

# Bridging the Gap between Prescriptions and Sales

by Luca Vegetti

**Is maximizing prescription volumes really enough to unfold a drug's full revenue potential?**

The equation “number of units prescribed equals number of units sold” holds very rarely for pharmaceutical products whose consumption does not take place in controlled settings such as hospitals. Poor adherence to prescribed treatments may be due to a variety of factors, including intolerance to side effects, patient-perceived lack of effectiveness and administration difficulties (e.g. self-injections); this affects, to different degrees, the majority of diseases whose care takes place at the patient's home. This issue has been increased by the recent trend, common in both Europe and the United States, of reducing hospitalization in favor of territorial care, in an effort to drive down the average cost per patient, especially for longer-term diseases.

Non-adherence represents one of the most relevant health-care challenges today: On the one hand, it costs billions of dollars in lost revenues to the global pharmaceutical industry; on the other hand, it often increases overall costs for health-care providers or insurers due to the higher likelihood of complications and hospitalizations. Studies on the incidence and impact of this phenomenon are usually pathology-focused; the punctual quantification of overall costs associated is complex, so that an accurate quantification of the overall financial impact is not readily available. However, with several medical studies confirming non-adherence rates often in the range of 20% to 30% of the prescribed population at 12 months for long-term diseases (e.g. Parkinson's and multiple sclerosis), the economic relevance becomes manifest. While adherence has traditionally been perceived as an issue of the health-care deli-

very system, taking the initiative to tackle the problem presents a growing opportunity for pharmaceutical companies to generate significant economic returns, directly and indirectly, especially in those therapy areas where the impact of lost revenues is highest.

These initiatives can lead to improvements in two significant areas:

- Boost to sales volumes at no incremental sales efforts, maximizing the value extracted from the existing prescription base;
- Improved relationships with the economic and administrative actors influencing the sales process of pharmaceutical products (e.g. regional agencies), supporting them in reaching their own health-care targets.

How can a pharmaceutical company design, develop and implement such an initiative? There are two main steps to be followed:

- deeply understanding patients, the “consumers”;
- defining how to approach the health system.

This requires trying to get a deeper involvement (when improving the relationship with economic buyers is a primary goal of the initiative) with an “institutional marketing” approach, or aligning key actors to receive regulatory authorization. Gaining an in-depth understanding of the end-users of medical treatments provides excellent insights about the root causes of non-adherence behaviors and how these could be acted upon to eliminate,



or at least reduce, consumption barriers; this usually can be achieved through a four-step process

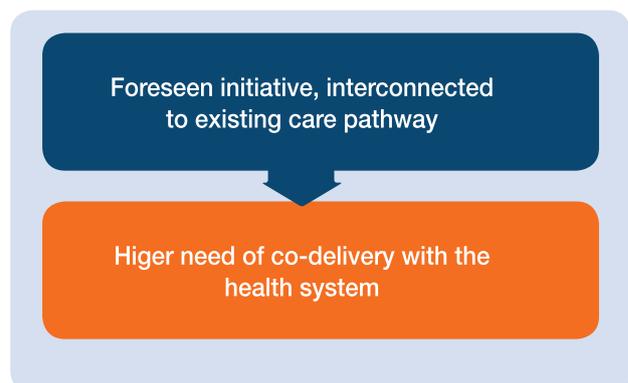
- Get to know and segment non-customers: What is the actual non-adherence incidence? What are the characteristics of the patients in which it is concentrated (previous treatment history, stage of the disease, access to insurance, socio-demographic factors)? What are the characteristics of patients with the highest risk of turning into “non-customers”? Are there patient clusters characterized by irregular consumption, while others who discontinue altogether? This preliminary activity can rely on a mix of retrospective studies analysis and ad hoc activities; it provides a comprehensive perspective on “non-customers”, including their characteristics, larger and smaller clusters, and a preliminary set of nonadherence predictors.
- Identify adherence barriers along the whole patient flow: What are the main factors turning patients into “non-customers”? What are the most critical steps experienced by patients while moving across the different stages of their care path? At what stage do they discontinue treatment – if they ever started it? A detailed mapping and analysis of all the occurrences experienced by a patient and of all the interactions with the different actors (GPs, hospitals, specialists, health system, insurance, relatives, other care givers) from the time of initial presentation to the physician until the end of the care path highlights key consumption, barriers and the underlying rationales.
- Map actionable levers: What are the main service components that could help overcome the barriers mapped along the patient flow? Is there anything the pharmaceutical company may do to lessen consumption barriers experienced by patients, eventually focusing on specific target clusters? What are the priority actions and the expected results? What are the desired interactions with institutional health providers and how can they be managed? Are there opportunities to build or improve the relationship with economic and administrative buyers?
- Design intervention packages: Are there viable and cost-effective actions the pharmaceutical company may put in place to support treatment adherence – maximizing the value generated from actual prescriptions? What are the markets in which this solution is to be implemented? Are there specific legal issues or delivery requirements to

be dealt with at the national level? Is it appropriate to envisage a “hot-housing” approach before planning a wide-spread launch? Who are the key individuals (medical, administrative) for whom an early involvement is to be planned?

Identifying and detailing a potential intervention strategy is not enough; its implementation must take place in someone else’s domain: that of the institutional health-care providers. Two different approaches and strategies may be envisaged, depending on the goals and priorities of the pharmaceutical company. At a minimum level, it can opt for a “low involvement” approach: communicate the initiative at the appropriate institutional level (national, regional), get all the required regulatory approvals and keep an update communication channel on the results of the initiative. Alternatively, the launch of an adherence focused initiative may involve a co-delivery with health-system actors, whereby the “front-end” provider is usually the health system, while the pharmaceutical company adds specific resources or components to reinforce some aspects of care provision.

There are various factors that affect the results of these two models (there may be a range of different outcomes between the two extremes):

- Pharmaceutical company goals: whether the primary objective is a sales growth by increasing treatment adherence, or strengthening the relationships with key influencers in administrative positions;
- Initiative interdependence with institutional health-care delivery: the more the initiative foreseen is interconnected to the existing care pathway (e.g. case management, such as in the first case discussed), the higher the need of co-delivery with the health system, while a more stand-alone approach can be undertaken in the case of an initiative that complements the health-care offering, for instance with a postprescription follow-up (e.g. the second case presented, on multiple sclerosis);
- Product lifecycle stage: a higher degree of involvement might be envisaged, for instance, for a new treatment that is to undergo its market launch, often within a broader effort aimed at determining reimbursement status or formulary position;
- Legislation: while some national legislations (in particular in the US) facilitate direct contact between a pharmaceu-



tical company and a patient, others (such as, to different degrees, the European ones) impose more barriers, favoring (if not almost requiring) a co-delivery solution (where entities such as patient associations might be a substitute for health-system bodies). The final issue, once an initiative has been designed and the involvement of institutional health actors has been defined, is how to organize and align resources. At a higher level, this implies putting in place governance mechanisms: from an operational standpoint, detailing the competences needed and sizing the resources required to run the initiative. As the type of competences and the nature of resources required is somewhat different from the core of a pharmaceutical company's operation and will likely have a temporary nature (due to product lifecycle and ROI considerations), different make-or-buy solutions must be evaluated to identify the most cost-effective solution.

How widespread is this model today? Are there any potential pitfalls that must be taken into consideration while considering such an initiative? Do actual results justify this kind of investment?

Adherence-focused initiatives sponsored and undertaken by pharmaceutical companies are somewhat more common in the US, mostly due to lower regulatory barriers and the size of the revenue potential to be gained back. Anyway, despite the difficulty of coping with a highly fragmented legislative environment, these kinds of initiatives are gaining a foothold and demonstrating their relevance also in Europe, as the multiple sclerosis case suggests.

Beyond legislative concerns, there are at least two important potential pitfalls of the model that can explain why these initiatives have been lagging behind in EU with respect to the US, and can thus provide insights for developing and fine-tuning further efforts:

- The complexity of managing a multitude of health-system actors (usually different bodies at local, regional and national level) not always aligned in terms of priorities and agenda;
- The difficulty in quantifying a proven ROI, as these initiatives might be beneficial to the whole market for a given treatment, without significant impacts on market share (thus favoring competitors who did not invest money in the initiative).

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There are also important factors that point to an increased relevance of this kind of initiative for the sales and marketing strategies of pharmaceutical companies:

- Significant changes, both from new legislation issued in several key markets and from the ethical codes of pharmaceutical companies, on the scope of marketing instruments, and the necessity to find new destinations for part of the marketing budgets;
- A track of previous experience in the design and management of adherence-focused efforts, whose best practices can provide significant support in overcoming the two pitfalls mentioned above. The most relevant consideration remains the bottom-line impact. Data on actual nonadherence enable a back-of-the-envelope calculation of how large the potential revenues (and profits) to be recouped, while results from similar initiatives (the multiple sclerosis case discusses good examples) provide a sense of how such efforts can turn into a moneymaking tool, enabling the company to fully capitalize on its sales and marketing budgets.

## Case study

### Case 1

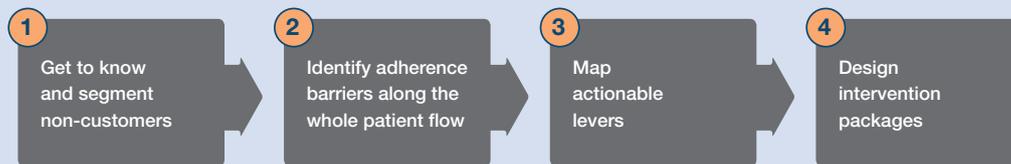
#### Partnering with regions to reduce overall cost of Gastro-esophageal Reflux Disease care

Gastro-esophageal Reflux Disease (GERD) occurs when the lower esophageal sphincter (the valve separating the esophagus and stomach) does not close properly, allowing acid to back up into the esophagus; it is a chronic condition and may lead to more serious medical implications.

Several drugs are available for treatment, even though they usually account for roughly 40% to 50% of the overall healthservice cost of care; costs (both medication and others) rise quickly for patients migrating from a mild to a severe stage of the disease, a risk increased by the frequent non-adherence to both prescribed treatment and prescribed modifications to the individual's lifestyle.

A leading global pharmaceutical company had to contend with reference prices for GERD treatments in some regions

### The four-step process



of a large European market, leading to a potential loss of up to 60% of turnover and a risk of adoption of this scheme in all other regions.

The company approached the issue in regions still without a reference-price system by partnering with them to support achieving budgetary goals by shifting the focus from the overall cost of treatment to enhanced prevention and, especially, improved compliance for mild patients. In the partnership, the company supported regions both in the design of levers (screening and prevention packages; case management system to enable follow-up, monitoring and outreach on mild patients) and in their implementation in pilot roll-outs. This value proposition of “helping the health system to create additional funds (or saving resources) whatever the product choice” proved credible and effective, also avoiding stringent clinical trials or requirements of ethics committees.

The pilot tests provided satisfactory results. For the NHS, total pathology cost-oriented measures proved to be more beneficial than pure medications price-cutting, and also offered administrators a politically desirable outcome: savings through better health-care management. For the company, it avoided the expansion of price-reduction risk, while creating incremental revenues through more systematic screening and enhanced compliance.

#### **Case 2** **Designing and implementing direct patient-support systems to boost multiple sclerosis treatment adherence**

Multiple sclerosis (MS) is an autoimmune condition affecting the capability of nerve cells in the brain and spinal cord to communicate with each other; its course is characterized by relapses (acute attacks) leading to disability increases and intervals of disease stability. While no final cure is known, there are some drugs in the market (disease modifying therapies – DMT) enabling to slow disease progression, mostly by preventing new relapses and the ensuing disabilities. With an aggregate worldwide value of several billion dollars, the market for multiple sclerosis is dominated by four companies; R&D pipelines suggest further entrants into this highly profitable market.

Treatment of multiple sclerosis is hampered by significant non-adherence issues. Long diagnosis time and poor communication at diagnosis, administration through self-injection, adverse effects, lack of a structured medical and social follow-up, and patient-perceived treatment ineffectiveness are just some of the causes leading approximately 25%–30% of patients – as confirmed by several medical studies – to discontinue the prescribed treatment within 12 months. Additionally, efforts by the health system to tackle non-adherence issues are usually very poor, as there are no infrastructures or services that allow a punctual post-prescription follow-up; at most, some limited services are provided at the local level by patient associations. This “vacuum” of presidium of the postprescription phase provided pharmaceutical companies an opportunity to step in, designing and delivering additional services to support patients in keeping compliant to the prescription made. A detailed mapping of the patient flow (from prescription to end of treatment) enables the identification of “critical points,” which can be ranked in terms of the impact or feasibility of solution (costs, ease of implementation) and around which the company can build different service components (such as self-injection guides or the provision of in-house nurses) and their delivery systems (directly, especially where no legal constraints are in place, or through patient associations or the national health service).

Detailed studies in settings where pharmaceutical companies provided patient-assistance services demonstrate a significant impact (and ROI), even in the short term, in terms of patient compliance; indirect benefits are achievable in terms of increased prescriptions due to a higher confidence in physicians. Additionally, this approach provides a potentially valuable defense for the incumbent product against potential new entrants with a more favorable adherence profile (e.g. tablets versus selfinjection), reducing the threat of market share dilution.

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