

OUTCOMES SHAPE THE NEW PAYER NETWORKS FOR PHARMA

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The role, identity and connectivity of the payer is shifting in the face of global cost containment that is seeing all major pharma markets globally adopt new healthcare infrastructures geared around delivering economically efficient longer term positive outcomes. Clinicians and traditional payers combine within these emerging networks designed to assess cost-effectiveness at the national, regional and local level, presenting new engagement challenges and evidence requirements for the pharma industry.

Over the last decade the healthcare 'payer' has rapidly become the key customer in many markets as the pharmaceutical industry has witnessed a shift towards more consistent decision making on the economic benefit of medical interventions, driven by the need to control spiralling budgets. In truth, expenditure on drugs represents typically less than 10% of such spend, but it is seen as an easy target for cost reduction.

This has led to the rise of increasingly elaborate cost containment systems, designed to blend the challenges of managing national budgets with the ability to meet local patient needs – a difficult balancing act that blurs the lines between prescriber and payer. As a result, we are now seeing complex interactive networks of local, regional and national payers emerge in many countries, which heavily overlap with clinical experts in making key decisions on the use of new medicines. Defining who the payer is and how they make their decisions has never been harder.

Within these networks and across regions the relative influence and evidence requirements for each payer can also vary significantly, resulting in more complex and protracted multi-step engagement processes for pharma. Critically, new medicines are no longer being assessed on the basis of just clinical attributes, but are scrutinised for cost-effectiveness and longer term outcomes – the ability to financially reduce the disease burden on society, rather than simply raising the treatment bar medically.

Before reviewing how this is specifically impacting on

different markets, it is worth summarising two of the key factors that are shaping the way pharma engages with its customers.

1. Seeking economically efficient health outcomes

Early cost control mechanisms, such as the UK's Pharmaceutical Price Regulation scheme (PPRS) do little to account for downstream spend and are therefore seen as relatively simplistic when it comes to managing the longer term healthcare budget. Equally, schemes that control the price at which a medicine is reimbursed (effectively limiting the price on the assumption that co-payment by the local prescriber, patient or insurer is undesirable) face the same challenge, as they have often historically calculated reimbursement level on the basis of short-term clinical benefit versus existing comparators.

"THE WAY THAT NICE FUNCTIONS COULD BE OF INTEREST TO US."

French payer

Newer approaches therefore take into account broader patient outcomes and the associated overall cost to the healthcare system, or beyond, as exemplified in the approach taken by bodies such as the UK's National Institute for Clinical Excellence (NICE) or Germany's Institute for Quality and Efficiency in Health Care (IQWiG). These are often referred to as the 'fourth hurdle' for market access, beyond proving product efficacy, safety and quality to the regulatory bodies.

However, these methods have proven resource intensive and require expert input from numerous stakeholders, including clinical experts, prescribers and health economists, in assessing the onward consequences of different treatment choices. They are also protracted processes, utilising complex predictive modelling techniques, such as NICE's health technology appraisal

(HTA) process and its use of Quality Adjusted Life Years (QALYs) as the major metric for assessment of outcomes.

Consequently, these outcomes-focussed assessments tend to take place at the national level and at a discrete time point shortly after new product launch, although there are signs that periodic revisiting of such decisions could become the new normal.

2. Meeting the specific needs of local patient demographics

As already outlined, the rigorous evidence, resource and budget requirements for cost-effectiveness evaluation do not lend themselves well to sub-national decision-making, but this must be balanced with the need for local prescribers to address the specific needs of their patients, with demographics and disease prevalence varying widely by region.

'Leader' (KOL) and prescriber networks are morphing into the new payer networks of national, regional and local cost-effectiveness decision-making.

England exemplifies emerging payer networks

As all markets develop towards blending cost-effectiveness assessment at both the national and regional level, involving both clinicians and traditional payers, the new NHS structure in England serves as a good reference case for the type of complex engagement processes pharma must master for effective market access. The key components of the new NHS structure for England are outlined in figure 1, whereby NICE, the new NHS Commissioning Board and its substructure, including the new CCGs, jointly coordinate access to medicines.

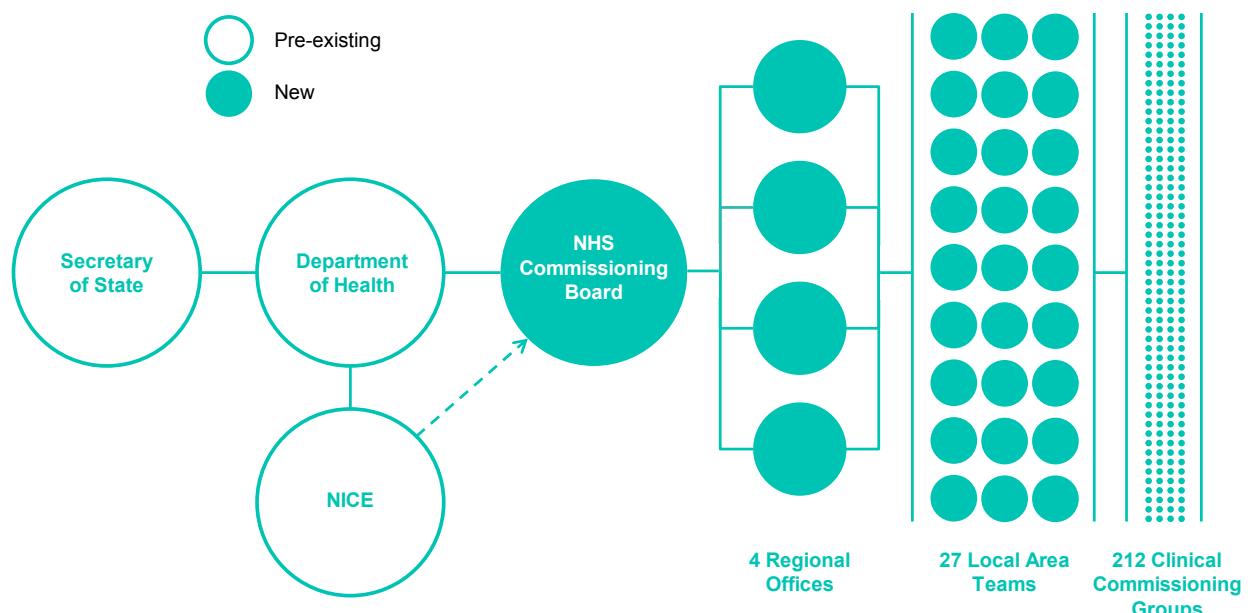


Figure 1: Core structure of the new NHS in England since 1st April 2013 (peripheral bodies not shown).

In many countries this is leading to two-, or even three-tier systems emerging where initial recommendations are made at the national level around use of medicines, but the prescriber on the ground is a secondary payer with their own budgetary considerations and flexibility to deviate from the guidance where necessary. This is most acutely visible in the UK's shift towards Clinical Commissioning Groups (CCGs), where GP consortia are now being asked to behave like local businesses when it comes to managing local healthcare delivery.

This new dynamic creates a number of challenges, not just for the pharma industry but also for the prescribers. Ethically, it is difficult to imagine prescribers never deviating from the cost-effectiveness script when faced with a patient in desperate need of a novel, but expensive treatment. In addition, these systems also open the gates for external influential bodies such as patient groups and non-payer clinical experts to exert influence at both the national and local level.

Taking into account both these factors necessitates the pharma industry to engage with payers at multiple levels and on a more frequent basis. Within every country, the customer engagement processes around 'Key Opinion

NICE – national recommendation

The majority of new medicines will be subjected to the NICE HTA process to determine cost-effectiveness (although lower priced treatments may not be assessed), through review by one of its expert Technology Appraisal Committees.¹ These groups typically combine pharmacists, commissioners, specialist consultants, nurses and health economists with expertise in the relevant therapeutic area, who will assess data provided by the drug manufacturer as inputs into modelling the cost-per-QALY benefit to patients. In 2013, NICE is also taking on greater responsibility for assessing orphan drugs and certain drugs prior to launch through the Evidence Summaries: New Medicines (ESNM) process.

Provision of appropriate data, designed with the HTA process in mind and ideally comparing the new drug to the current gold-standard comparator, therefore remains a key factor and failure to do so will delay the process or lead to rejection. Whilst NICE has often been accused of operating to rigid boundaries around cost-per-QALY (£30,000 per annum is often viewed as a threshold figure), special consideration is given to end-of-life therapies such as cancer treatments.

Nor is the decision of NICE final, with output guidelines subject to review in the face of new evidence, as recently observed for the asthma treatment Xolair, produced by Novartis. Originally recommended by NICE for use in adults and children over 12 with severe persistent allergic asthma, this recommendation was withdrawn in late 2012, effectively blocking Xolair from the market. However, in the face of new evidence in early 2013, Xolair was once more recommended for use by NICE.²

Such back-and-forth decision-making by NICE is only likely to increase as real-world data becomes more widely available and pharma becomes more adept at quickly collecting it to challenge unfavourable decisions. Submission data requirements are only likely to get more strenuous when value-based pricing is introduced in 2014, with the pivotal role of NICE here in moving the UK away from free pricing already confirmed.³

NHS Commissioning Board and substructure – local implementation

In theory, high level recommendation by NICE should encourage use by local prescribers, but implementation of such guidelines is not guaranteed and has, historically, been variable. The new NHS Commissioning Board is focussed on addressing this challenge, in addition to supervising more consistent delivery of overall healthcare at the local level.

Structurally, the old strategic health authorities (SHAs) have been replaced by four new Commissioning Board regions (North of England, Midlands and East, South of England and London), within which now sit the 212 CCGs, with local prescribing flexibility and budgetary control.⁴ The CCGs are led by GPs, but also include specialist consultants, nurses and pharmacist advisors, with a remit to commission broad healthcare services in their region, including planned hospital care, urgent and emergency care, rehabilitation care, community health services and mental health services.

“WE ARE TAKING INTO ACCOUNT MUCH MORE THE RELATIONSHIP BETWEEN COST-EFFECTIVENESS AND OUR BUDGET LIMITATIONS.”

Italian payer

In between the Commissioning Board and the CCGs sit 27 Local Area Teams (LATs), responsible for commissioning larger regional services such as pharmacy, dentistry and specialist services such as cancer support. CCGs and LATs may also commission Acute Trusts within hospitals for provision of secondary care services within a defined budget. Drugs and Therapeutic (D&T) Committees (also known as Medicines Management Groups), sitting within the CCGs and LATs, are responsible for deciding what is on formulary. NICE recommendation enforces mandatory formulary inclusion, but guidelines can be adapted for local circumstances based on additional expert input from pharmacists and specialist consultants within these groups.

Payment by results and patient access – routes into market

Where NICE refuses to recommend a new drug treatment at the national level (or it is awaiting review), pharma companies can propose patient access schemes (also known as ‘risk-share’ schemes) whereby a separate

agreement is made either nationally or with local CCGs or Acute Trusts. Such schemes seek to balance the risk of cost versus outcomes via one of two broad mechanisms:

- Financial discounting / capping, where the manufacturer agrees a discount based on increasing drug usage or simply caps the amount spent by the NHS per patient. For example, Novartis employed this approach with its treatment for age-related macular degeneration, Lucentis, where it agreed the NHS would only pay for the first 14 injections.⁵
- Outcomes based, where an initial price is agreed which can be adjusted, up or down, based on subsequent outcomes. This approach was used for the multiple myeloma treatment, Velcade, after the cost-per-QALY was determined to be too high by NICE.

Whilst such agreements have drawn scepticism, they have also played a role in getting some new drugs onto the market and NICE has openly suggested that manufacturers should be proposing such schemes from the outset where they feel a negative appraisal is otherwise likely, rather than treating them as a last resort. Such schemes also prove popular with patient organisations, which see them as critical access tools where new treatments might otherwise be blocked.

In a similar manner, the Payment-By-Results (PBR) tariff, which adopts a similar approach to VBP, also seeks to control the risk of spiralling treatment costs. Under this scheme, the NHS allocates a fixed price for each patient procedure, including patient hospital stay, any surgical interventions performed, drugs administered, nursing time and other incurred costs related to the procedure. This fixed cost is then charged to the local provider of that procedure, thus encouraging local negotiation.

The developing picture of the UK when it comes to drug market access is therefore one where prescribers and payers are virtually indistinguishable, with expert clinicians providing input into the national HTA process and local prescribers also becoming budget holders as part of the CCGs. In addition, the complex decision-making processes open the gates to the patient voice, through vocal charities and disease organisations that can sway decisions around access to new medicines.

Global trends towards outcomes and multi-level payers

Looking beyond the UK it is possible to construct a picture of where other major markets sit currently on two axes relating to drug market access – local versus national control and focus on price versus outcomes (see figure 2), with an interesting picture emerging that suggests the UK model could pave the way for the future.

In Germany, healthcare is funded very differently (around 90% of the 70 million population are covered by statutory health funds paid into by employers and employees), but it is following the UK’s lead in embracing a strong centralised focus on outcomes. Until 2011, pharmaceutical manufacturers could freely price new drugs, but the Act on the Reform for the Market of Medicinal Products (AMNOG), introduced at the start of that year, launched a new system of assessment whereby only new treatments demonstrating significant therapeutic benefit compared to existing therapies could command premium prices. Such decisions may be supported by the Institute for Quality and Efficiency in Healthcare (IQWiG), which uses an evidence-based statistical assessment process for evaluating cost-effectiveness, which is comparable to NICE’s techniques.⁶ Interestingly, the

German Federal Joint Committee has started to apply such analyses retrospectively to older drugs already on the market.⁷

However, local hospital-based and primary care prescribers within Germany still retain considerable autonomy in their treatment decisions, working within fixed budgets. For hospitals these are based on diagnosis-related group (DRG) codes that specific appropriate costs by indication, whereas primary care physicians have a budget determined by their patient numbers. Pharmacists, heads of departments and consultants make

experts such as pharmacists, doctors and specialist physicians. These groups also play a role in a final hurdle presented by the Commission du Médicament et des Dispositifs Médicaux Stériles (COMDIMS) - the Formulary Committee of hospitals where medicines are subjected to an additional review on use.

Market access in the Italian and Spanish markets is much more decentralised, being driven by the decisions of regional payer committees (20 within Italy and 17 in Spain), which operate on a semi-autonomous basis. Of the two, Italy arguably retains more centralised control, with its regulatory body Agenzia Italiana Del Farmaco (AIFA) making national decisions over pricing and reimbursement levels for new drugs.⁹ However, the regional committees (PTORs) can then make independent decisions on local formulary inclusion and adjust the level of patient co-payment. Here, pharma engagement at the national and regional level is important.

Spain has seen a gradual decentralisation of decision-making around healthcare provision over the last decade, away from the Sistema Nacional de Salud (SNS), its national health service.¹⁰ Whilst national reimbursement and pricing decisions are still made initially by the SNS, separate negotiation with the 17 autonomous regions is then critical for effective access. Outcomes play an increasingly important role here as Spain has both a central HTA decision-making body in the guise of the Instituto de Salud Carlos III (ISCIII) and regional equivalents.

Finally, as the major global market for pharmaceuticals it is important to understand how the US is developing with regards to market access and the payer environment. The US is, on a geographic level, a completely decentralised market when it comes to decisions around access to medicines and is seen as a free pricing market.

Here, the key payers reside within the federal / state run and private insurance organisations, which operate tiering systems to determine the level of co-pay required by the patient. Each insurer has its own pharmacy and therapeutics committee, which is responsible for formulary decisions designed to steer patients towards the most cost-effective treatment for their condition. In addition, specialised treatment centres are taking a more 'commercial' view of how they run their operations and starting to push back on medicines where the price is deemed too high. One high profile of example of this was

"CCGS ARE GOING TO BE MORE COST AWARE BECAUSE WE ARE SUPPOSED TO SAVE £20BN IN THE NHS OVER THE NEXT FIVE YEARS."

UK payer

observed in late 2012, when Sanofi had to halve the price of its colon cancer treatment, Zaltrap, after the high profile Memorial Sloan-Kettering Cancer Center in New York refused to use the \$11,000 per month treatment.¹¹ Interestingly, the reimbursement level evaluation approach for new medicines conducted by insurers and private providers increasingly focusses on cost-effectiveness. In addition, the US is one of the most advanced markets with regards to the use of electronic medical records, driven by private insurers' desire to understand real-world outcomes and benefits, which could dramatically change the assessment process over the next ten years and deliver real-world based HTA assessment of outcomes.

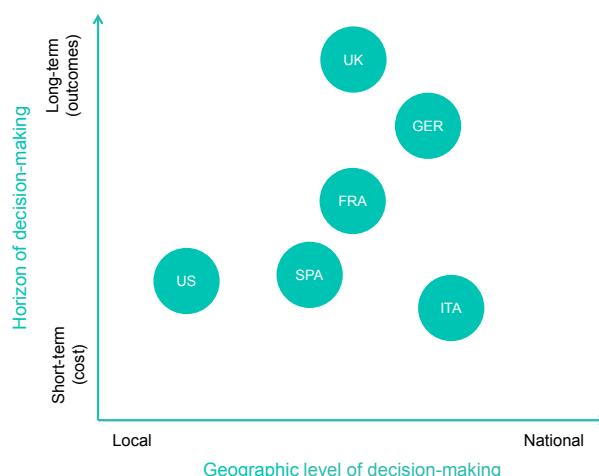


Figure 2: Position of the EU5 and US markets with regards to geographic level and time horizon decision-making for drug market access, with the general trend towards the UK position outlined.

hospital formulary decisions designed to best meet the DRG restrictions and therefore remain key secondary care payers, whilst primary care physicians retain flexibility on treatment choice whilst keeping one eye on their budget. The French market is perhaps the most disparate with regards to local versus national control of medicines access, as operates a two tier system. A 'free pricing' segment covers over the counter (OTC) drugs and certain hospital drugs that are viewed as the least innovative, whereby pharma companies negotiate on price directly. But the 'regulated' segment, covering pharmacy-prescribed drugs and more innovative hospital treatments, adopt a more rigorous approach.

In the first of two stages, the Commission de la Transparence (CT) (under the supervision of the Haute Autorité de Santé, or HAS) reviews the benefit offered by new medicines in order to determine a suitable reimbursement level. This assessment is based on two scales – the 'Rendered Medical service' (SMR), which reviews the efficacy and safety of the medicine in the context of disease severity, other treatment options and public health issues and the 'Improvement in the Rendered Medical Service' (ASMR), which places each medicine into one of five categories based on expected impact on disease management.⁸ Subsequently, the Comité Economique des Produits de Santé (CEPS) conducts price negotiations with the pharmaceutical manufacturer, with the ASMR rating being a key consideration alongside broader economic factors such as pricing in other European markets. Whilst CEPS is very much an organisation of governmental decision makers, determination of SMR and ASMR at the earlier stage involves assessment by medical

Overall, there remain key differences in how countries categorise medicines, the balance between national and local pricing and reimbursement decisions and the relative stakeholders involved in such decisions. However, there is a clear trend towards more rigorous assessment of cost-effectiveness based around HTA type processes, with the major differences being in the geographic level of control as all countries look to blend national consistency with local flexibility.

Essential pharma adaptation for successful market access

There are clear global trends emerging around a focus on more rigorous, centralised cost-effectiveness analysis for new medicines combined with ensuring local prescribers can adapt such guidance to meet their specific patient needs. In order to be successful in the future, pharmaceutical companies must take on board a number of lessons from markets like the UK, where such payer networks are most advanced, as illustrated in figure 3.

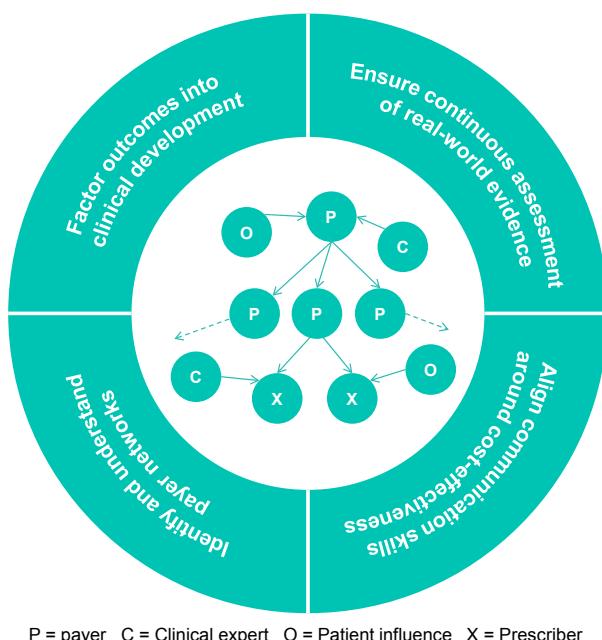


Figure 3: Successful engagement with emerging payer networks requires pharma to adapt in four key ways.

1. Factor outcomes into clinical development

Securing regulatory approval can no longer be viewed as the sole endpoint of the clinical development process – securing market access must be factored in early on. Those markets that employ rigorous cost-effectiveness analysis to define access can no longer be seen as minor outliers when planning global trials, which must factor in (at least from phase II onwards):

- Head-to-head comparison with those therapies currently seen as the gold-standard most cost-effective treatment. This is unlikely to be placebo and may not even be another recently launched drug, but could be an older, cheaper generic drug.
- Careful consideration of appropriate endpoints that will deliver the market access evidence required. Surrogate endpoints are useful for speed of regulatory access, but they may not 'cut it' when fed

into the HTA model that is looking for hard economic benefit.

- Inclusion of appropriate diagnostics in the clinical development programme to allow for defined selection of the ideal target patient population for clinical trials and treatment. This will improve outcomes and help healthcare budget holders understand likely financial impact.

2. Ensure continuous assessment of real-world evidence

Even if recommendation is secured from national or regional payers, a picture is developing of decisions being challenged over time as new real-world evidence emerges and becomes ever easier to capture and analyse. If healthcare systems are collecting such data it is imperative that pharmaceutical companies also conduct frequent observational studies with cost-effectiveness in mind, considering all of the above factors.

This will serve to build a library of data with which to respond to potential market access challenges or early warning of such challenges looming on the horizon. With the ability to collect increasingly robust real-world data through digital channels, such studies will themselves become more cost-effective over time and play an important role in maintaining access.

"WE ARE INTERESTED IN HEALTH ECONOMIC DATA AND PHARMA COMPANIES MUST KEEP IN CLOSE CONTACT WITH IQWIG AND THE G-BA."

German payer

3. Identify and understand payer networks

The pharmaceutical industry has traditionally invested significant commercial expenditure on identifying clinical leaders and prescribers who can ensure rapid uptake of new medicines. With the development of new payer networks that bring together both traditional payers with expert clinical advisers, the old KOLs are either becoming payer influencers or are increasingly irrelevant.

Investing in understanding the local, regional and national networks of payers and medical payer influencers is now critical to securing effective market access for new treatments. Payer decision-making pathways are now as important as clinical treatment decision-making pathways and the appropriate time point at which to engage, evidence required and mechanisms for challenging decisions will vary depending on the payer groups. Without a good understanding of all these factors, the chances of clearly communicating cost-benefit for new treatments and securing market access are significantly diminished.

4. Align communication skills around cost-effectiveness

Early development of the pharmaceutical industry's commercial infrastructure in response to the challenges of cost containment and restrictive market access have seen specialised teams emerge that can engage with payers and provide the cost-effectiveness evidence required, working alongside traditional prescriber teams focussed on clinical benefit.

As the payer and prescriber networks merge into one, the ability to discuss both clinical- and cost-benefit must be

possessed by all customer facing personnel. All sales and marketing activities and associated training must factor in the payer arguments in order to be successful and market research must address cost-effectiveness arguments in order to develop a robust position for new medicines.

In the new commercial reality of cost-constrained healthcare environments globally, the payer is everywhere, imperceptibly intertwined in all clinical discussions. Failing to adapt to this new environment could leave the pharma industry locked out, but understanding and engaging with these new payer networks provides the key to a new door, behind which lies better prescriber engagement and improved patient outcomes.

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