The Evolution of the Global Pharma Industry

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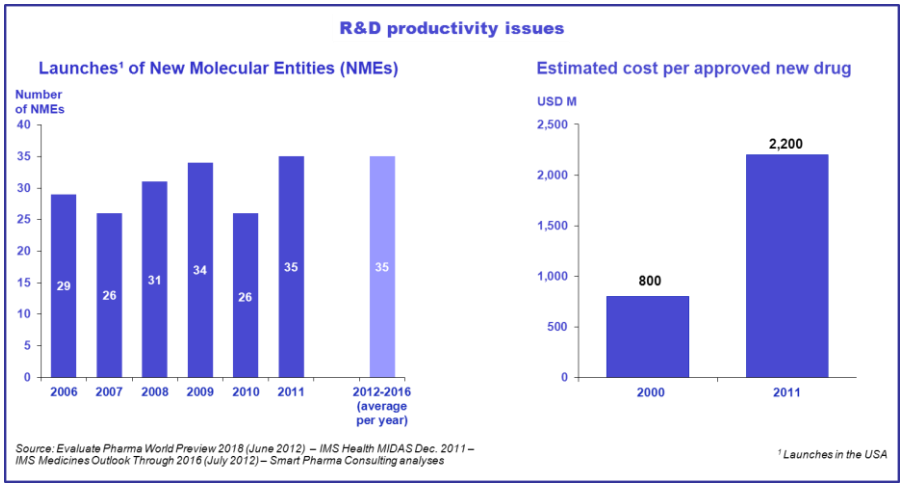
The pharma sector has experienced a long evolution process which, year after year, has progressively redefined the features of the market and the conditions required to succeed.

Pharmaceutical companies face several major changes:

1. The number of new molecular entities (NMEs) launched has been stable at ~30 per annum while their cost has significantly increased. Many of the drugs under development are aimed at treating complex conditions while the regulatory approval process has become more sophisticated and stringent. As a result, the likelihood of ultimate success has become lower and the average R&D cost for a NME increased from USD 800 million in 2000 to approximately USD 2,200 million today. Breakthrough therapeutic innovations are very rare and are limited to one or two NMEs per annum.
2. The entire healthcare system is under unprecedented price pressure. However, cost-containment measures implemented by payers (public and/or private) mainly target pharmaceuticals for which those measures are easy to implement (little or no negotiation with manufacturers is required) and the impact is immediate.
3. Over the recent years, payers have also increased their influence on treatments prescribed by physicians and those co-paid by patients. Public and/or private payers decide which products to list on formularies and which ones to reimburse. They also influence therapeutic guidelines which are written based on health and economic considerations.



4. One of the effects of the increasing influence / power of payers is the spectacular development of generics, which accounted for 26% of the global pharma market value in 2011 and should reach 35% in 2016.
5. Increasingly, payers compare treatment alternatives based on outcome analyses. Thus, they evaluate the global impact of drugs on overall patients' health and not only on their symptoms. They take into consideration not only the proposed drugs, but also the associated services offered by manufacturers to:
   a. facilitate the prescription by physicians,
   b. simplify the distribution by pharmacists,
   c. improve the adherence and persistence of patients to treatments.

   Payers expect global solutions from pharmaceutical companies to better manage patients' overall health.
6. Patients have become increasingly aware and knowledgeable about their diseases, especially in the case of severe and/or long-lasting illness (diabetes, cancer, degenerative diseases such as rheumatoid arthritis, etc.). Thus, an increasing number of patients discusses with and even influence the prescription of their physician. Internet and other more conventional media such as healthcare magazines or TV programs have contributed to improve the knowledge of patients. In the USA, almost 70% of adults use Internet to search for information related to health either for themselves or their relatives.

7. As a result of the strong detailing pressure from pharma companies on the same high potential prescribers, the increasing influence of payers, and the scientific information available on Internet, a growing proportion of physicians refuses or limits face-to-face calls by medical representatives. In 2011, spending of pharma companies in detailing decreased by 5% vs. 2010.

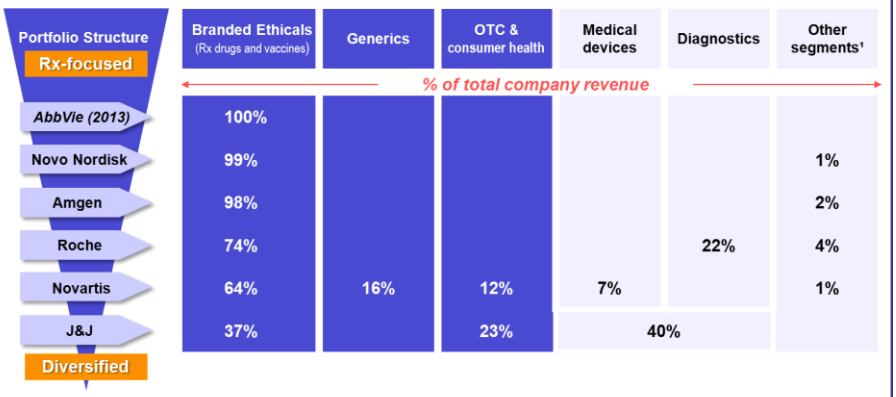
These major structural changes of the environment are compelling pharmaceutical companies to reconsider:

1. The market segments on which they want to compete.
2. The way they should interact and collaborate with their stakeholders.

Big pharmaceutical companies can adopt two opposed corporate strategies to adjust to these major changes of the environment:

1. Diversify their activities to become healthcare companies selling drugs (Rx-driven, OTC, originators and generics), food supplements, medical devices, diagnostics, etc. like Novartis or J&J.
2. Refocus their operations in those segments exhibiting the best sales growth and the highest profitability such as most secondary care segments, and especially those led by biotech brands. This is the strategy followed by Amgen, Novo Nordisk and soon to be followed by AbbVie, the research-based pharmaceutical spinoff of Abbott.

Business structure of the leading pharmaceutical companies (2011)



Source: Annual reports 2011 – Evaluate Pharma World Preview 2018 (June 2012) – Smart Pharma Consulting analyses

¹ Includes royalties, alliance revenues, unclassified sales, contract manufacturing, etc.

Both strategies make sense but they pursue different objectives:

1. The diversification strategy gives a greater importance to the mitigation of business risk by operating on different strategic segments subject to different business drivers.
2. The primary objective of the focus strategy is to concentrate all the resources on the most innovative and highly valued business segments which will drive the highest sales and profit growths.

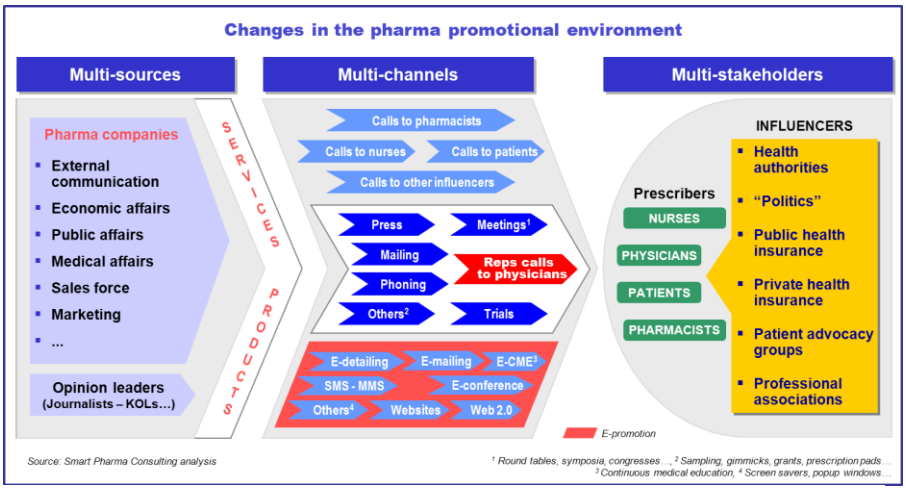
These market changes have a direct impact on the operational activities and capabilities required by pharmaceutical companies to succeed in this changing environment:

1. Market access for NMEs or new indications – including registration, pricing, reimbursement and listing – has become more difficult and requires high quality health economics and outcome research studies, showing strong and convincing results. Reimbursement and listing on formularies are not guaranteed, even for innovative products, if their cost-efficiency ratio is not competitive enough. For instance, the biologic drug, Belatacept (Nulojix) from BMS, indicated in renal transplant, has not yet obtained its reimbursement in France. Market access capabilities are not only required at national level, but also at regional and hospital centers' levels, to optimize price and listing on formularies.
2. To be registered at national level, listed and prescribed at centers' levels, ad hoc studies or multi-centric studies are increasingly required. Payers and prescribers want to generate their own medical and economic data. This evolution should prompt pharmaceutical companies to reinforce their medical and clinical activities and develop tight partnerships.
3. Marketing and sales activities need to be significantly adjusted to remain efficacious and efficient in the new pharma environment. As prescription decisions increasingly depend on multiple stakeholders, pharma companies need to adopt a more complex and coordinated promotional approach.

Physicians' expectations from medical representatives are changing. Physicians expect not only medical information about brands and pathologies but also health economics and outcome research data. In addition, physicians' expectations from pharmaceutical companies regarding medical services (e.g. grants, sponsorship, support to publications, participation to clinical trials, medical and management training, etc.) are increasing, in spite of more stringent regulations to limit initiatives likely to influence their prescribing behavior in favor of specific brands.

Beyond physicians, nurses, patients and pharmacists may play a role of prescriber, while the decision power of the "influencers" is also getting stronger. Some patients do not hesitate to refuse certain brands or ask their physician for a specific one. The role of influencers and the way to interact with them should be carefully qualified to determine the whether it is necessary to communicate to them.

Conventional promotional channels can be complemented by electronic channels which represent an opportunity for pharma companies to maintain a certain level of "noise" towards physicians who tend to limit the number and duration of calls per medical representative.



E-promotion allows the delivery of complex information to physicians, in a more flexible way.

Promotion of products and associated services, either conventional or electronic, should be implemented through the mobilization of multiple sources of information including:

1. Medical representatives and their area managers.
2. Key institutional managers (KIM) dealing with influencers.
3. Medical support functions such as medical scientific liaison (MSL) and clinical research assistants (CRAs).
4. Commercial support functions such as key account managers (KAMs) meeting hospital listing decision makers (e.g. pharmacists, purchasers, head of medical department, etc.).

In this context, interactions between stakeholders and pharmaceutical companies representatives must be well-planned and well-coordinated to ensure that the activities carried out are relevant to their needs and the quality of execution meets their expectations.

The pharma sector is clearly moving:

1. From a B-to-C to a B-to-B model.
2. From a product- to a solution-driven business.
3. From a cost- to a value-driven proposition.

The pharma leaders of today and tomorrow should transform their organization and change the mindsets of their collaborators to become and remain the "best-in-class" on these three key dimensions.

About the author: Jean-Michel Peny, is President of the Strategy and Management consulting firm Smart Pharma Consulting, Director of Smart Pharma Institute of Management, Lecturer in Pharmaceutical Strategy and Marketing at the ESCP Europe and ESSEC Business Schools, as well as the Faculty of Pharmaceutical Sciences (Paris XI).

Prior to founding Smart Pharma Consulting in 2001, Jean-Michel advised many of the leading global pharmaceutical companies during his 19 years as a Strategy and Management consultant with Bain & Co, AT Kearney, Arthur D. Little, and ISO HealthCare Group. Prior to his consulting career, Jean-Michel was a General Manager in the pharmaceutical industry for over seven years with Servier and Novartis.