GALBRAITH WIGHT Re:thinking Market Access

Helping healthcare companies enable patients & their carers gain rapid & maintained access to life saving & enhancing healthcare, through **innovative** Market Access **solutions** globally.

Three Vital Areas for Improving Market Access – for Industry & Payers

Colin Wight: Chief Executive GalbraithWight

Agenda

1 Removing ‘unforced errors’ from market access planning & implementation

2 Focusing beyond achieving national pricing & reimbursement

3 Focusing on all healthcare costs, not just medicines

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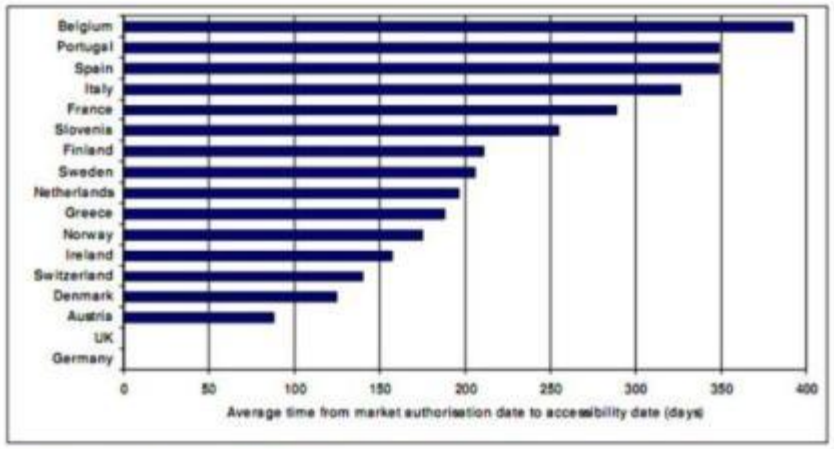
Pharma industry now takes Market Access seriously

We actively **measure** it

Figure 9: Average time from EU market authorisation to accessibility date for medicines with first EU marketing authorisation in the period 2007-09



Source: Patients WAIT Indicator 2010, EFPIA

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

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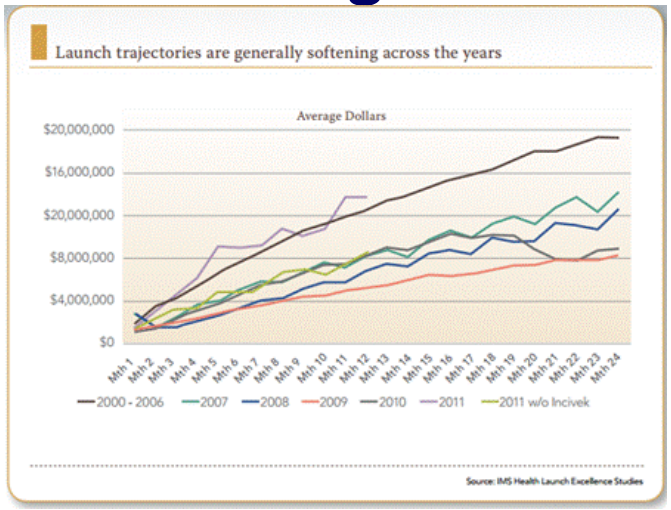
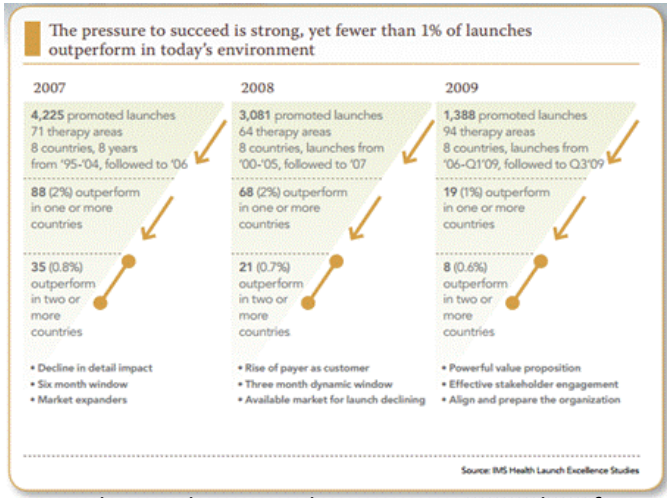
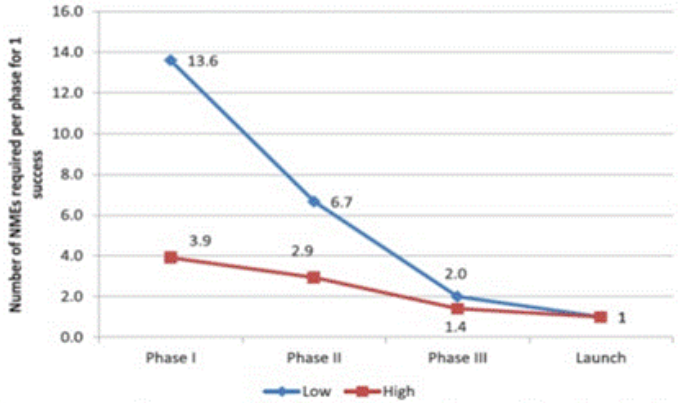
But…Pharma performance in launching new products is declining





Success Rates

Figure 2.6. Number of NMEs required per phase for one successful NME, based on recent estimates for probability of success (high and low estimates)



Source: Mestre-Ferrandiz, J., Sussex, J. and Towse, A. (2012) *The R&D Cost of a New Medicine*. London: Office of Health Economics.

OHE concluded that overall, cumulative clinical success rates appear to have decreased over time.

According to data provider IMS, commercial performance of Pharma launches is declining.

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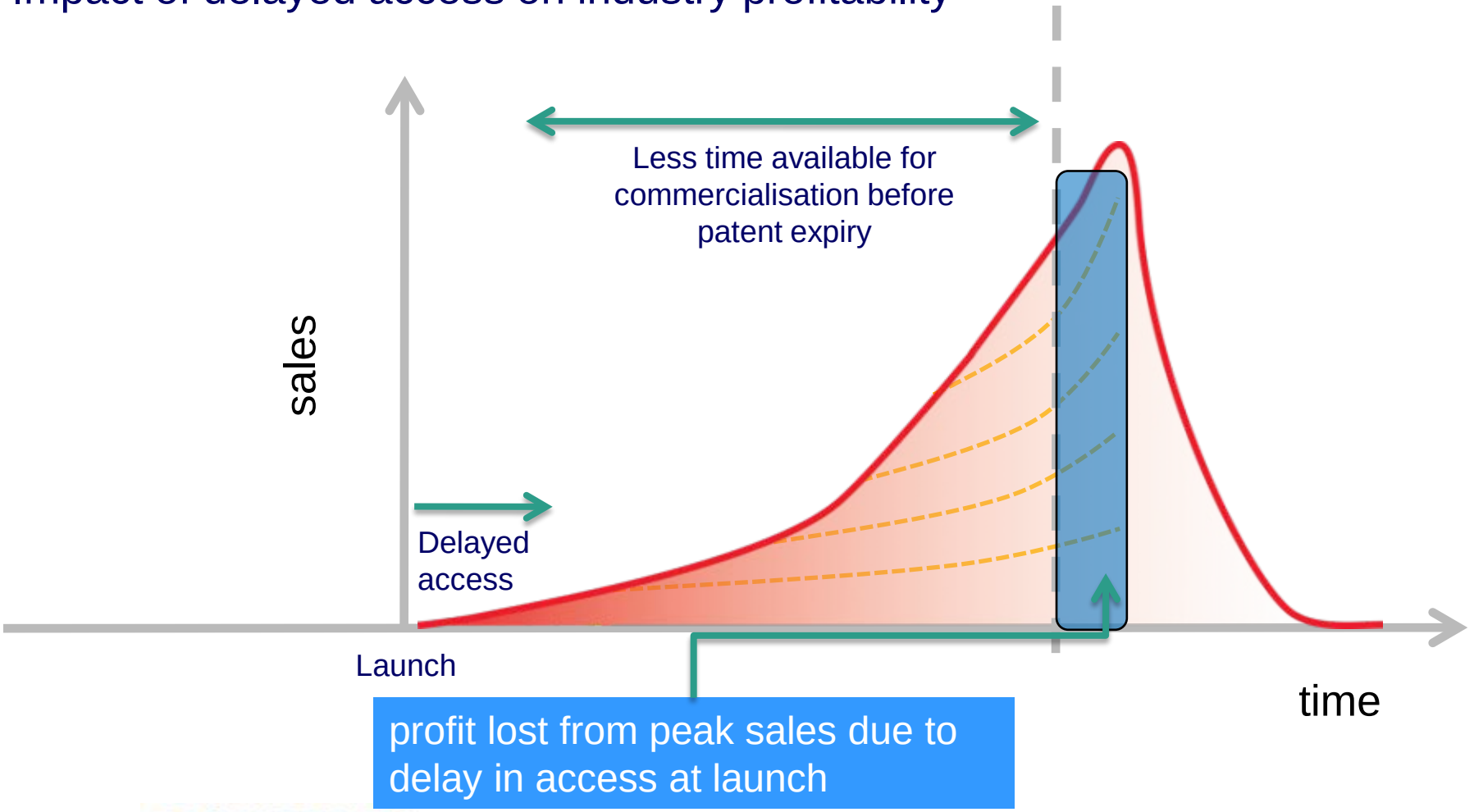
The financial risk not launching brands successfully is huge – through delayed access

Impact of delayed access on industry profitability



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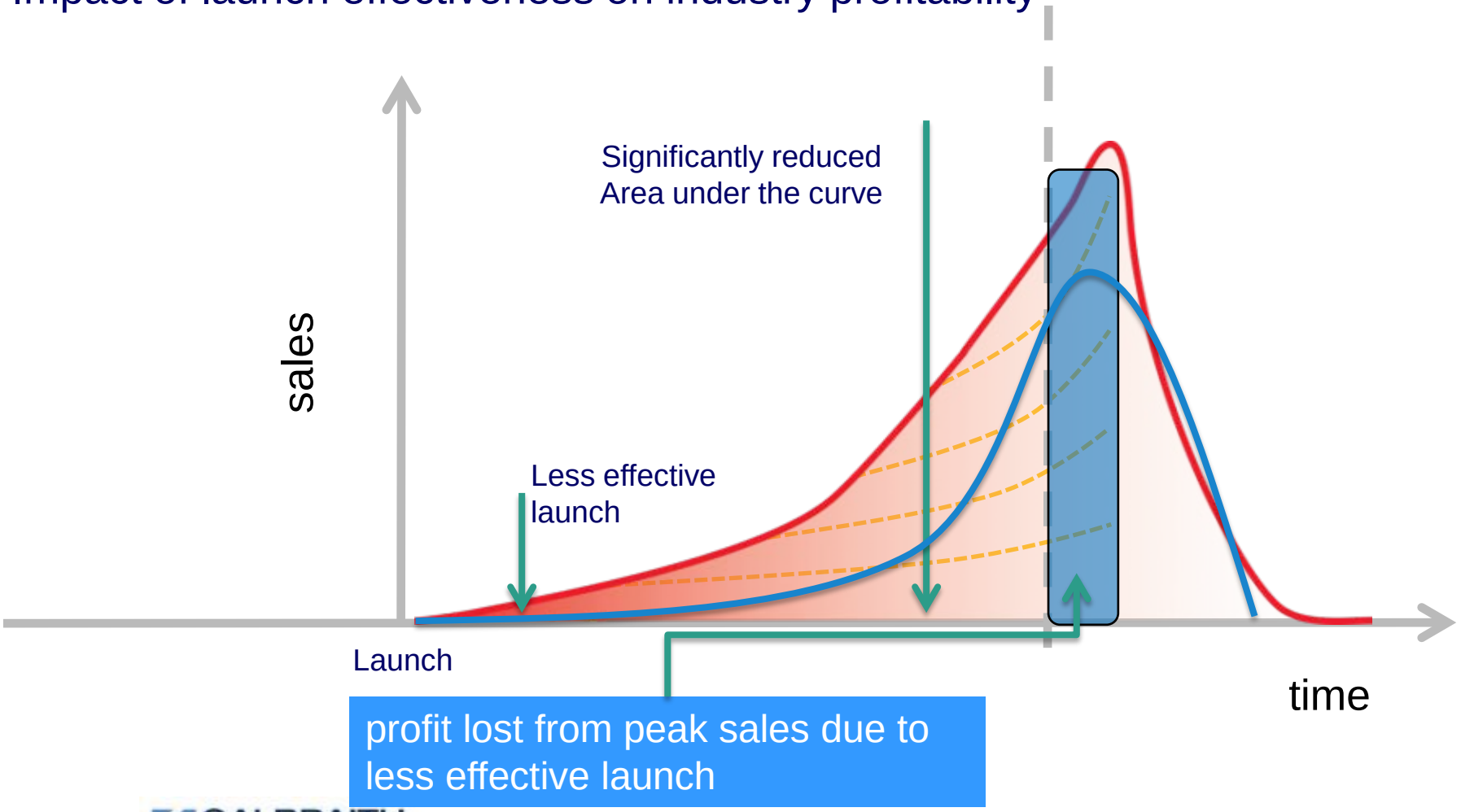
The financial risk not launching brands successfully is huge – through poor launch panning & implementation

Impact of launch effectiveness on industry profitability



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Market Access

Pharma industry still making too many unforced errors

1 Most market access work starts **much too late** as Senior Managers do not yet fully appreciate the timing and investment needs

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

"Every phase in the whole development process requires a different involvement from third parties – patient groups, payers"

"The process has to start when you put the molecule together, asking what the molecule should be able to deliver compared to what's out there right now"

"It has to start when you develop the TPP"

"(Market access) should not start too early, when it is not really known what the product can do"

"I would like to see this discussed – our evaluation is when we have decided on the final indication"

"These are discussions that have to happen before you go into Phase III"

"I'd like to see market access being considered at Phase IIb, from a labelling/indication standpoint"

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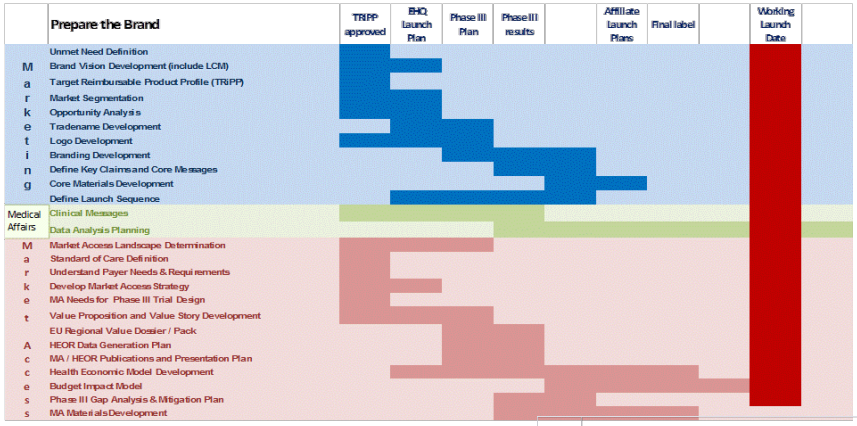
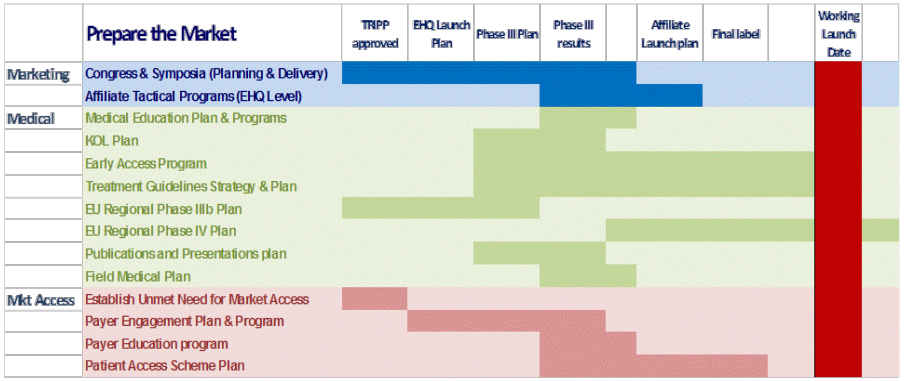
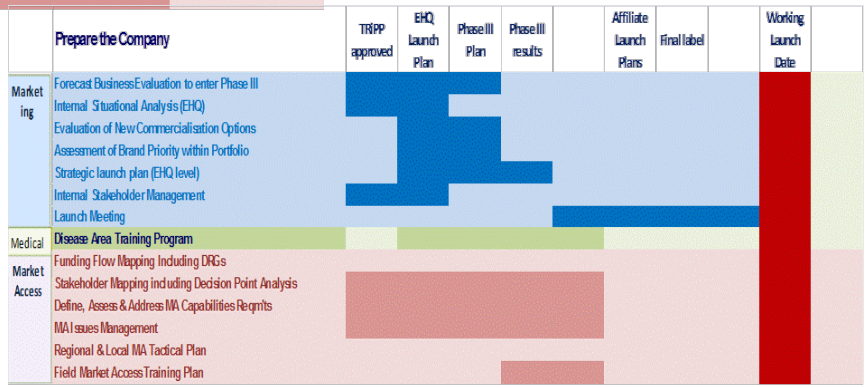
** Research conducted among global heads of commercial, market access, discovery research, clinical development, regulatory, production, plus regional heads of Europe, US & Asia Pacific*

Working out what to do when for Market Access & Launch Excellence has been well established







Decision Gate 1	Decision Gate 2	Decision Gate 3	Decision Gate 4	Decision Gate 5	Decision Gate 6	Decision Gate 7	Decision Gate 8	Decision Gate 9	Decision Gate 10	Decision Gate 11	Decision Gate 12
Research project initiation	Decision to select lead candidate	Decision to select final candidate	Decision to enter Phase I	Decision to enter Phase IIa	Decision to enter Phase IIb	Decision to enter Phase III	Decision to submit MAA	Decision to launch	CHMP Decision - Decision to submit Value Dossier	Decision to enter Phase IV	First Launch

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
- 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
- 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

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Market Access is different in America – causing inappropriate lateness in market access planning for some US-based Pharma companies

- No national pricing & reimbursement agency or process
- ‘Expensive’ innovative new medicines always get covered
- Culturally opposed to rationing of healthcare (“death panels”)
- Affordable Care Act prevents attaching economics to decision making
- Even CMS delivered through competing private MCOs

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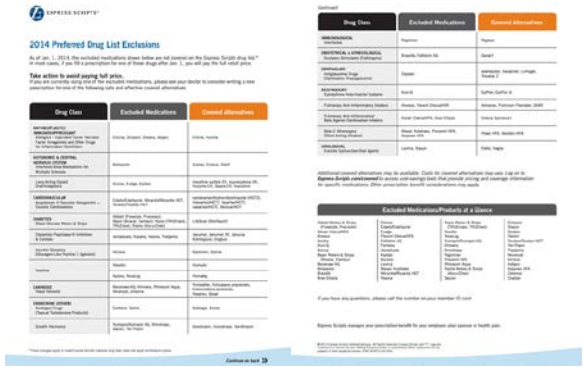
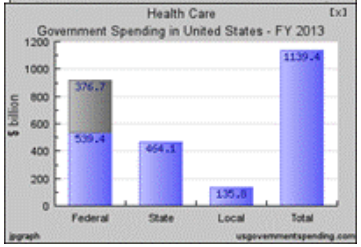
But…America is changing – slowly

- CER ‘on the agenda’
- MCOs & Care Pathway companies want cost & cost-effectiveness data & are willing to make decisions based on this type of analysis
- CMS now represents more than 50% of medicines cost for America, and wants to find savings
- Plans increasingly restrictive on access to ‘expensive’ medicines – higher tier, high co-pay, prior authorisations, bigger rebates – e.g. Express Scripts new exclusion list
- International exchange of cost effectiveness information & methodologies – inter-governmental, ISPOR, HTAi, INAHTA





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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

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Pharma industry still making too many unforced errors

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We need to change the perverse internal incentives around market access

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

There is an apparent **complicity** between many Marketers that market access is **'too complicated'** with HEOR 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

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

No functional group on their own has the answer!

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

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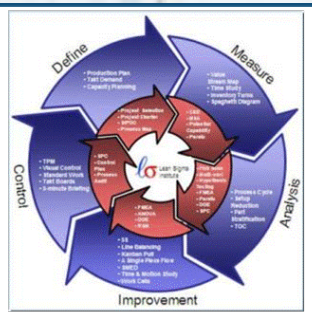
Great! Another new corporate initiative!

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**

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



LAUNCH EXCELLENCE

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


Market jitters as Spain credit downgraded

Spain credit rating downgraded

10th March 2011

France credit rating downgraded

13th January 2012


Moody's downgrades France's credit rating to AA1

Agency says outlook remains negative, despite Hollande's pledge that his reforms will reduce public deficit to 3% by 2013

Ken Willsher in Paris
The Guardian, Tuesday 20 November 2012

Moody's suggested that Hollande's proposed reforms were 'unlikely to be sufficiently far-reaching to restore competitiveness'. Photograph: Philippe Wojazer/Reuters


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

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

6th August 2011

UK credit rating downgraded

23rd February 2013


UK AAA downgrade: Budget is now George Osborne's make or break moment

If next month's Budget wasn't already the make-or-break moment of George Osborne's political career, it is now.

Osborne staked his reputation on preserving the triple-A from the moment the Tories gave a cast-iron pledge "to safeguard Britain's credit rating" in their 2010 election manifesto. Photo: DAVE THOMPSON/PA

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

4th October 2011

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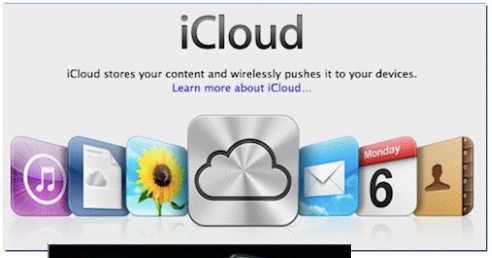
Incremental Innovation – we recognise & value it when we see it – except in medicines development?

1984

1982

1978



iTunes

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Defining ‘unmet need’ for a Payer is not the same as clinical unmet need & must be shaped from a Payer’s perspective

“A new treatment for prostate cancer which delivers equal efficacy with few side effects is needed”

“Despite existing therapies for treatment naïve prostate cancer, patients continue to progress and die prematurely, and suffer a poor quality of life due to the side effects of subsequent chemotherapy. The costs of premature death and management of chemotherapy-related side effects are estimated to cost the healthcare system € per year”

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A systematic approach to developing the Value Proposition, Value Story & Value Messages is required

The **Value Proposition** (an internal document which the Customer will never see) setting out the disease/indication-specific main 'building blocks' in terms of:

- The unmet need as perceived by the Payer (or to be perceived by the Payer after market shaping activities) clearly identifying Payer perception of current &/or 'emerging' SoC (or SoC options) for this unmet need & setting out the clinical & economic burden
- The specific patient population (specific enough to count them & identify them) in which there is this specific unmet need
- The clinical rationale for why this new medicine should be used relative to SoC
- The economic & financial rationale for why this new medicine should be used, relative to SoC
- The summary statement of the above elements

The **Value Story** is the translation of the Value Proposition into a Customer-facing communication which sets out the rationale in a logical step-by-step manner for the new medicine to be price approved, reimbursed, funded, included in plan coverage etc. The Value Story is divided into 'bite size chunks' of information which are easy to understand and assimilate by Payer customers, many of whom are generalists and not specialists in the disease area or in complex health economics. The Value Story sets out the best order to present the information to build Payer customer belief in the value of the new medicine

The **Value Messages** are the individual elements of each step of the Value Story which are communicated to the Payer Customer, setting out each compelling message 'headline', sub messages which support the main headline message, the data which supports this message headline, and the reference sources for this data providing robust support for each message throughout the Value Story

Each element of the Value communication should be thoroughly tested & validated with Payer Customers in the key markets

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In most Pharma companies, R&D is still incentivised only on regulatory rather than reimbursement approval

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. Little evidence of TPPs which addresses Payer needs & requirements – such as a Target Reimbursable Product Profile (TRiPP©)

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

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

5. Push back from R&D on fragmentation of Payer opinions (e.g. NICE vs G-BA) & ‘durability’ of Payer decisions relative to FDA/EMA

6. Early scientific advice still in it infancy, with ‘competition’ developing for income between agencies (e.g. NICE vs. EUnetHTA) – but **could** lead to a common EU clinical effectiveness assessment conducted by or with EMA

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

- 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?

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Value delivered by the same medicine varies by disease

- Bevacizumab in combination with a taxane for the first-line treatment of **metastatic breast cancer** - ICER for bevacizumab plus paclitaxel versus weekly paclitaxel was between £110,000 and £259,000 per QALY gained
- Bevacizumab in combination with oxaliplatin-containing regimens as a second-line treatment for **metastatic colorectal cancer** the ICER was £103,000 per QALY gained.
- Bevacizumab in combination with paclitaxel and carboplatin for first-line treatment of **advanced ovarian cancer** gave a range of ICERs from £128,000 to £161,000 per QALY gained.

- Etanercept for **active polyarticular-course juvenile idiopathic arthritis** whose condition has not responded adequately to, or who have proved intolerant of, methotrexate the ICER is in the region of £15–30,000 per QALY
- Etanercept for **first-line treatment for early RA**, the estimated ICER with methotrexate is £78,100 per QALY
- Etanercept in **adults with active psoriatic arthritis**, the ICER was £12,480 per QALY gained when compared with best supportive care.

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Source: www.nice.org.uk

The value of innovative medicines is delivered over decades, with the majority of benefit delivered by generic use post patent expiry

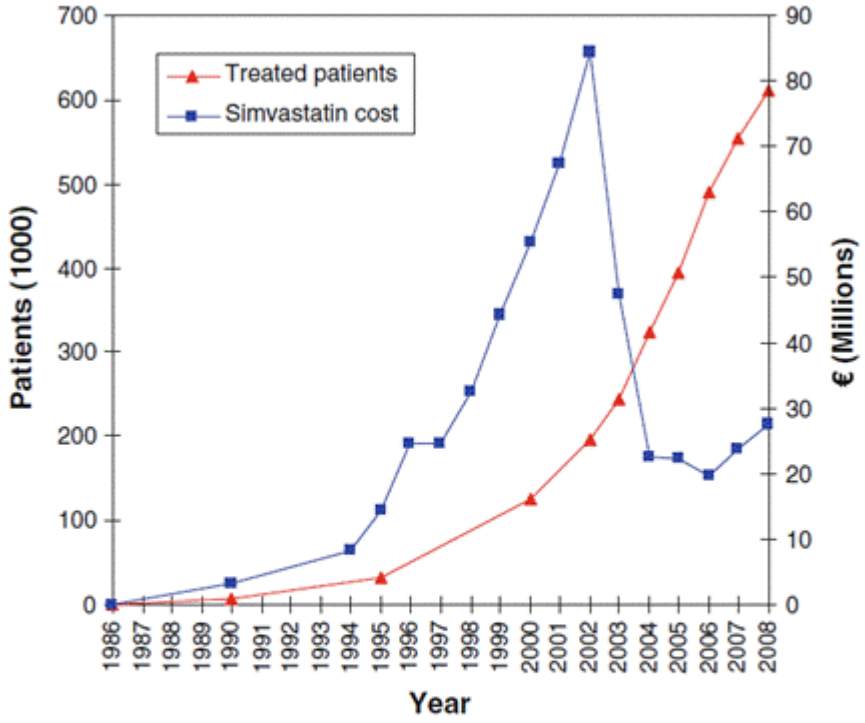

Fig. 1 The total cost of simvastatin prescriptions and the number of patients treated in Sweden 1987–2008. Source: National board of Health and Welfare [21], sales data from MSD Sweden AB and Apoteksbolaget AB (data on file)

"The fact that such a large proportion of the social surplus being appropriated by others than the innovator highlights the relevance of a societal perspective in economic evaluation. It may also make a case for considering looking a dynamic cost–effectiveness when assessing the introduction of new therapies."

Source: Cost–effectiveness of statins revisited: lessons learned about the value of innovation. Peter Lindgren, Bengt Jönsson. Eur J Health Econ (2012) 13:445–450

Innovative Pricing – some potential ideas

Medicines, (and the package of care around them), could be priced according to 'value' which would mean by indication

Issues such as fraud prevention can be managed through already existing Registries or other independent patient tracking measures

These patient tracking methods would also allow the prospective gathering of health outcomes & PROMs data, which could be of great importance to Payers, Patients & industry for future value assessments

These patient tracking methods can be managed by some of the innovative approaches of the supply chain companies such as Celesio & Alliance Boots/Walgreens

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Solutions already exist – in concept

Healthcare systems already conduct differential pricing by intervention – through DRGs

Hospitals routinely charge different amounts for the same operating theatre, using the same surgical team, but differentiated on the procedure, through the DRG system

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

A pricing & value strategy 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 to pay for health outcomes, not 'pills'!

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6 Same old **commercial model**

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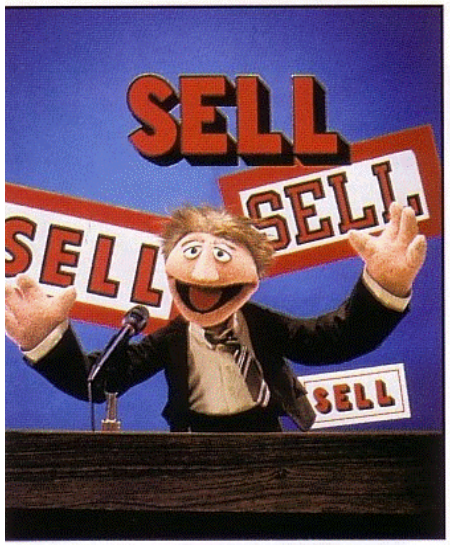
Same old commercial model – still….

"All big pharma sales force models are the same and have not changed since 1935 - it's time they did,"
Andrew Witty, CEO, GSK
Financial Times global Pharmaceuticals and Biotechnology Conference 2006



"Every new launch is the opportunity to experiment with a new commercial model"

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7 Industry has to overcome its **mind set problem** with Payer customers

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Pharma industry still making too many unforced errors – which would you vote is the worst issue?

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Achieving national pricing & reimbursement approval are just two steps in the process & are no guarantee of success

abpi
Bringing medicines to life

Posted in category News Release by Press Office on 16/10/2013

Innovation Scorecard fails to measure up for patients' access to medicines

NEWS

The ABPI has welcomed the publication of the third update of 'NICE Technology Appraisals in the NHS in England - Innovation Scorecard' by the NHS Health and Social Care Information Centre (HSCIC), on behalf of NHS England. There is however concern that this falls short of providing patients with the clear information they need to make decisions about their treatment. Read more

hscic Health & Social Care Information Centre

NICE Technology Appraisals in the NHS in England (Innovation Scorecard):
to June 2013, Experimental Statistics

Published 16 October 2013

The New York Times

Sanofi Halves Price of Cancer Drug Zaltrap After Sloan-Kettering Rejection

By ANDREW POLLACK
Published: November 8, 2012

In an unusual move, a big drug company said on Thursday that it would effectively cut in half the price of a new cancer drug after a leading cancer center said it would not use the drug because it was too expensive.

Add to Portfolio
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The move — announced by Sanofi for the colon cancer drug Zaltrap — could be a sign of resistance to the unfettered increase in the prices of cancer drugs, some of which cost more than $100,000 a year and increase survival by a few months at best.

Zaltrap came to market in August at a price of about $11,000 a month. Soon after, Memorial Sloan-Kettering Cancer Center in New York decided not to use the drug, saying it was twice as expensive but no more effective than a similar medicine, Avastin from Genentech. Both drugs improved median survival by 1.4 months, doctors there said.

Three doctors at Sloan-Kettering publicized the cancer center's decision last month in an Op-Ed article in The New York Times.

"Ignoring the cost of care is no longer tenable," they wrote. "Soaring spending has presented the medical community with a new obligation. When choosing treatments for patients, we have to consider the financial strains they may cause alongside the benefits they may deliver."

Sanofi executives argued that the price they had set was very similar to that of Avastin. "The intent was not to charge a premium," Christopher A. Viehbacher, the chief executive

"At Memorial Sloan-Kettering Cancer Center, we recently made a decision that should have been a no-brainer: we are not going to give a phenomenally expensive new cancer drug to our patients. The reasons are simple: The drug, Zaltrap, has proved to be **no better than a similar medicine we already have** for advanced colorectal cancer, while its **price** — at $11,063 on average for a month of treatment — is **more than twice as high**"

Peter B. Bach, Leonard B. Saltz, and Robert E. Wittes. Memorial Sloan-Kettering Cancer Center. New York Times 14th October 2012

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Market Access planning must be considered at sub-national level in some countries – increasing the time delay to access for patients, & increasing costs for industry

The following regions have their own Health technology assessment agencies:

- Agencia de Evaluación de Tecnologías Sanitarias de Andalucía
- Instituto Aragonés de Ciencias de la Salud
- Agència d'Avaluació de Tecnologia i Recerca Mèdiques de Catalunya
- Axencia de Avaliación de Tecnoloxías Sanitarias de Galicia
- Agencia Laín Entralgo de Madrid, Unidad de Evaluación de Tecnologías Sanitarias, Comunidad de Madrid
- OSTEBA, Osasun Teknologien Ebaluazioko Zerbitzua, País Vasco
- Servicio de Evaluación del Servicio Canario de Salud

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The ten steps of Market Access Planning

Following pricing & reimbursement approval significant work is required to ensure the appropriate **funding** streams, including issues such as J code or DRG inclusion, plus those instruments which surround the **ability to prescribe**:

- Formulary inclusion
- Guideline inclusion
- Prescribing protocols
- Prescribing software inclusion

Both Industry and Payers have an **obligation & responsibility** to address the access for patients post national pricing & reimbursement approval

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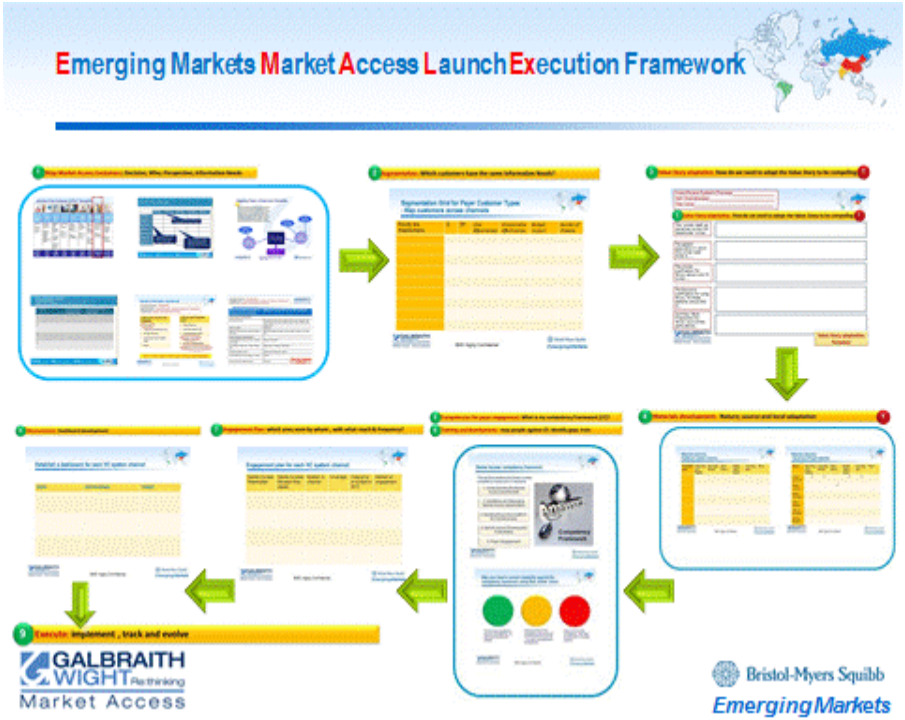
Market Access tools & processes to facilitate Funding and Enabling Prescribing have been developed & can be implemented locally



This example shows a 9-step market access execution framework process developed by GalbraithWight – a comprehensive & systematic process for segmenting Payer customers and adapting the Value Story to meet their specific needs & requirements.

This framework is being adopted for global market access competencies

Agenda

1 Removing ‘unforced errors’ from market access planning & implementation

2 Focusing beyond achieving national pricing & reimbursement

3 Focusing on all healthcare costs, not just medicines

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Countries have signalled the need to take action to address the unaffordable growth in healthcare expenditure – we all agree reform is needed

"The United States spends over $2.2 trillion on health care each year—almost $8,000 per person. That number represents approximately 16 percent of the total economy and is growing rapidly. If we do not act soon, by 2017, almost 20 percent of the economy—more than $4 trillion—will be spent on health care".
President Barak Obama (http://www.whitehouse.gov/omb/fy2010_key_healthcare/)

"France's social welfare budget, including pension and health spending, is expected to run up a 30 billion euro deficit".
President Sarkozy in a televised New Year's Eve address to the nation January 2010

For EU Member States, the highest allowable expenditure deficit in the public sector is 3% of GDP according to the Maastricht Treaty. Several countries have exceeded this limit (e.g. France, Greece)

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UK Value Based Pricing: Four years of confusion


FOR HEALTHCARE LEADERS
HSJ
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JILL MABEN
Support staff to put patient care first

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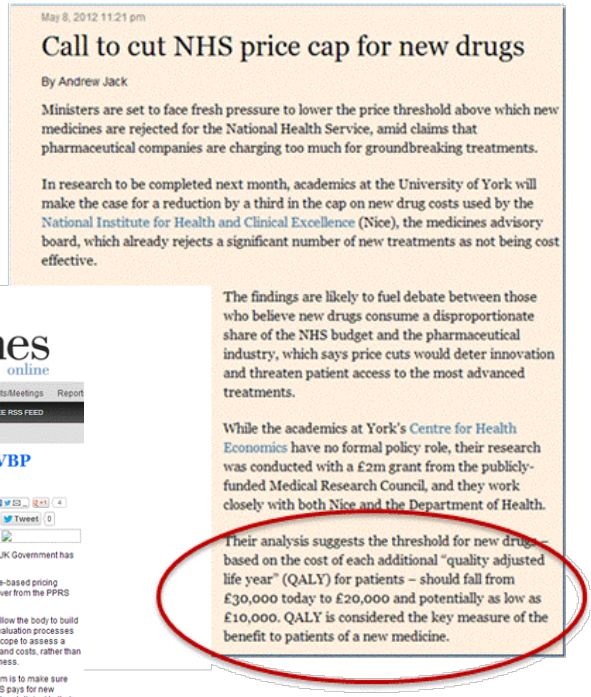
Delay in pricing plan for new drugs

4 OCTOBER, 2013 | BY JAMES ILLMAN

The introduction of a pricing system for new drugs which attaches greater value to how much they benefit patients is to be delayed until late 2014, HSJ has discovered.


May 8, 2012 11:21 pm

Call to cut NHS price cap for new drugs

By Andrew Jack

Ministers are set to face fresh pressure to lower the price threshold above which new medicines are rejected for the National Health Service, amid claims that pharmaceutical companies are charging too much for groundbreaking treatments.

In research to be completed next month, academics at the University of York will make the case for a reduction by a third in the cap on new drug costs used by the National Institute for Health and Clinical Excellence (Nice), the medicines advisory board, which already rejects a significant number of new treatments as not being cost effective.

The findings are likely to fuel debate between those who believe new drugs consume a disproportionate share of the NHS budget and the pharmaceutical industry, which says price cuts would deter innovation and threaten patient access to the most advanced treatments.

While the academics at York's Centre for Health Economics have no formal policy role, their research was conducted with a £2m grant from the publicly-funded Medical Research Council, and they work closely with both Nice and the Department of Health.

Their analysis suggests the threshold for new drugs – based on the cost of each additional "quality adjusted life year" (QALY) for patients – should fall from £30,000 today to £20,000 and potentially as low as £10,000. QALY is considered the key measure of the benefit to patients of a new medicine.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NICE given central role in VBP scheme

UK NEWS | MARCH 22, 2013
BEN ADAMS

NICE will take on responsibility for assessing the full value of medicines when new pricing arrangements are introduced in 2014, the UK Government has announced.

The Institute says this will be "a crucial role" in the future value-based pricing arrangements for branded medicines, which are set to take over from the PPRS scheme from January 2014.

Related Links
MPs call for urgent decisions on new drug pricing regime
VBP alone will not solve new drug access issues, govt warned

The new plans will allow the body to build on its current drug evaluation processes by giving it broader scope to assess a medicine's benefits and costs, rather than just its cost effectiveness.

NICE said that the aim is to make sure that the price the NHS pays for new medicines is more closely linked to their value to NHS patients and society, which are the main tenants of VBP.

The government confirmed the plans in its official response to the Health Select Committee's report on the future role of NICE which has been published this week.The HSC's report was damning in its criticism of the government for not having firm plans on value-based pricing and the role of NICE. It had to respond by the end of March, and it looks as if this should be enough to appease the MPs who were concerned over the drug pricing plans.

The health minister Lord Howe said: "We are delighted to announce the central role NICE will take in assessing the value of new medicines. This will allow us to draw on NICE's world-leading expertise as we develop the value-based pricing scheme.

"The role of NICE is developing and growing as it takes on new responsibilities in social care. We are grateful to the Health Select Committee for their detailed report and helpful recommendations covering various aspects of NICE's work.

Simon Jose, past President of the ABPI and President Stiefel Division, GSK

"**the devil is in the detail** in terms of how the VBP system will function. However, noises from (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

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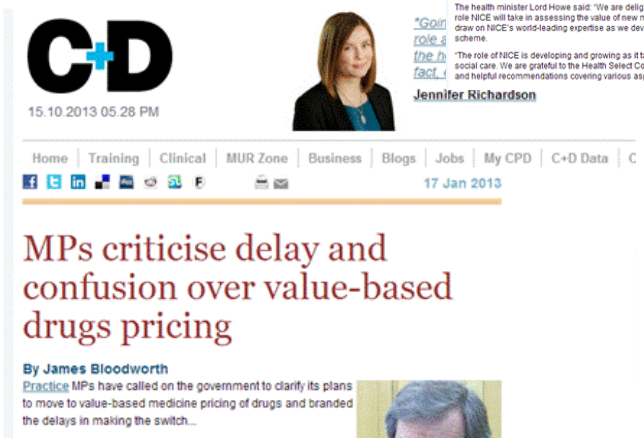
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Jennifer Richardson

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17 Jan 2013

MPs criticise delay and confusion over value-based drugs pricing

By James Bloodworth

Practice MPs have called on the government to clarify its plans to move to value-based medicine pricing of drugs and branded the delays in making the switch...

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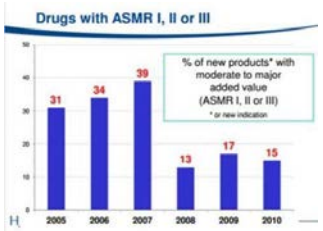
What have we learnt about the focus on medicines in EU countries? Governments are short term & politically expedient – it's in their nature



France

- HAS determines burden of disease (through SMR rating) and level of innovation (through ASMR rating) – ASMR is by indication – to be replaced by combined ITR
- 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
- AMNOG requirement to deliver a €2b saving each year – so a conflict of interest with higher cost new medicines
- Clear evidence of **generics chosen as the comparators**, a likely means to push down prices of new products
- GB-A over rides IQWIG when it is politically expedient

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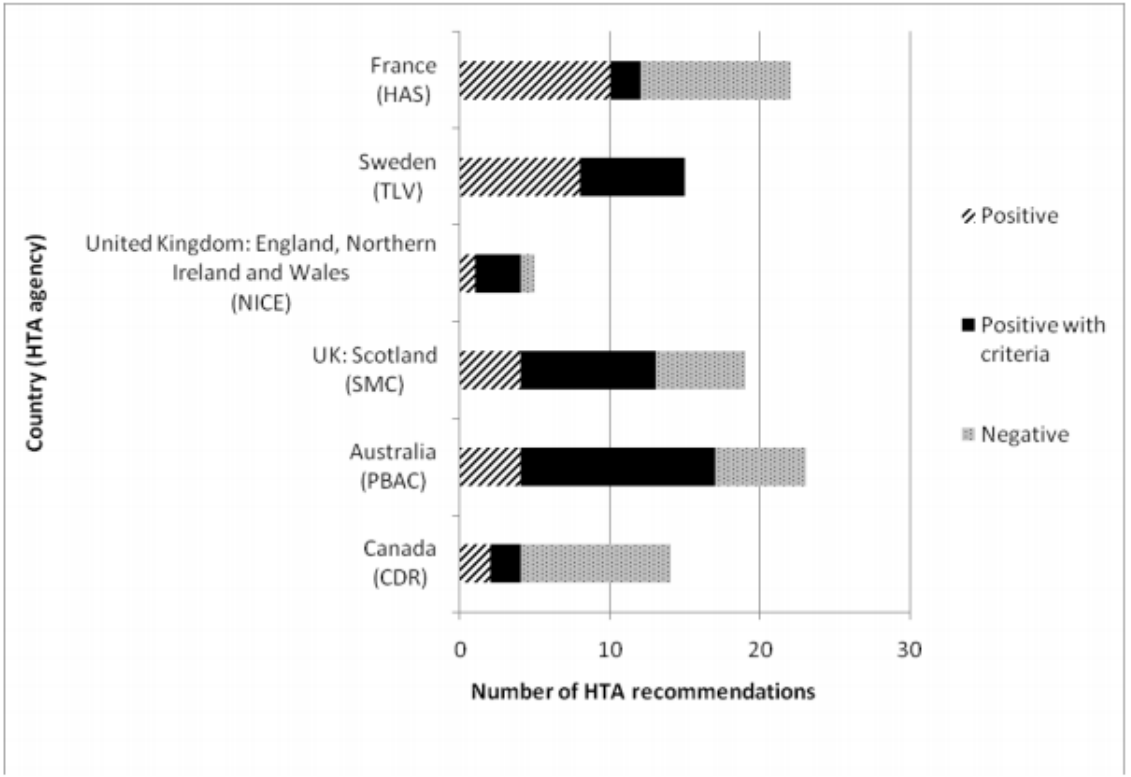
There is much duplication & inconsistency in HTA decision making between HTA bodies which wastes time & money & denies patients access to innovative medicines

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

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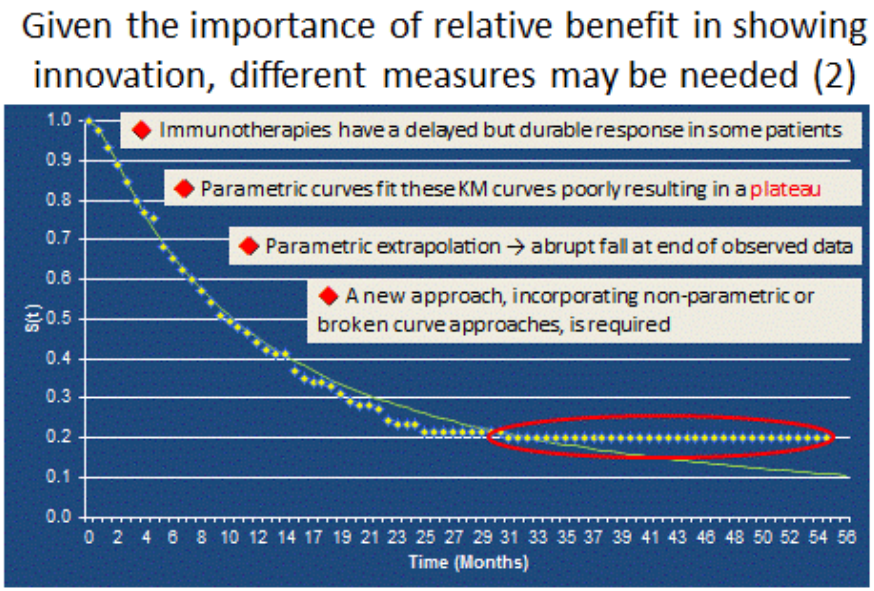
Industry needs to do a much better job in leading the debate around measuring & rewarding 'value' for innovation

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



Source: Annemans L, Asukai Y, Berzey V, et al. 2011. Extrapolation in Oncology Modelling: Novel Methods for Novel Compounds. Presented at the ISPOR 14th Annual European Congress, Madrid, 5-7 November.

"The Committee acknowledged that few advances had been made in the treatment of advanced melanoma in recent years and ipilimumab could be considered a significant innovation for a disease with a high unmet clinical need"

NICE FAD November 2012

http://www.nice.org.uk/nicemedia/live/12092/61322/61322.pdf

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

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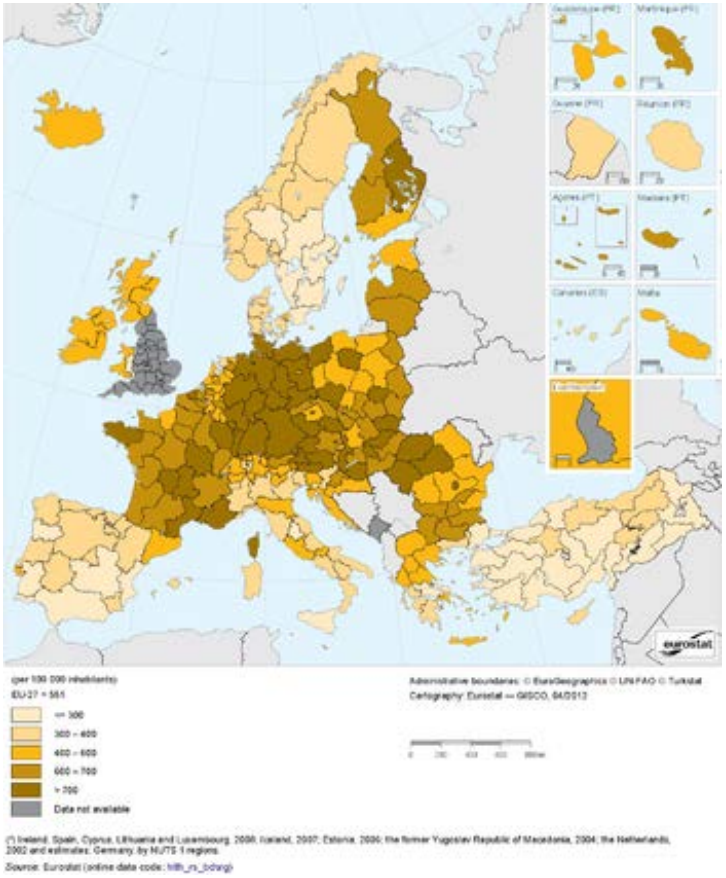
Affordability of medicines? 80%-85% of healthcare costs include over capacity in hospital beds, inflexible fixed costs in secondary & tertiary care & trades union working practices

Hospital beds per 100,000 inhabitants 2009*



There should be open debate about the affordability of improving health outcomes across **the healthcare system** – not just the 'medicines silo'

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Governments must accept responsibility for their policies: poor adoption of innovative new medicines has a direct impact on investment

ANALYSIS-Antibiotics crisis prompts rethink on risks, rewards

REUTERS

Text Size

Published: Monday, 18 Mar 2013 | 12:06 AM ET

By: Ben Hirschler

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* Big Pharma retreat leaves antibiotic pipeline bare

* Low prices and limited usage key deterrents for industry

* Regulators plan "reboot" of drug approval process

* GSK boss sees need for new, creative market models

LONDON, March 18 (Reuters) - Thirty years ago, when the world faced the terrifying prospect of an untreatable disease known as AIDS, big drugmakers scented an opportunity and raced to develop new medicines.

Today, as the world confronts another crisis, this time one of antibiotic resistance, the industry is doing the opposite. It is cutting research in a field that offers little scope for making money.

Antibiotics have become victims of their own success. Seen as cheap, routine treatments, they are overprescribed and taken haphazardly, creating "superbugs" they can no longer fight.

These "superbugs" are growing, but are not yet widespread, so the costly research needed to combat them is not worthwhile. Medical experts say this dilemma could return medicine to an era before Alexander Fleming discovered penicillin in 1928.

Fixing the problem will need both faster approval of last-resort drugs and new ways to guarantee rewards for companies, according to both industry leaders and public health officials who have been sounding the alarm.

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Andrew Witty, CEO of GSK, commented in 2012 that by the time a viable commercial model for new antibiotics existed, it would be too late to avert a serious pandemic. “The market has failed,” he concluded.

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Most major Pharma companies now exploring how to deliver outcomes, not 'pills' – of major benefit to patients & to healthcare systems

We're not just about pills – we're a partner.

We like to work with you as part of a team to help you achieve your aims.

With our vast experience in delivering a world-class portfolio of innovative medicines, MSD can support you with our other areas of expertise. We can utilise our business experiences to help bring rigour to your work.

We already work in a variety of partnerships helping Health Care Professionals address local issues. We are proud of our successes to date, and look forward to more innovative partnerships in the future.

So let us show you how we can help you find solutions for achieving better outcomes for the NHS and, ultimately, for patients.

Deepak Khanna – Managing Director, MSD UK

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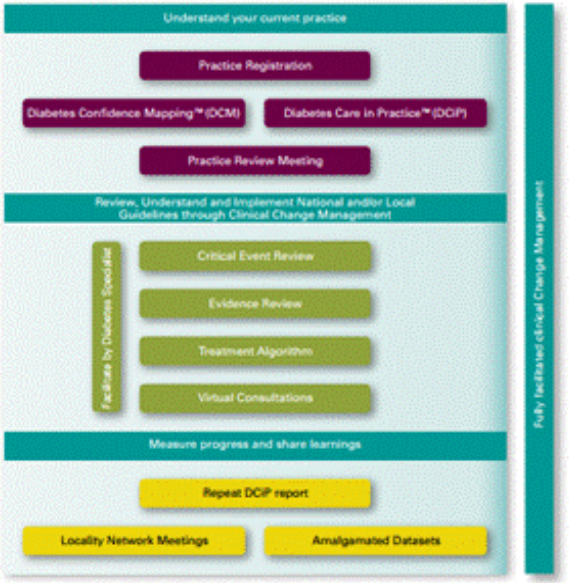

To find out more about Evidence into Practice please call on

Tel 01992 455400 or Email evidenceintopractice@merck.com or visit our website at www.evidenceintopractice.co.uk

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Why markets don't work in healthcare & why people need access to education about their healthcare

"……the normal economics assumption that the consumer is well informed and able to judge among competing products is not true with health. The customer/patient relies on the expertise of a doctor and is unable to choose rationally among doctors.

……major health problems are very expensive, **far too expensive for most people to be able to pay out of regular income**. As with other infrequent but catastrophic costs, people therefore buy insurance policies, which turn a regular affordable payment into a contingent large receipt in the event of a serious illness or accident."

Arrow, K., Uncertainty and the Welfare Economics of Medical Care, The American Economic Review, December 1963

We need to work together on delivering better health outcomes for patients while managing total healthcare costs – that's what value really means

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Summary

1. Pharma industry is wasting time & money making too many unneccessary errors in market access planning & implementation. These need to be addressed as a matter of urgency

2. Pharma industry needs to rethink the way it prices medicines – to reflect real value of innovation, and to deliver price in a way which makes sense to the payer and the healthcare system – price on value and outcomes, not mg/Kg

3. While national price & reimbursement approval are very important, they represent only 2 of the 10 steps of market access. Also focus on the funding flows and constraints around the prescriber to ensure a patient does gain access to innovative medicines

4. Payers need to de-commission ineffective healthcare to free up funds for innovative alternatives which deliver better health outcomes & represent better use of money

5. Need to open the debate about costs & cost effectiveness to all healthcare, not just medicines

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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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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.

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