT Re:thinking Market Access

LAUNCH EXCELLENCE

The R&D Process – a series of 'Decision Gates'

(extended to incorporate commercialisation decisions)

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When does **new product planning** begin? & end?

When does **launch excellence** begin? & end?

When does **market access** begin? & end?

When does **brand planning** begin? & end?

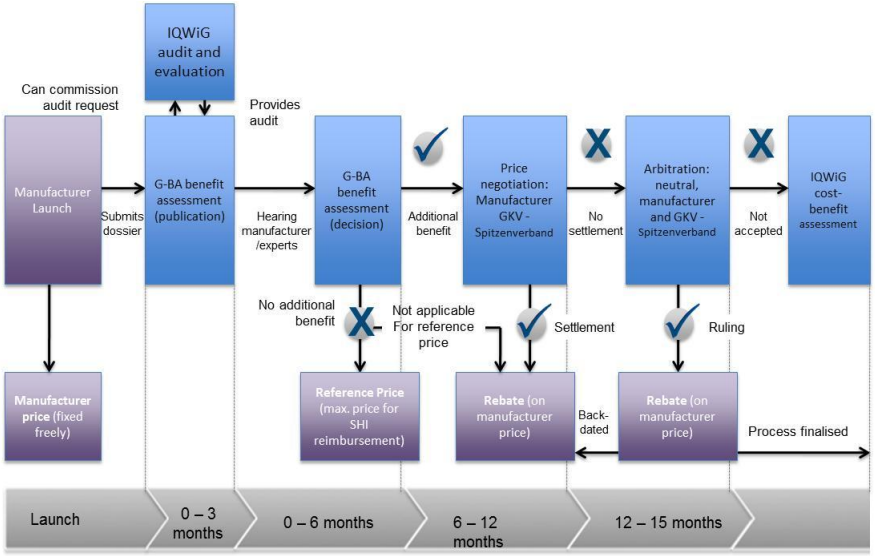
Great! Another new corporate initiative!

Many initiatives are started as **stand alone** projects so they do not get ‘too complicated’ – in particular initiatives which are ‘Big Consultancy led’ tend to be **designed as stand alone** deliverables

What companies & teams really need is **integrated processes** which promote **joined up thinking** & **cross-functional working**

New Product Planning, Launch Excellence & Brand Planning are all elements of a **continuum**

Pharma industry still making too many unforced errors

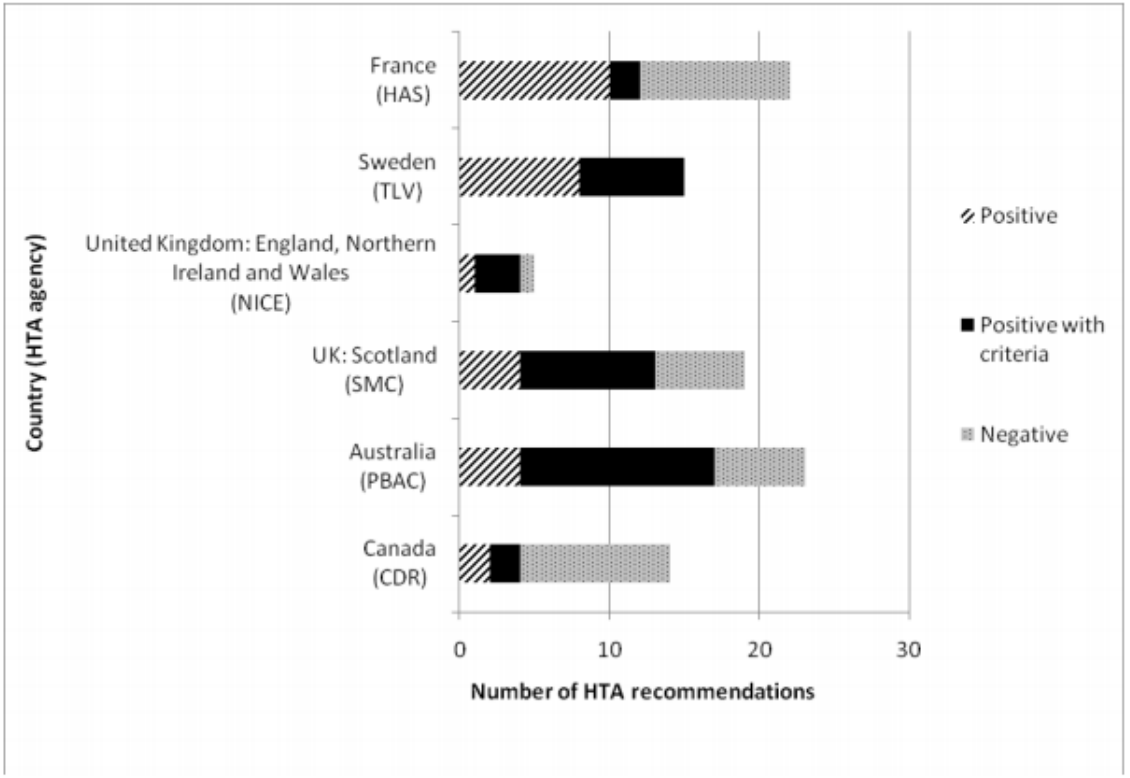


So far industry has failed to **shape the way 'value' is measured** by governments & insurers

There is duplication & inconsistency in HTA decision making between HTA bodies

There is inconsistency in decisions between different HTA bodies, thus making it difficult (& more costly) for Pharma companies to satisfy the plethora of different HTA body needs (in contrast to the more explicit needs for data from a regulatory perspective by FDA & EMA)

Figure 17: HTA outcomes in three Member States and two comparison countries for 25 Central Nervous System (CNS) drugs



Note: In the case of France, a negative recommendation is ASMR V, which essentially says that the drug has no *additional* therapeutic benefit in relation to comparators.

Source: Differences in prices of and access to pharmaceuticals in the EU, Policy department EP, 2011

Industry needs to do a much better job in shaping the debate around measuring & rewarding 'value'

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Home U.K. Home News Sport U.S. Showbiz Femail Health Science Money Rig

Health Home | Health Directory | Health Boards | Diets | MyDish Recipe Finder

Don't give out cancer drugs if it's just to extend life: Treatment costs can't be justified, say experts

- NHS spends £5bn annually on cancer treatments up from £3bn in 2002
- Around 310,000 Britons a year are diagnosed with cancer

By SOPHIE BORLAND

Last updated at 2:50 PM on 27th September 2011

Comments (472) | Add to My Stories | Share | Like 681

Patients with terminal cancer should not be given life-extending drugs, doctors said yesterday.

The treatments give false hope and are too costly for the public purse, they warned.

The group of 37 cancer experts, including British specialist Karol Sikora, claimed a 'culture of excess' had led doctors to 'overtreat, overdiagnose and overpromise'.

The life-prolonging drug called Sutent which is given to kidney cancer patients. Right, Karol Sikora who is one of the 37 experts who warn that the cost of cancer treatments cannot be justified

Value Based Pricing: Is industry beginning to smell a rat?

Engelbert Gunster, Country Manager, Germany Boehringer Ingelheim (right of picture)

Boehringer-Lilly won't launch Trajenta in Germany

Published on 05/09/11 at 07:30am

The drug was launched in the US, where it is know as Tradjenta, in June

Boehringer Ingelheim and Lilly have decided not to launch their new diabetes drug Trajenta in Germany and say the country's new pricing controls are to blame.

Gunster said that the drug could become available only if there was **more transparency** regarding Germany's pricing process.

"We want to offer patients with diabetes our drug at a reasonable price. We believe Trajenta is an innovative therapy that may improve their standard of care and their long-term health,"

September 2011

Value Based Pricing: Is industry beginning to smell a rat?

Simon Jose, President of the ABPI and General Manager GSK UK

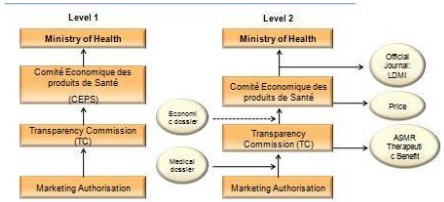
"**the devil is in the detail** in terms of how the VBP system will function. However, noises from Lansley (Secretary of State for Health) suggest an ex post system - which would mean companies could launch their drugs at whatever price they like and then face a review of prices some time after"

"... VBP should not be used to "**squeeze the medicines bill**"

August 2010

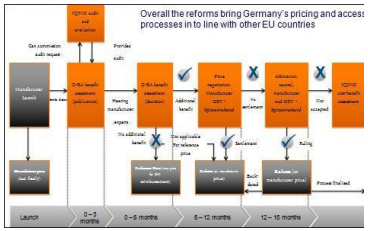
.

What have we learnt about 'VBP' schemes in other EU countries? Governments are short term & partisan – it's in their nature



France

- HAS determines burden of disease (through SMR rating) and level of innovation (through ASMR rating) – ASMR is by indication
- CEPS negotiates price-volume based on the 'bundle' of ASMR ratings on behalf of CNAM etc
- Clear evidence of a **'downward' trend in ASMR ratings** awarded - likely due to economic pressure on French public sector deficit & Eurozone economic crisis



Germany

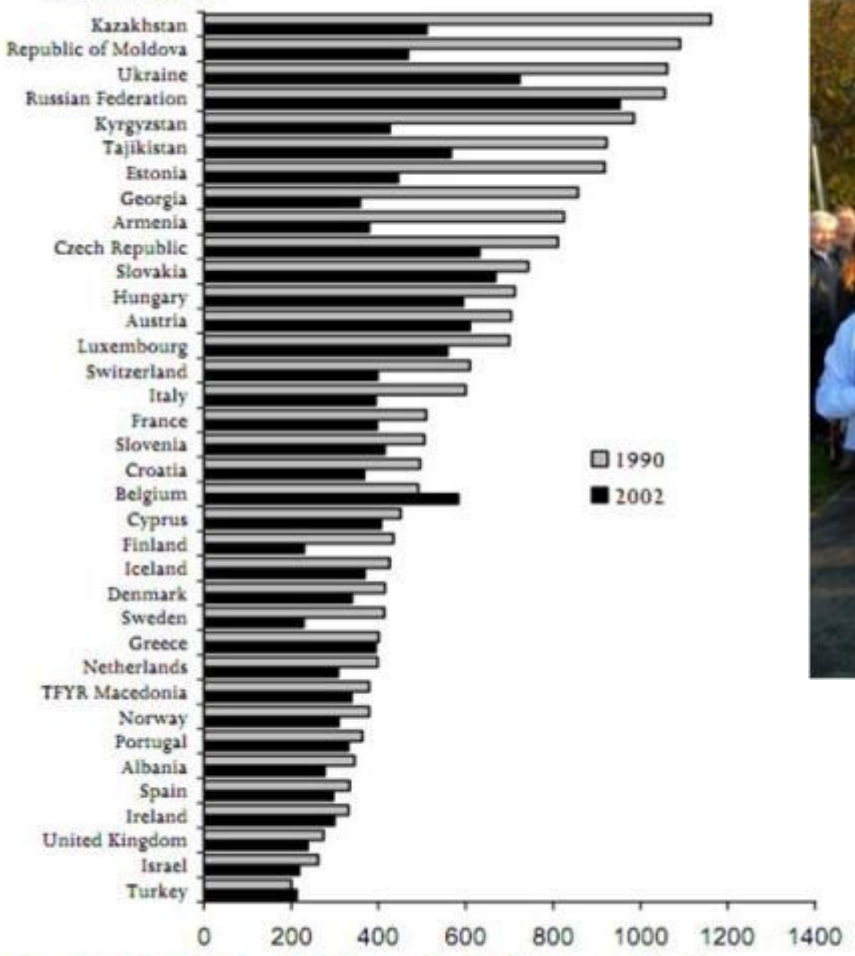
- New AMNOG law introduced January 2011
- Clinical benefit assessed by GB-A/IQWIG – rating scale not dissimilar to ASMR ratings (but not the same)
- Based on clinical benefit, price negotiated with GKV/Krankenkassen
- Clear evidence of **generics chosen by GB-A/IQWIG as the comparators**, a likely means to push down prices of new products (e.g. metformin proposed as comparator for assessment of Trajenta benefit /price reference – not Januvia)

In most countries, Medicines represent only ~15% of total healthcare costs - they are not the solution to the 'big issue' of managing total healthcare costs

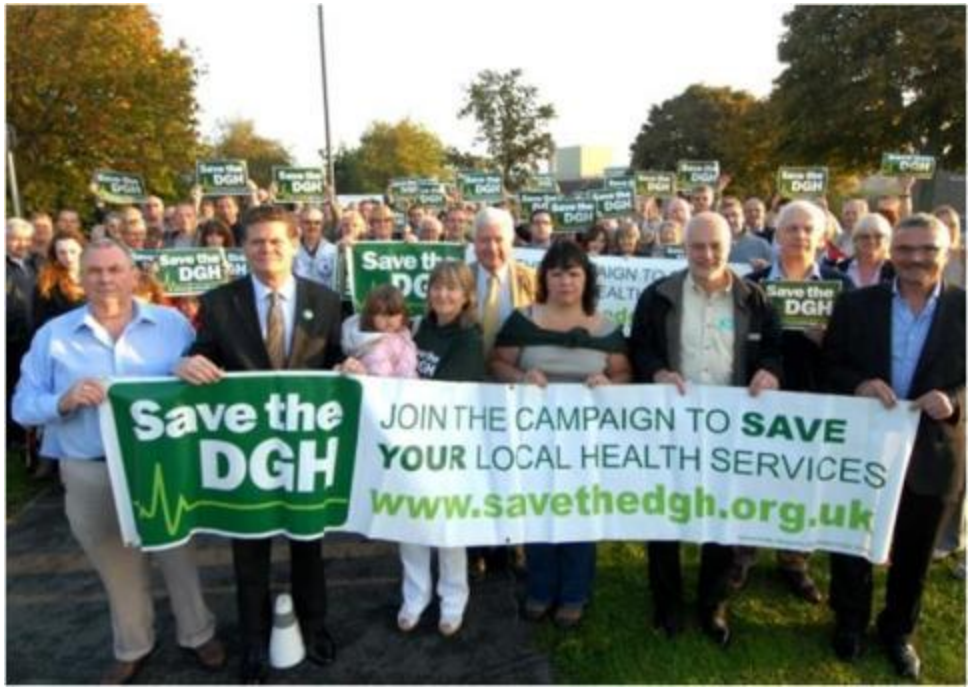
80%-85% of healthcare costs include massive over capacity in hospital beds, huge fixed costs in secondary & tertiary care & multiple trades union practices which block change

GALBRAITH WIGHT Re:thinking Market Access

Fig. 1. Acute hospital beds per 100 000 population, 1990 and 2002 (or latest available year)



Source: European health for all database, WHO Regional Office for Europe, 2004 (5).



We must open the debate about improving health outcomes across **all healthcare costs** – not just the medicines silo

Pharma industry still making too many unforced errors

Our **pricing** strategies are **stuck in the dark ages** when we used to be chemical manufacturers

Considerations for us when thinking about Pricing & Reimbursement discussions with Payers….

GALBRAITH WIGHT Re:thinking Market Access

- At filing we know very little about the **performance** of our medicines in **delivering health outcomes** in a range of different patients at launch due to the very controlled nature of Phase II & III trials – Payers now assume the 'real life' results will be less good

- We seldom know what the **'right' dose** is of our new medicines until they have been used for several years in many patients – Payers have been 'hit' by 'dose creep' (e.g. Zyprexa) causing greater budget impact than predicted, which makes Payers distrust our forecasts

- Most medicines are developed for **multiple indications** (~80% of a total brand value comes from indications & forms after the first marketing authorisation), **over several years**, many of which will have a **different value (ICER)** from each other

- We've told Payers for many years that the cost of our medicines to them is dependent on how much of it they use in each tablet, vial, infusion or injection – but **manufacturing costs rarely feature in making Pharma pricing decisions** – so why do we continue with this myth?

Quick calculation – what's the cost of my new cancer medicine?

Patient weighs 75kg

Dose is 10mg/kg

Infusion is 1 infusion per month

Vials contain 500mg in 50ml diluent

Treat to progression

Price is €7,000 per 500mg vial

Label specifies single use vials

Quick calculation – what's the price of my new cancer medicine?

Patient weighs 75kg - Dose is 10mg/kg = 750mg per infusion

Vials contain 500mg in 50ml diluent - Price is €7,000 per 500mg vial so for 750mg infusion 2 vials are needed (label specifies single use vials) = **€14,000 per infusion**

Infusion is 1 infusion per month – so cost is **€14,00 per month** (of which €3,500 is wasted due to singe use vials)

Plus infusion time

Treat to progression? – **who knows**!

Some **better answers**? (dependent on 'value' calculation)
€14,000 per patient per month – based on real use
€14,000 per patient per month, irrespective of vial consumption
€14,000 per patient per month of progression free survival above SoC
€30,000 per patient total lifetime cap

We need to forge Price based on value in terms of delivering Health Outcomes – which evolves over time

A pricing strategy & value proposition which recognises the many unknowns at launch, but is based upon delivering improvement in health outcomes, not Kg of chemical.

A healthcare system which realises value is not all delivered at launch, that health outcomes take time to show, and that value changes over time – parametric evaluation is required

Patients, Healthcare Professionals & Payers want health outcomes, not chemicals!

Market Access defined

The **process** to ensure that all **appropriate** patients who would **benefit**, get **rapid** and **maintained** access to the brand, at the **right price**

Customers – all stakeholders (individuals, committees & organisations) who make or influence **decisions** about price, reimbursement & funding which enable access for the patient

Market Access is much more than **a department**, it is **a way of doing business**

GalbraithWight is a team of **expert practitioners** with extensive **international**, **senior level operational experience**……

who **design** & **deliver** **Consulting** & **Training** solutions for the **global** healthcare business….

focused on
Market Access,
New Product Planning & **Launch Excellence** &
Brand Planning & **Marketing Excellence**….

with **class leading understanding & practice** of **Market Access** at their **heart**, because **Market Access** is the single most important determinant of commercial success, **globally**.

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GALBRAITH WIGHT Re:thinking Market Access

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Patient Experience Network

www.patientexperiencenetwork.org

- Our mission is to recognise, share, measure and embed, sustain and celebrate best practice in patient experience.

- Improving the patient experience not only makes patients feel cared for, but also
  - Improves health outcomes
  - Improves healthcare system efficiencies
  - Improves employee engagement
  - Improves healthcare organisational reputation and goodwill.

PEN is a not-for-profit company established & supported by GalbraithWight

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GALBRAITH WIGHT Re:thinking

Helping healthcare companies improve lives & create value through **innovative** commercialisation **solutions** & **capabilities**, globally!

Colin Wight
Chief Executive, GalbraithWight
22nd March 2012

Pharma Pricing & Market Access Outlook EUROPE