Putting patients at the center of a new biopharma business model

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The pharmaceutical industry is suffering. Expiring patents, increasing demands from regulators and decreasing healthcare budgets are putting companies under pressure, and the industry has to walk a narrow tightrope between keeping profitability up and quickly developing attractive medications. As patients are increasingly well informed, organized and powerful, a novel approach that some companies are looking into is patient-centrism. This means integrating patient inputs in each stage of the value chain, from drug development through commercialization to lifecycle management. We carried out 50 in-depth interviews with industry experts to find out how this new model can hold the future for the biopharma business.

For more than a century – ever since the patenting and commercialization of Aspirin by Bayer in the late 1890s – the biopharmaceutical industry has achieved remarkable success, reaching more than $750 billion in global sales while saving countless lives and improving the quality of life for billions of people. But, since the start of this century, the industry itself appears to have been suffering from a variety of ailments:

- Patents on blockbuster drugs are expiring and under attack by generics, while the efficiency of research into new drugs is declining.
- Regulators are demanding more evidence of the safety and efficacy of new drugs before approving them.
- The patient population is fragmenting into ever-smaller segments, as unmet needs are becoming more specific, making it harder to recoup R&D investments.
- Healthcare budgets are under pressure, leading public authorities and health insurers to implement a variety of cost-containment measures.
- New technologies such as diagnostic tools, medical electronic devices and IT solutions, while presenting the opportunity to create better treatments, are complicating the rules of the game for established biopharma companies.

Industry executives and observers generally point to the following cures for the biopharma industry:

1. Go back to core science, i.e. identify specific unmet needs and invest more in fundamental research to find answers.
2. Integrate new technologies, i.e. instead of relying only on a chemical molecule to cure a disease, integrate the

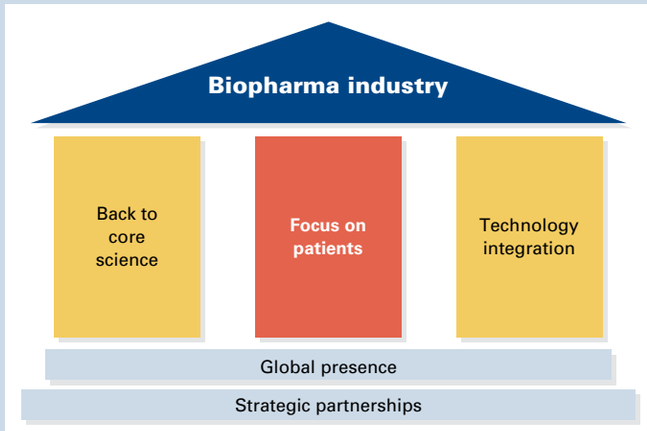
drug with other tools such as devices and information systems.

3. Establish a true global presence, i.e. build the ability to run a truly worldwide R&D program, and benefit from the higher growth rate of emerging markets such as the so-called BRIC (Brazil, Russia, India, China) countries.

4. Engage in worldwide strategic partnerships, in order to complement in-house discovery with academic, biotech and technology innovation, as well as partnering for optimal commercialization.

We wholly agree that these four components are critical for the biopharma industry to thrive in the future (see Table 1). But in this article we will explain why one component – in fact the most important one – is missing: patient centrism, i.e. putting patients at the center of all of a biopharma company's activities along the value chain.

Table 1 **Key components of the new business model**



Source: Arthur D. Little analysis

We will explain why patient centrism has become a necessity and how it affects biopharma companies. Then we will demonstrate that a business model based on patient centrism has the potential to create more value for a biopharma company than the traditional model. Finally we will explain how a biopharma company can make patient centrism happen in practice.

In this article we use the term "biopharmaceutical" to refer to the combination of the classical pharmaceutical and biotechnology industries, as these are increasingly converging into one.

The necessity of patient centrism

Biopharma companies have historically focused on prescribers (i.e. physicians) and regulators rather than on their key customers, i.e. patients. Today patients are emerging as the central node in healthcare transactions. Four forces are pushing inexorably in that direction (see Table 2):

- The prescriber is expected to inform patients better and is keen on avoiding claims of malpractice.
- The regulator is involving patients more extensively in the risk/benefit assessment of new cures.
- The payer is putting more emphasis on health economics when deciding on reimbursement policy.
- The biopharma company is searching for a new business model that reflects these trends.

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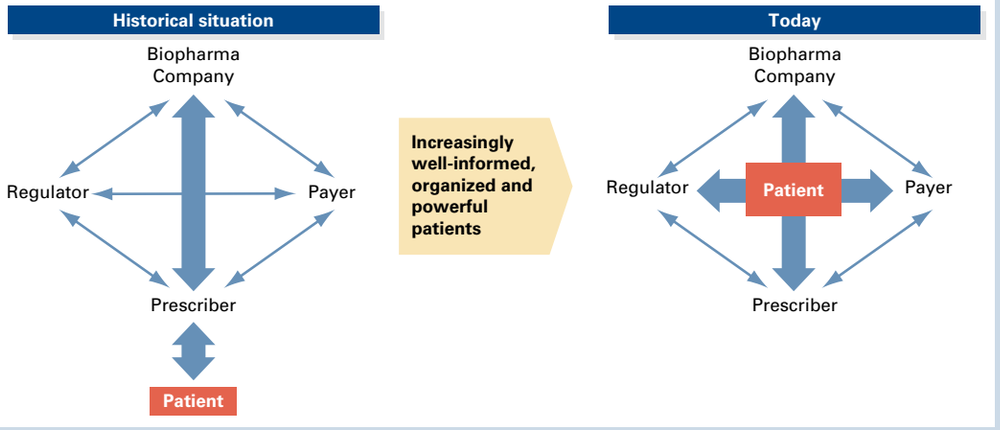
At the same time patients in the developed world are taking a much more active role when it comes to healthcare. They have become much better informed and hence more powerful. They are also increasingly aware that they are not only disease sufferers or caregivers (as patients' relatives), but that they are also voters and taxpayers. Healthcare has become a key political and electoral issue in many modern democracies.

This new patient power takes many forms. For example, there are two patient representatives on the board of directors of the EMEA (European Medicines Agency). The EMEA and the FDA (the US Food and Drug Administration) systematically invite patient advocates – and not always biopharma companies – to regulatory advisory committees. Patient organizations have played a critical role in the re-evaluation – and the ultimate approval – of the risk/benefit of drugs such as the multiple sclerosis drug Tysabri. And the British NHS has been forced to bend to patient lobby-

Table 2 **The position of the patient in healthcare transactions**



Source: Arthur D. Little analysis

ing in decisions on the reimbursement of drugs for multiple sclerosis and Alzheimer's, as well as novel antipsychotics and oncology drugs.

The implications of patient centrism for biopharma companies

A number of biopharma companies have repeatedly achieved market leadership by focusing on satisfying patient needs better than their competitors, or by exquisitely understanding the disease experience of their patients and harnessing it to deliver superior value in a treatment solution. The boxed text provides some successful examples of such patient centrism at work.

1. Joint drug development and testing with patients
Lilly was the true innovator in the insulin market, launching the first human insulin (Humulin 1983) and the first insulin analog (Humalog 1996). But Novo Nordisk has systematically been ahead of Lilly in developing innovative delivery devices. It developed and tested these with patients in order to make their experience more convenient, more discreet and less painful. For example, it launched the first insulin pen, the first pre-filled syringe and the first pre-filled disposable pen as well as a range of the shortest, thinnest and sharpest syringe needles. While having no measurable advantage in terms of product efficacy or safety, Novo Nordisk succeeded in taking over leadership in the global insulin market, and a 42 % market share in the US, Lilly's home territory.

2. Harnessing patient activism
Novartis Oncology harnessed patient activism very early in the clinical development of Gleevec, a drug treating a form of leukemia known as CML. As highly positive results for early clinical trials were announced, a global patient community was formed which helped drive US FDA approval in record time (72 days). Approval in the EU and Japan followed very quickly. In addition to close patient links during clinical trials, Novartis initiated an innovative pricing strategy that extended exceptionally broad discounts to uninsured patients. By 2008, the drug was Novartis's second-largest brand, with $3.67 billion in worldwide sales and growth of 20 % over 2007. The programme gave Novartis a competitive advantage as an innovator and social leader, building significant corporate equity for Novartis Oncology and facilitating future launches. (Source: F. Simon, "Gleevec: Success by Design in Oncology", Columbia Business School case, 2009).

3. Understanding patients' experience of a disease
Genzyme has been a pioneer in orphan diseases, i.e. diseases with a small population, which may be as low as 1,000 patients worldwide. By focusing on these, it has developed a unique understanding of patients' experience of a disease. Its competitive advantage includes knowing how to find patients (through its sub-specialist network)

and reduce trial recruitment time significantly, sharing their experience through close links with families, helping form associations through patient and caregiver leaders, and providing deep clinical and reimbursement support. For its flagship brand Cerezyme, used in the treatment of Gaucher disease, a high price is generally accepted by payers due to its small target population of about 5,000 patients worldwide, but also due to Genzyme's expert reimbursement assistance. (Source: F. Simon and P. Kotler, "Building Global Brands: Taking Biotechnology to Market", Free Press, 2003).

4. Leveraging patient insights for drug commercialization

UCB has invested heavily in patient understanding for its anti-epileptic drug Keppra, for example by developing its promotional campaigns with the help of patient advocacy groups or training "disease champions" in the US and Europe to encourage other patients to optimize their current (often suboptimal) treatment. UCB also ensured that it launched Cimzia in the very competitive rheumatoid arthritis marketplace with a prefilled, self-injection device carrying the Arthritis Foundation™ Ease-of-Use Commendation, allowing it to better compete with Humira and Enbrel.

5. Using patient convenience to extend drug lifecycle

Amgen's Neupogen is a drug used to fight neutropenia (white blood cell deficiency) in patients undergoing chemotherapy. When Neupogen was nearing the end of its lifecycle, Amgen launched a successor called Neulasta. In order to protect its Neupogen franchise, Amgen succeeded in positioning Neulasta as more than a lifecycle management move. It did so thanks in large part to highly media-driven cancer support programmes such as "Stand Up to Cancer", "Breakaway from Cancer" or "By My Side". Also, the "Voices of Experience" partnership with the non-profit organization Cancer Hope Network has successfully matched cancer patients with cancer survivors. Neulasta's positioning was strongly patient-relevant since it focused on convenience: Neulasta required only one injection per chemotherapy cycle compared with 10 or 11 for Neupogen. Between 2002 and 2004, Amgen's anti-neutropenia portfolio sales grew from $1.8 to $2.9 billion as a result of creative franchise management and successful patient conversion to the new drug.

From these examples, and from the 50 in-depth executive and expert interviews we conducted in the US and Europe in the year to July 2009, we can distill a number of best practices in patient centrism.

Most biopharma companies have typically involved patients in new drug development at a late stage, usually just before and after launch. The approach we propose is radically different: it puts patient insights and input at the core of every strategic decision by the biopharma company, and they form the basis of each step in the development and marketing of every new treatment. By integrating patient inputs in each stage of the value chain, biopharma companies are in a much better position to tailor product design, product pricing and market communications to end-user requirements.

Let's have a more detailed look at these stages of the value chain.

Drug development

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Patient centrism can be the integrator of a truly new approach to drug development. Deep insights among patients into the symptoms of their disease and its impact on their physical and social functioning will lead to more focused research. Attention will shift from the general pathophysiology of the disease to improving the most debilitating symptoms and the patient's quality of life. Development of new treatments with the close cooperation of patients can make the process more efficient.

In practice a biopharma company could consider the following steps:

- Identify key opinion leaders among patients (via the subspecialist network) and conduct ethnographic studies with direct patient observation to discover unmet needs and the patient's experience of the disease.
- Consult patient associations to determine the economic requirements for the treatment (comparator drug, assessment of costs vs. benefits for the new therapy and its competitors).

- Integrate drug, diagnostics and delivery systems to optimize drug utilization and patient compliance with the prescribed therapy.

- Involve patient associations in trial recruitment and design, including patient-relevant endpoints (i.e. the measures used to evaluate the effect of the treatment) such as quality of life.

- Help form patient associations via unrestricted grants (especially for orphan diseases).

Registration and market access

Patient centrism is key to ensuring rapid market authorization through effective patient support during registration and label negotiations, and leveraging patient power in the increasingly challenging process of pricing and reimbursement.

In practice a biopharma company should consider the following actions:

- Work with advocacy groups on pricing approaches, and develop value strategies based on price-sensitivity research with physicians, patients and payers.

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- Set up drug utilization programs (e.g., through diagnostics that ensure that the therapy goes to the right patients, and through distribution by speciality pharmacies that provide physician and nurse clinical support).

- Develop global patient access programs (e.g., distribute therapies at a discount or free of charge to uninsured patients).

- Collaborate with patients and payers to identify relevant patient-driven outcomes and demonstrate the economic value of a treatment, and establish creative risk-sharing and pay-for-performance arrangements.

Commercialization

Close pre-launch links with patients can greatly optimize a product introduction by increasing disease awareness, enhancing screening and thus accelerating sales uptake.

Best-practice actions at this stage of the value chain include:

- Conducting ethnographic research on patient experience (this is sometimes called "insight mining"), and using the results as a key component of the brand plan.

- Collaborating with medical and patient associations to develop screening, disease awareness and education programs, including tools to improve physician/patient communications.

- Identifying and training "patient ambassadors", and establishing patient advisory boards for each disease.

Building patient loyalty for a therapy ensures that the entire franchise (related therapies, successor molecules, multiple indications and formulations) survives beyond patent expiry.

- Involving patient representatives in the design of all consumer and healthcare professional communications materials.

- Offering support to patients in reimbursement procedures.

Lifecycle management

All value-chain action steps must be supported by a lifecycle management strategy involving patients from the earliest stages of drug development. Building patient loyalty for a therapy ensures that the entire franchise (related therapies, successor molecules, multiple indications and formulations) survives beyond patent expiry.

In practice the most relevant actions in this field are:

- Start lifecycle management early in development with patient-relevant trial endpoints.

- Plan early for successor molecules, multiple formulations and indications.

- Develop "total care" solutions including innovative technologies such as online patient communities and support and a compliance program in collaboration with physicians and pharmacies.

Patient centrism is a powerful model for reaching sustainable profitability in the industry, even with drugs targeting smaller markets.

Many of the above-mentioned steps involve close interaction between patient associations and biopharma companies. It is up to both parties to find the correct balance between preserving the impartiality of patient advocacy groups on the one hand and developing a listening capacity for the needs of these patients on the other hand. As the Gleevec example has shown, constructive interaction can have a dramatic impact on drug acceptance by both the market and regulatory authorities.

The business case for patient centrism

So far we have demonstrated that patient centrism can lead to better treatments and faster drug development and commercialization. But how do these optimizations translate into value creation for biopharma companies?

The business case below demonstrates that patient centrism is a powerful model for reaching sustainable profitability in the industry, even with drugs targeting smaller markets. The simulation compares the financial results of a "traditionally developed" drug with those of a "patient-centric" drug, both in the current environment. Even assuming the traditional drug is a blockbuster, with peak sales of $1.2 billion while the patient-centric drug reaches peak sales of only $500 million, the internal rate of return is the same for the two, namely 13.5 %, based on the distribution of cash flows over the lifecycle (see Table 3).

The patient-centric drug remarkably achieves the same profitability as the blockbuster drug for several reasons:

- **Shorter R&D** timelines thanks to factors including better mobilization of patients and accelerated trial recruitment, and despite slowing factors such as regulatory scrutiny and biomanufacturing complexity.

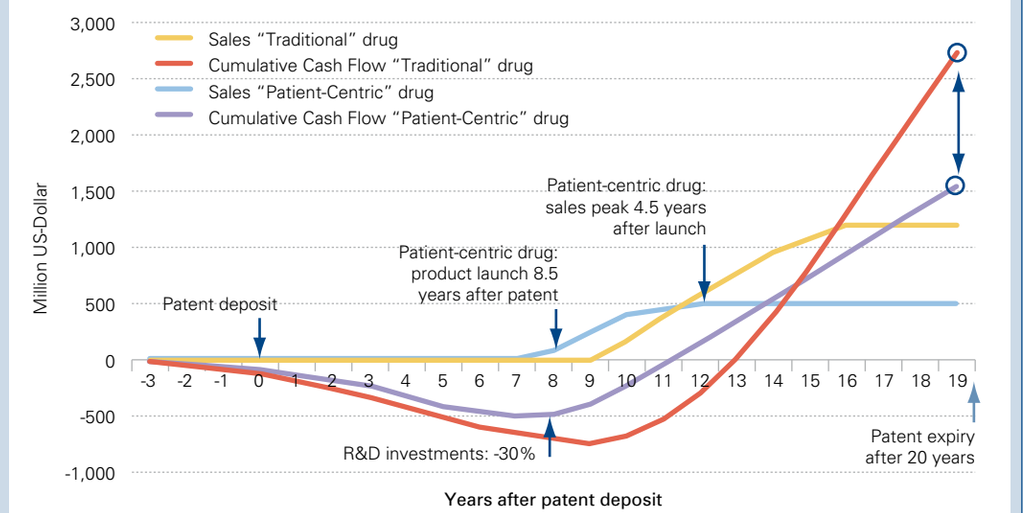
- **Lower R&D** investment thanks to an R&D process that is optimized in terms of timing and costs.

- **Faster regulatory undertakings** thanks to the well-proven economic value of the new drug, patient support and better defined pricing strategies.

- **Faster sales uptake** thanks to the superior effectiveness of the drug, the strong relationships already developed with patients, patient advocacy groups and physicians, more convincing promotional material and help in reimbursement procedures.

- **Same (or better) product margin** thanks to more efficient marketing and sales efforts and a higher price (given the higher relative value of the drug), even though some costs may be higher (e.g. extensive market research).

Table 3 **Financial results**



Source: Arthur D. Little analysis

Making patient centrism happen

There are three key requirements for a biopharma company to make patient centrism happen in practice: it must re-organize for outward focus, strengthen its network of alliances and convince all stakeholders of the benefits of patient centrism.

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Get organized for outward focus

Patient centrism requires a particularly outward-focused company culture, which is rather atypical of most biopharma companies. Traditionally their culture has been shaped by the different sciences needed to create a new drug and by the corresponding silos into which they are naturally organized. To create a patient-centric culture, a biopharma company should establish the right incentives at every level of the organization and modify the internal structure so that patient inputs can be brought in.

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A variety of simple measures have proven effective in this regard, such as involving patients in every management meeting of the company; giving concrete incentives to employees to participate in patient advocacy; creating a "patient chair" in each meeting room, where one of the attendees to every meeting will take on the role of the patient, thinking and acting as the final user of the biopharma company's products and services; and creating patient-driven programs such as a prize for the best patient advocacy initiative. Other measures that embed patient centrism more structurally are the inclusion of patient-centric objectives in the appraisal system of every employee involved in product creation and commercialization; installing a permanent (non-disease specific) patient advisory board; and nominating a patient representative on the company's board of directors.

Last but not least, to demonstrate its commitment to the concept, a biopharma company needs to make a top management member responsible for patient centrism. With the proper authority, patient presence – real or virtual – across the product lifecycle will be strengthened. This also ensures that the most advanced technologies are used for the patient's disease treatment. In a process-minded industry such as biopharma, this high-level executive is the gatekeeper of a renewed drug discovery and development process, now managed with and for the patient.

Strengthen the network of alliances

Patient centrism also implies even greater attention to development speed than is the case today. The market will reward the ability to rapidly convert an unmet patient need into an effective treatment. Partnerships and alliances will be necessary to leverage know-how and get faster access to complementary skills or integrated technologies. The biopharma company should see itself as the federator in a web of stakeholders, including academic centers, biotech companies, patient advocacy groups and technology suppliers, focused on delivering an integrated treatment solution. This requires developing a unique capability to manage complex alliances effectively.

Convince all stakeholders of the benefits of patient centrism

Possibly the biggest challenge for biopharma companies willing to embrace patient centrism will be to reset their relationships with two of their key customer groups.

Possibly the biggest challenge for biopharma companies willing to embrace patient centrism will be to reset their relationships with patients and prescribers.

First, biopharma companies should establish a framework enabling patient advocacy groups and individual patients and caregivers to embrace this shift from a passive end-user role to a co-developer role, and gain their commitment to do so. There are numerous and intricate constraints to consider, such as data protection and privacy, regulations on non-promotional communication to patients, transparency and management of possible conflicts of interest.

Second, biopharma companies should involve the industry's historical primary customer, i.e. the prescribers, in this new relationship with patients so that they see it as a viable strategy to improve treatment collaboratively, rather than a gimmick to circumvent them. This requires a profound change in the way the industry has traditionally approached these customers, shifting from secretive, internally focused product development and commercialization to a transparent, cooperative and externally focused business model.

Insights for the executive

The biopharma industry has a distinguished record of life-saving innovations. But today it is beset by a range of challenges – scientific, regulatory, commercial and financial. The task of the biopharma industry is to rethink its

business model without abandoning the core framework of its historical success.

This new model must put the patient at the center of all its endeavors, whether in product development, market access, commercialization or product lifecycle management. In essence, biopharma companies must include the patient in the understanding of a disease and its treatment. They must take radical and visible steps to internalize patient insights, and be widely perceived as taking patients' and caregivers' points of view seriously. This profound change reflects the emergence of patient power, which can play a key role in accelerating product approval, supporting reimbursement and driving faster diffusion.

An effective patient-centric strategy involves close collaboration between companies and patients at all stages of the value chain:

- In product development, patient insights can drive broad adoption, as Amgen and Novo Nordisk demonstrated with patient-relevant dosing and delivery systems.
- Effective market access includes co-developing with patients an equitable pricing policy that preserves profitability while serving the uninsured populations, as Novartis did with its flagship brand, Gleevec.
- Successful commercialization also depends on close patient links for disease awareness and communications, as Genzyme pioneered for its orphan drug business.
- From the earliest development stages, lifecycle management involves patients in determining new indications, formulations and successor molecules, to maintain a franchise beyond the expiry of patents.

As a consequence of patient centrism, the biopharma company will have an even more significant impact on patient health, increase its R&D investment efficiency, reduce the time to market, increase sales uptake and enhance patient compliance whilst strengthening its alliance with healthcare professionals and improving the company's image among all stakeholders.

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