

# Understanding Healthcare Systems to Conduct Better Pricing and Reimbursement Research

Anyone involved in building price and reimbursement strategies across the U.S. and Europe sooner or later has to come to terms with the bewildering array of healthcare systems that exist in each of the markets. If that were not enough, these systems are in a constant state of flux, as national governments and private providers desperately attempt to contain the apparently limitless demand.

As market researchers, we are frequently asked to deliver some primary research input to strategy development. But in so doing, we have to confront head-on the daunting task of building a global methodology that both reflects the range of healthcare systems in the test markets and delivers a credible result that incorporates the perspectives of all relevant decision-makers.

In this article, we are focusing on the sampling considerations in attempting to conduct any primary research rather than on any specific techniques that might be employed to generate required information. In order to keep under control at least some of the complexities, the considerations will be confined to innovative ethical product introductions.

## Sampling Considerations

As for any piece of research, one of the first considerations is to build a sampling framework. Immediately we encounter the challenge of distributed decision-making so characteristic of healthcare, in that we have to consider at least three categories of decision-maker and influencer:

- **Payors** Holder of the purse strings or primary influencer of healthcare professionals (HCPs). They are accountable to organizations such as governments (tax payers) and stockholders.
- **Healthcare Professionals (HCP)** Most typically physicians, who are the gatekeepers with the technical knowledge to make clinical choices, within a framework set by the payor. They are accountable to payors, their profession and the patient
- **Patients** (End user and sometime payor) We then need to overlay onto these categories the workings of the healthcare system by market, with their oftentimes subtle implications for who has decision-making authority, so that we arrive at a sampling frame.

## Application of Decision Making Unit Concept

In order to manage the complexity, an approach we find helpful is to define the “decision-making unit” (DMU) that is relevant to each market. A DMU is defined as the smallest group of interacting payors, physicians and patients (and in some cases, other influencers) that can be considered to act with some degree of autonomy in terms of determining market access and actual use of new products. In this process we can encompass the wide range of DMU types (from individual hospitals to whole countries) and yet adopt a consistent research approach based on understanding the flow of influence leading to decisions within the DMU. The concept also provides a means to adopt a micro-modeling approach to defining price—restriction and price—volume relationships. However a more detailed description of this approach is beyond the scope of this article.

With the DMUs defined, determination of sampling then becomes a matter of identifying an appropriate selection of DMUs from which individual respondents can be identified.

## DMU Application to Key Markets

In the remainder of this article, we have applied the DMU concept to key markets typically considered in a global assessment in order to illustrate how a research sample can be constructed to deliver high utility research.

### U.S.

The US healthcare system is characterized by a diverse range of DMUs, such as HMOs, PPOs, Medicare and other managed care organizations (MCOs). Individual payors and patients operate within only one DMU, while HCP may operate across a range of DMUs. Typically the most relevant (in terms of population coverage and commercial interest to Pharmaceutical Companies) are the MCOs. In these, patients are offered coverage for payment of fees (directly or through salary provision), with varying levels of copay according to MCO-defined categories known as tiers.

- **Payors** Typically the relevant representatives in the sample frame are the Pharmacy Directors or Medical Directors of the MCOs. They are able—and usually willing—to reflect on the value of a new product introduction, what means of assessment would be applied (comparators, expected price etc) and can offer a probability of particular outcomes for different price scenarios in terms of a likely tier.
- **HCP** HCPs (physicians) are either contracted to specific MCOs or operate across a range of MCOs. In either case it is the patient’s coverage that is the determining factor, and the physician has no particular role in determining the appropriateness of a product based on its price. However, HCP may take an advisory role for patients in offering a view on value for money, particularly where there are a range of choices with similar clinical performance (see inset box, next page).
- **Patients** The majority of patients typically pay at least some part of the cost of the product directly. Hence it is relevant to investigate with patients whether they are willing to pay for products offered, but also whether they will continue with the product in terms of refilling prescriptions over a period of time.

### Europe

Europe is characterized by a wide range of healthcare systems, particularly variable in terms of market access controls applied for new and existing products. There are some features that are broadly comparable to the US in some markets, such as no direct price controls (UK, Germany), insurance-based systems (Germany) and drug price related co-pays (France, Italy, Spain). By contrast, European markets are generally distinct from the US in terms of:

a relatively unified national approach;

less variation in patient co-pay resulting from type of healthcare coverage;

presence of national decision-making or influencing on market access for new products.

There follows examples of key markets within Europe to serve as illustrations of the practical sampling consideration.

## France

The French healthcare system is characterized by centralized, national price and reimbursement decision-making. The exception is for products in the “hospital only” category, which can be freely priced by the Pharmaceutical Companies in negotiations with hospitals or hospital groups. The reimbursement category determines whether and how much patients will pay. The copay is a percentage of the product price.

- **Payors** Unless the product is classified “H” (Hospital Use only), it will be subject to a nationally imposed reimbursement category and price. The relevant national committees usually cannot be accessed for the purpose of market research but Opinion Leaders who have in the past, or may in future, act as technical advisors to these committees can be interviewed. Such respondents are typically willing to discuss the clinical merits of a new product offer, but may have limited willingness or ability to offer opinions on likely outcomes of price and reimbursement negotiations. Representatives of mutuelle insurance funds (see below) can be interviewed but typically are not involved at the level of individual product considerations.
- **HCP** HCPs (physicians) have no particular role in determining the appropriateness of a product based on its price as this decision is taken nationally and they are free to prescribe approved products. However, depending on the extent of patient co-pay, HCP may take an advisory role for patients in offering a view on value for money, particularly where there are a range of choices with similar clinical performance (see inset box). As most patients have their co-pay covered by separate “mutuelle” insurance there is no strong pressure for physicians to act as “value for money” advisors.
- **Patients** For an increasing number of prescription products, the majority of patients pay at least some part of the product cost. However, as noted above, the copay is typically covered by a mutuelle insurance. Hence it may be relevant to investigate with patients whether they are willing to pay for products offered, but their consideration may be indirect, in terms of insurance premium impact.

## Germany

The German healthcare system is characterized by free pricing with market access controlled through a mix of local budgetary mechanisms and federal level “guidance” (BAK). Patients pay a prescription charge which varies according to the size of the prescription (pack size) rather

than the product price. There is also comprehensive use of reference prices but these are typically less relevant to the control of innovative product introductions.

- **Payors** Opinion leaders who sit on advisory committees for the BAK can be interviewed for market research. They are willing to offer valuations of new product offers and typically are willing to speculate on likely guidance that the BAK would issue for the product if launched at particular prices.
- **HCP** HCPs (physicians) have either actual or notional responsibility for management of budgets which include prescription products. This, coupled with the fact that the patient has no particular price concern where there is no reference price (see below), means that the HCP should be considered an important decision-maker in terms of price and market access in Germany. Physicians can provide estimated intended prescribing volumes for different price scenarios but may be hindered in their judgment by the lack of guidance from the BAK or other sources, where this is considered necessary to the decision.
- **Patients** Unless products are subject to reference pricing, the patient will not have a product price-related copay and therefore their input to the uptake decision based on price is of limited value. There are several changes to the German system which may affect the selection of research respondents. In particular, there is the recently formed Institute of Quality, which is expected to have a role similar to the National Institute for Clinical Excellence (NICE) in the UK. Hence it would be important to consider the likely judgment from such an Institute and its impact on the prescribing behavior of those under its influence.

## U.K.

The UK healthcare system is characterized by a free pricing with a mix of company level profit control, local structures with budgetary responsibility (Primary Care Trusts PCT) and national prescribing guidelines issued by NICE. Patients pay a fixed prescription charge unless exempt. In reality, only a minority of prescriptions is subject to a copay due to the high level of exemptions amongst the bulk end user patient groups (i.e. elderly).

- **Payors** Representatives of NICE, or independent academics who advise NICE, may be interviewed and can offer valuations on product offers. They vary in their willingness and ability to offer insight into likely NICE guidance. Members of PCT prescribing committees can be interviewed. Again they can offer judgments on the value of new product offers but may be unable or unwilling to speculate on likely decisions that the committee would take for the product. They also refer to the presence or absence of NICE guidance as a key factor in determining the outcome for a new product.
- **HCP** HCPs (physicians) may have actual or notional responsibility for management of budgets which include prescription products (particularly in hospitals), or they will be constrained by the provisions of their PCT formulary. Since the patient has no particular product price-related concern (see below), the HCP should be

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In scenarios where products are non-reimbursed, patients will pay the whole price for the prescription either directly or indirectly. In this context, the physician does not need to act as 'responsible' prescriber on behalf of a third party payor. Instead the physician can potentially operate under a number of guises in considering a product on behalf of patients:

**Dispassionate provider:** Makes patient aware of choices but offers no advice on the most appropriate choice for a given patient (irrespective of patient request for advice).

**Positive advisor:** Actively promotes specific product choices. This can be proactive or in response to a patient request for advice. It can also be indirect in that only one choice may be presented to the patient.

**Negative advisor:** Actively discourage specific product choices. Again this can be proactive or in response to a patient request for advice. It can also be indirect in that the availability of the product may not be made known to the patient.

Patient diary studies offer insights for marketing purposes. Objectively examining the specific symptoms patients are suffering from (the length of time they last, the impact on their day-to-day activities, etc), combined with Q.O.L. measures, enables us to gain a much more accurate perspective of a patient's condition. Patients tend to downplay their symptoms and the effect the condition has on their lives. Diary studies have highlighted what can happen if a physician's perspective of their patient is distorted because the patient has tried to "play down" their symptoms. The consequence can be that either a sub-optimal treatment option will be selected, or the patient may be given no drug treatment at all by a physician preferring to "wait and see" how the condition develops. The implications for a pharmaceutical company are obvious.

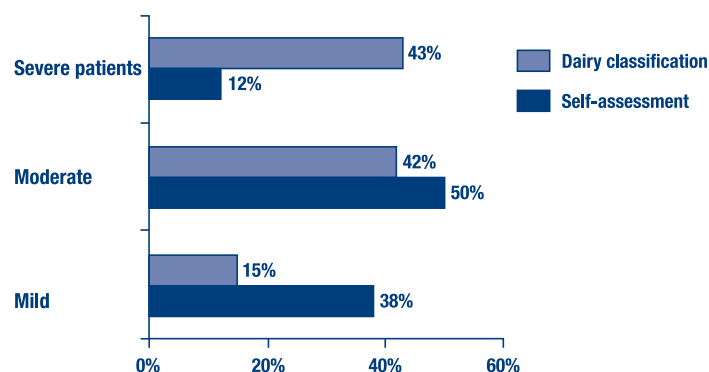
In a study of heart failure patients, (the exact nature of the findings have been adjusted for confidential reasons), patients were asked how serious they believed their condition to be. The diary results were shown to a series of physicians (not the patient's doctor) for evaluation. The result clearly showed the difference between the patients' perspective and that of the physician (Figure 1).

The patients' self-assessment of their condition indicates that 38% considered themselves to be mild sufferers, while an additional 50% felt they were moderate sufferers. However, based on an evaluation of their symptoms by physicians using a point scale that embraced a variety of symptoms and activities, the "true" level of the patients' severity is shown alongside. Clearly, the proportion of severe patients is much higher than patients themselves would have a physicians believe. This clearly has serious consequences for the decisions the physician makes about the treatment option and its ultimate success or failure.

Other studies of this type have also been conducted in hypertension, angina and RA/OA and BPH.

Studies of a more extensive nature sometimes involving several hundred interviews and incorporating life style and psychographic questions can also be helpful in providing revealing data about a condition that can be used by a company for promotional purposes. This type of work is often conducted in conjunction with a physician advisory board or committee and can provide a basis for patient segmentation.

Figure 1



Such studies conducted in the GI and asthma areas have been a source of valuable information that has enabled companies to support various aspects of their product stories and create considerable interest amongst the respective physician communities. These studies have also revealed the need for physicians to consider more carefully **what patients are actually saying**, and going further to establish what symptoms are still being encountered and how often. **Understanding patients' hopes and possible fears of treatment** are also important issues in assessing likely future compliance problems.

The purpose of this article is to illustrate that there is considerable value in conducting patient research before and after a product is launched. In the event of budgets becoming tighter, patient research should not, as a recent "straw poll" at the annual EphMRA meeting Basle revealed, be the first to be cut! Patient studies should be considered a vital part of the strategic development of a product and can often provide a "marketing angle" when management starting to struggle for that "unique selling point" or where to turn next.

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considered as a source of intended prescribing volumes for different price scenarios but their views will be constrained by the PCT formulary, and presence and nature of any NICE guidance, to varying degrees according to physician type.

- **Patients** Patients either pay a fixed prescription fee with no relation to the product price, or are exempt from all or most of the fee through age or other criteria. Therefore UK patient input to the uptake decision based on price is of limited value.

In conclusion, we offer the following considerations to anyone contemplating primary research in support of global price and reimbursement strategy development.

Compared to other healthcare primary research setting, primary research to support global price and reimbursement strategy requires more careful planning of the sampling frame, which in turn requires a comprehensive and up-to-date knowledge of the healthcare systems in target markets. While research targets can be identified as described above, it is universally the case that the actual decision making process is more complex than that which can be represented by the opinions of individual representatives

considered on average. Both the research design and the means of analyzing and integrating the outcomes from the different customer groups need to reflect these complexities for the research to inspire confidence.

With these challenges, it is important that the design of the research project gives sufficient consideration to:

1. Clear identification of objectives for the primary research that reflect its inherent limitations;
2. Cross fertilization of the proposed primary research with the internal (secondary) investigations to maximize the benefit of both; and
3. The management of internal customer expectations of what primary research can deliver for the price and reimbursement strategy development.

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Source: Adelphi International Research