

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

7 unforced errors in the implementation of market access & how to avoid them

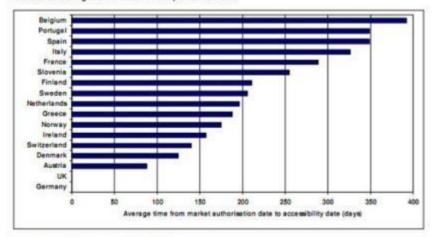
Colin Wight: Chief Executive GalbraithWight



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



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

Source: Patients WAIT Indicator 2010, EFPIA

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



There are good examples of **best** practice











Unforced errors in Pharma Market Access

1. Market access work starts much too late as many Senior Managers do not fully appreciate the timing and investment needs





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"

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

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

considered at Phase IIb, from a

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"

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

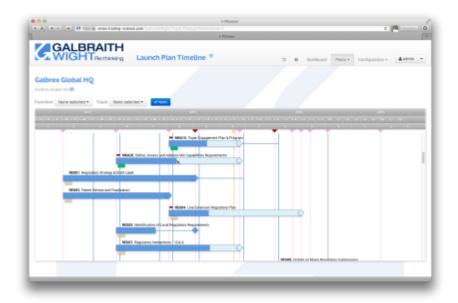
"I'd like to see market access being labelling/indication standpoint"





* 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

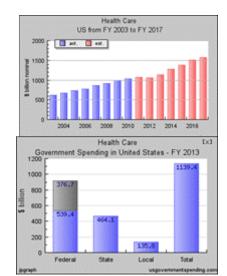






Market Access is different in America – causing inappropriate lateness in market access planning for some US-based Pharma companies

- 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







But...America is changing – slowly

- CER 'on the agenda'?
- MCOs, Care Pathway companies & Beacon Communities want cost & cost-effectiveness data, are making better use of IT, & 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 intergovernmental, ISPOR, HTAi, INAHTA











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



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

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



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



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

SHARPS FOLLOW

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

Add to Portfolio

Caroli SA

The move — amounted by Sabrif 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 nost

more than \$100,000 a year and increase survival by a few months at

Zahrap name to market in August at a price of about \$11,000 a month. Soon after, Memorial Soon, Extering 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, America from Generated. Both drugs improved medican survival by 1.4 manths, doction there said.

Three doctors at Singu-Eettering publicated 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 tenallé," they wrote. "Souring spending has presented the medical immunanty with a new obligation. When choosing treatments for patients, we have to consider the financial strains they may cause alongside the benefits they may delive."

Saudi ensention argued that the price they had set was very similar to that of America. The intert was not to charge a premium. Christopher A. Vishbacher, the chief ensention of East of the internal but made.

GALBRAITH WIGHTRethinking Market Access "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

There are ten steps of Market Access Planning – not just P&R

10 The right conditions surrounding the Prescriber 9 The right Funding 8 The right Reimbursement/Coverage 7 The right Price **6 The right Label 5** The right Regulatory strategy **4 The right Phase III Development Program 3 The right Phase II Development Program** 2 The right Asset selection 1 The right Disease strategy

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





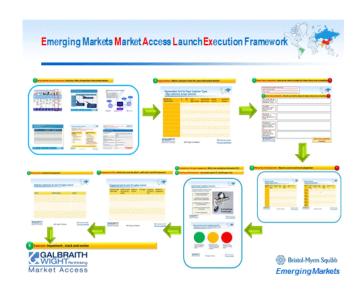
Market Access planning must be considered at sub-national level in some countries – increasing the time delay to access for patients, & increasing costs for industry



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

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 was adopted for global market access competencies







Solution: 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

- When it starts
- 2. What to do when
- How much investment
- 4. Global, Region, Country







Unforced errors - & how to avoid them

2. Starting early enough means Commercial Strategy must be in time for Market Access strategy to align – it often isn't!





Market Access must be aligned with Commercial Strategy – so Commercial Strategy must be developed before or in parallel

Value Strategy

Identification

Value Evidence Generation

Value Communication

Develop the commercial, market access & regulatory strategy to maximise the value (e.g. NPV) of the asset or franchise to the Client by delivering greatest value to patients, physicians & payers



Identify the evidence which will be required by regulatory agencies, pricing & reimbursement & HTA agencies & budget holders to enable achievement of the strategy

Value

Generation of the clinical, HEOR & Real World evidence to meet the requirements & criteria for the regulatory agencies, P&R/HTA agencies & budget holders

Develop, test & train the materials required to communicate the evidence to regulatory agencies, P&R/HTA agencies, Policy makers & budget holders

- Commercial strategy
- Market Access
 strategy
- 3. Pricing strategy
- Regulatory strategy
- 5. Launch sequencing strategy

- Payer Landscape
 Research Insights
- Scientific advice from Regulatory agencies
- Scientific advice from P&R /HTA agencies
- Market Access
 requirements from
 Budget Holders

- CSRs
- Economic models (CE & BIM)
- Systematic
 Literature Reviews
- Meta-analyses & IndirectTreatment Comparisons
- Treatment Pattern Studies
- 6. Database reviews
- Publications & Presentations

- . Global Value Pack
- Value Story & Messages
- 3. Regulatory dossiers
- 4. P&R /HTA Dossiers
- 5. Formulary Pack
- Market Access
 Training Programs
- MSL slide deck
- Payer & Medical
 Education
- 9. Publications & Presentations





Practical Application of Market Access process

Value Strategy

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- Market Access
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 Regulatory
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Payer Landscape
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 Scientificadvice

the strategy

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Develop, test & train the materials required to communicate the evidence to regulatory agencies, P&R/HTA agencies, Policy makers & budget holders

- Global Value Pack
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While these are shown as linear & separate, the reality is they are iterative & integrated.

For example:

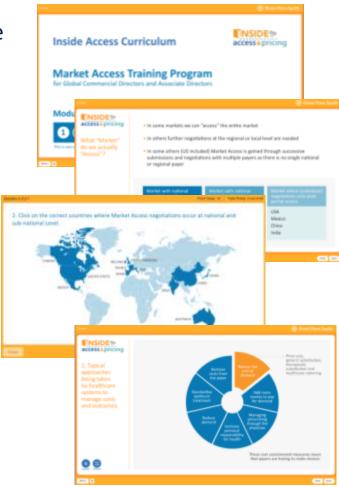
- i. In Value Communication, you may uncover areas of evidence that have been missed, which would require further work in Value Evidence Generation.
- ii. In Value Evidence Generation you may get a set of clinical results which require a rethink on Value Strategy
- iii. For an asset in Phase III (i.e. during Value Evidence Generation), much of the Value Communication work will be developed in parallel, awaiting results.





Solution: Educate Commercial Teams on Market Access & ensure Commercial process timeline matches market access needs

Educate Commercial teams on the Market Access requirements for their brands, and the timelines required for development of Commercial Strategy to enable and facilitate early market access planning







Unforced errors - & how to avoid them

3. Market access capabilities are siloed and limited with no clear definitions & performance standards





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







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"





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 companywide capability







Solution: Build Market Access Capabilities Cross-Functionally & Build Market Access into all commercialisation processes

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

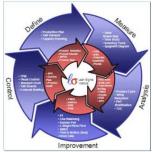
Market Access, New Product Planning, Launch Excellence & Brand Planning are all elements of a continuum

Market access is a critical component of a wide range of R&D & commercialisation processes and needs to be embedded within;

- ✓ Clinical development from early phase
- ✓ Business development/licensing due diligence
- ✓ New product planning
- ✓ Launch excellence/launch readiness
- ✓ Brand planning
- ✓ Marketing/commercial excellence





















LAUNCH EXCELLENCE

Unforced errors - & how to avoid them

4. R&D focus is still marketing authorisation, not reimbursement





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 & PMDA 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[©])
- 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
- 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







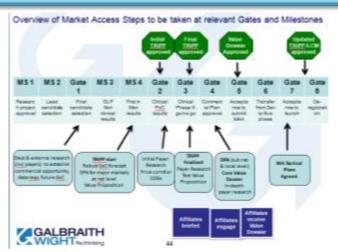
Solution: Educate R&D & Help Embed Market Access Processes in R&D

Case Study: An agreed new process for what Market Access activities are required when, embedded into the organisation's existing process for R&D Gates and Milestones, rolled out to all teams across the organisation

- Full senior management support for the need for MA to be integral to all stages of product development
- Market Access tools bringing consistency in timing, format and standard of all MA activities, assessments & deliverables



Market Access at the core of the organisation in a way that was practical and straightforward for the company to adopt







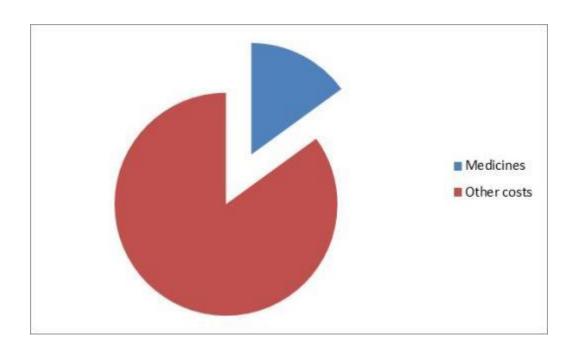
Unforced errors - & how to avoid them

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





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







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



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 Wilhelser in Plans The Guardian, Tuesday 20 November 2012



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.



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

4th October 2011







UK Value Based Pricing: Four years of confusion





Delay in pricing plan for new drugs

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.

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



Call to cut NHS price cap for new drugs

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

> 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

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 publiclyfunded Medical Research Council, and they work closely with both Nice and the Department of Health.

heir analysis suggests the threshold for new drug 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.









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







% of new products* with moderate to major added value

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?





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



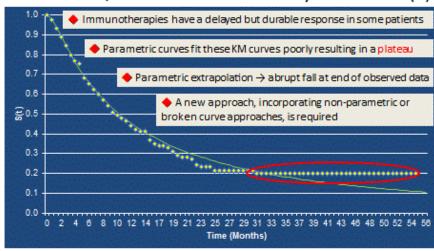
Don't give out cancer drugs if it's just to extend life: Treatment costs can't be justified, say experts

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



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

Given the importance of relative benefit in showing innovation, different measures may be needed (2)



Source: Annemans L, Asukai Y, Barzey V, et al. 2011. Extrapolation in Oncology Modelling: Novel Methods for Novel Compounds Presented at the ISPOR 14th Annual European Congress, Madrid, 3-7 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





Value delivered by the same medicine varies by disease

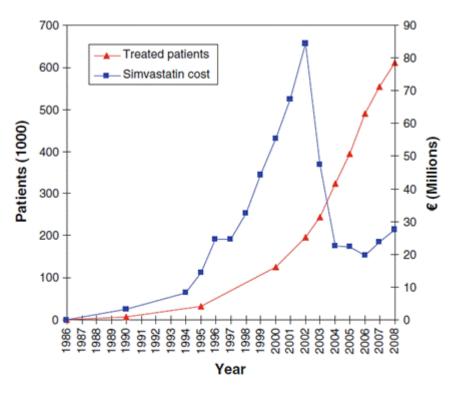
- Bevacizumab in combination with a taxane for the first-line treatment of metastatic breast cancer - ICER for bevacizumab plus paclitaxel versus weekly paclitaxel was between £110,000 and £259,000 per QALY gained
- Bevacizumab in combination with oxaliplatin-containing regimens as a second-line treatment 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.





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



"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 costeffectiveness when assessing the introduction of new therapies."

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)





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'!







Solution: 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





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





Unforced errors - & how to avoid them

6. Same old commercial model





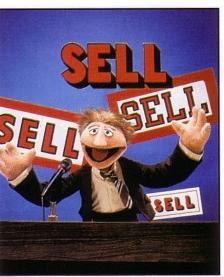
Same old commercial model – still....

"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









Solution: Use every new launch to explore & Pilot new

Commercialisation models

RWE

New locations for service delivery

Prospective outcomes research

Technology Idea Change

Innovation

Research Improvement

Development Analysis

Concept Invention

New methods of engagement

Multi channel support

Innovative pricing methods

Customer Partnerships



Unforced errors - & how to avoid them

7. Market Access is about hearts & minds within the company, not just processes & templates







Unforced errors - & how to avoid them

- 1. Market access work starts **much too late** as many Senior Managers do not fully appreciate the timing and investment needs **educate Senior Management**
- 2. Starting early enough means **Commercial Strategy must be in time** for Market Access strategy to align **educate Commercial teams**
- 3. Market access **capabilities** are **siloed** and **limited** with no clear definitions & performance standards **develop clear definitions, competencies, capabilities & cross-functional responsibilities global, region, country**
- 4. R&D focus is still marketing authorisation, not reimbursement- educate R&D teams & build market access requirements into R&D processes
- 5. Our **pricing** strategies are **stuck in the dark ages** when we used to be chemical manufacturers **develop innovative pricing solutions fit for 21**st **century**
- 6. Same old commercial model create opportunities to pilot innovative commercialisation models
- 7. Market Access is about hearts & minds within the company, not just processes & templates build belief & passion among teams for Payer Customers & the Value of your medicines





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







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.

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

For more details contact: Ruth Evans, Director +44 (0) 7798 606610



