

**The New Challenges In The Pharmaceutical Industry, What Strategy
To Face Them? Sanofi Experience.**

التحديات الجديدة في الصناعة الصيدلانية، أي استراتيجية لمواجهةها؟
تجربة سانوفي

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Received: 13/11/2019

Accepted: 25/11/2019

Published: 31/12/2019

Astract: This research discusses the pharmaceutical industry new challenges, like the slowdown of market growth, slowdown of biosimilars and advanced technologies, and tries to highlight the main axes of the facing strategy, by taking the experience of the French company Sanofi as example. Ending by giving some ideas about what could the Algerian pharmaceutical companies get from this experience. As results, there is trending towards biotechnological companies which makes the acquisition or merger with them very important. Second, collaborations are necessary to provide better health solutions. Third, the inevitability of digitalizing the sector and keeping good relationship with investors and society.

Key words: pharmaceutical industry, challenges, strategy, merger, Sanofi, R&D.

الملخص:

يناقش هذا البحث التحديات التي تواجه الصناعة الصيدلانية كإخفاض معدل نمو السوق، انتشار البدائل الحيوية، مواكبة التكنولوجيات المتطورة، كما يعمل على تسليط الضوء على أهم المحاور التي يمكن أن تبنى عليها أي استراتيجية لمواجهة هذه التحديات، بناء على تجربة الشركة الفرنسية الرائدة في هذا المجال سانوفي Sanofi ، مع ربطها بإمكانية توظيف الأفكار المستخرجة من هذه التجربة بالصناعة الصيدلانية في الجزائر.

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يخلص هذا البحث إلى وجود توجه عام نحو الاندماج مع الشركات البيو تكنولوجية كونها تمثل مستقبل هذه الصناعة، ضرورة الدخول في شراكات وبناء علاقات تعاون في مجال البحث والتطوير، رقمنة الصناعة الصيدلانية، بناء علاقة جيدة مع المستثمرين والمجتمع ككل.

الكلمات المفتاحية: الصناعة الصيدلانية، التحديات، الاستراتيجية، الاندماج، سانوفي Sanofi، البحث والتطوير.

I INTRODUCTION

The pharmaceutical industry is one of the main pillars of economy, and a part of the healthcare system, based on research and discover of health solutions which empower the discoverer company to get patents allow only it to produce and sell the new drug, unlike the other competitors who should be forbidden for significant period, before giving them the right to produce.

This industry has multi-engagements toward patients and producers, and witnesses fast technology development, as widespread for biosimilars, plus the patents expiration. Thus, put any company and we choose to take the leader French company Sanofi as example, in face of new challenges should be taken seriously, through putting a well thought out strategy that determines the primordial challenging axes and the way should the company react with. Therefore, our research problematic will be resumed in the following question:

How could Sanofi be a leader? And how would it face the new challenges in the pharmaceutical market?

Aiming to answer this question, the research will address many points such the main pharmaceutical industry challenges, the facing strategy and its main axes, and some propositions concluded from Sanofi company experience to develop and strengthen the pharmaceutical industry in Algeria.

II PHARMACEUTICAL INDUSTRY DEFINITION

The pharmaceutical industry is a part of the healthcare system, and drugs substances represents a wide range of pharmacological activity and toxicological properties. Both of public and privet organizations act to discover, develop, manufacture and market medicines for human and animal health that aims to prevent or treat diseases and disorders.

This industry is based on the scientific research, and the new technological advances accelerate the discovery and development of medicines to be more effective with less side effects. Molecular biologists, medicinal chemists and pharmacists are improving the benefits of drugs through increased potency and specificity. These advances create new concerns for protecting the health and safety of workers within the pharmaceutical industry.¹

According to the Algerian industry ministry, the pharmaceutical industry is *«strategic economic sector that gathered research activities, making and marketing of medicaments for human or veterinary medicine. It is considered among the most profitable and economically important industries in the world that is practiced by the pharmaceutical laboratories and biotechnology companies²»*.

III PHARMACEUTICAL INDUSTRY CHALLENGES

In the last years, pharmaceutical industry knew many new challenges:

A The Slowdown Of The Pharmaceutical Industry Growth

The united state pharma industry plays a big role in the international pharmaceutical market, and it is leading it for many years, so, any slow growth for it, can be reflected bad on the global economy, and there is an expectation of growth between 6% and 9% through 2021, which is less than 12% in 2015³, because the market is close to its saturation, and these estimations are out of any invention of effective medicaments.

Historically, since the penetration of generic medicaments, especially those for Hepatitis and Cancer, the pharmaceutical market knew a sporadic growth rates⁴.

B The Showdown Of Biosimilars

Biosimilars are officially approved version of original innovator products, and can be manufactured when the original product's patent expires⁵. These biosimilars have shown a good efficacy and safety for patients with less costs, that's why, a wide range of patients tend to buy them, which depends on researchers in pharmaceutical industry hurts their innovation capacity⁶.

C Changing Regulations

As the developing country's economy is growing they are emphasizing more on the public health and their well-being. The regulated countries like Europe, US is emphasizing on more stringent guidelines and regulation concerning the development and manufacturing of the drugs for human use.

Gone are the days when the emphasis was given only on quality, now the regulators have become more demanding and expecting the industry to match the standards which comply with the concepts such as quality by space, quality by design, quality risk management⁷.

D Patient-Centric Healthcare

Technology trends are driving a shift towards patient-centric healthcare, as evidenced by wearable biometric devices and telemedicine. This trend is resulting in more informed patients who are likely to take a more active role in any treatment plan their doctor may prescribe.

Patient-centric care can provide challenges and rewards for the pharmaceutical industry. The main challenge for 2019 will be determining how to leverage the power of health technology and shifting focus from partnerships with the medical community to partnerships directly with the consumer. In 2019 and beyond, the direct consumer may become the pharmaceutical company's most strategic partner⁸.

IV OVERVIEW ON SANOFI PHARMACEUTICAL COMPANY

Sanofi is a leader in pharmaceutical industry, it is French multinational pharmaceutical company headquartered in Paris, has founded in 1973 as a spin-off of Elf Aquitaine the popular oil company of France⁹.

Sanofi is specialized in research and development, manufacturing and marketing prescription drugs that cover 7 major therapeutic areas:

cardiovascular, central nervous system, internal medicine, oncology, thrombosis¹⁰ and it is a leader in diabetes area and the world largest producer of vaccines¹¹.

Today, Sanofi is a global healthcare, with €34.463M sales in 2018, and hiring more than 100.000 employee with 145 nationality, it is present in 100 country, has 75 manufacturing site distributed on 33 country, and provides healthcare solutions in 170 country around the world¹². It is a component of Euro Stoxx 50 stock market index¹³, CAC 40 and NYSE indexes¹⁴.

V HOW COULD SANOFI BE A LEADER IN PHARMACEUTICAL INDUSTRY?

Extend or die, is the market principle that Sanofi believes and apply, and during its history, Sanofi knew many extensions via merger and acquisition, almost of 13 time since its founding to 2018¹⁵. The second inevitable principle for existing is innovation.

A Merging-Acquisition As A Style Of Life And Survive

Sanofi merger-acquisition targets the famous and successful pharmaceutical and biotechnological companies¹⁶ and laboratories around the world, which have already their reputation, structure, strategy, successful businesses, specialized in specific therapeutic area, and the most of them are already found in many countries around the world.

However, there were two main mergers made Sanofi a leader and among the largest pharmaceutical companies in world. The first one was in 1999 with the French laboratory Synthelabo, that time Sanofi was the second largest pharmaceutical group in France, and Synthelabo was the third¹⁷, and the new company named Sanofi-Synthelabo.

The second landmark merger happened in 2004 with the French-German pharmaceutical company Aventis, where the French government played a big role to finalize it¹⁸, and the name of company has changed again to be “Sanofi-Aventis”, this new company had created in 2005 “Sanofi-Pasteur”¹⁹, a subsidiary of vaccines for variety of conditions: Tetanus, Hepatitis A, Hepatitis B, MMR, Polio And Influenza. This subsidiary is today one of the world largest vaccines producers²⁰.

In 06 May 2011, the word Aventis is dropped from the name of company, and became just “Sanofi”, in order to make it easy, as it was hard to pronounce in several languages and countries such China²¹.

The biggest acquisition in Sanofi history till now was the acquisition of Genzyme in 2011, it is an American biotechnological company headquartered in Cambridge, specialized in the treatment of orphan diseases, renal diseases, endocrinology, oncology and bio-surgery²². In 2010, Genzyme was the world’s third largest biotechnological company²³.

Through 2008 to our day, Sanofi had done many acquisitions around the world such Zentica from Prague, Medly Pharma from Brasil, Shantha Biotech in India...and many others. The most notably, that Sanofi focuses on biotechnological companies with view to the future that it will be for the development of genome technologies²⁴.

B R&D is The Second Sanofi Successful Key

In a field such pharmaceutical industry, innovation, research and development are the keys of continuity, with time branded medicament’s patents expire, and the drug composition will be available for all producers, and that what is known by generics. By consequence, companies have to innovate and get new patents to live. In order to keep its place as market leader, Sanofi had invested huge amounts of money in research and development through time with ascending way from €4.430 M in 2006²⁵ to €5.894 M in 2018²⁶.

R&D in Sanofi company is focusing on 5 therapeutic areas: oncology, immunology and inflammation, rare blood disorder, rare and neurological diseases, diabetes and cardiovascular.

Sanofi today has more than 23 laboratory²⁷ for research and development, which allow it to keep innovating, and in order to make this operation more efficient, richer, quicker and more profitable, Sanofi seeks to make partnerships and collaborations with companies and individuals, and it considerates this as one of the crucial elements in its strategy, and believes that “sharing expertise, driving innovation”²⁸. Till 2018, it has collaborated with more than 25 partner²⁹, their participation represents 50% of the development pipeline.

VI WHAT STRATEGY DOES SANOFI HAVE TO FACE THE NEW CHALLENGES IN THE PHARMACEUTICAL MARKET?

We have previously mentioned the main challenges in the pharmaceutical industry that oblige companies in this field to change and react with ways that help to face the challenges and move on. In other side, funding challenges, budget and affordability constraints persist, which put the entire healthcare value chain under significant pressures. Sanofi as a leader, has to take these challenges in consideration and put strategy that empowering it to keep its place in the pharmaceutical world. This strategy is working on several axes:

A Reshape The Portfolio And Deliver Outstanding Launches

Reshape the portfolio means three things:

Keep the leadership in the areas that is already leader in, and they are: diabetes, cardiovascular, vaccines, rare diseases and emerging markets.

Enhance the areas do not have a competitive position yet, and they are: multiple sclerosis, oncology, immunology and consumer healthcare.

Explore strategic options for animal health and European generics businesses.³⁰

Sanofi growth is driven by its new launches; up to 18 new product will be on sale by 2020. It expects that six of them could generate €12 M to €14 M by 2025³¹.

B Sustain Research And Development

Sanofi seeks a lot about R&D function, and works incessantly to strengthen it, and evolve its model based on projects teams and alignment with its global business units. Continue in the collaborations and partnership policy, foster the existing ones, and make new others to increase its capacity for external innovations³². Sanofi has determined three major potential areas for partnership:

Mature Markets: we mean by the mature market, when the rate of growth slows, it could reach zero, and the market functions without change or innovation³³, and it is good place to focus on the therapeutic areas in which Sanofi operates, and enhance the actual portfolio³⁴.

Emerging markets: are countries that have some characteristics of developed markets, however do not satisfy all standards of the developed markets³⁵, they are known by their volatility and low income³⁶. Sanofi sees a big opportunity in emerging markets for the late-stage development products, marketing brand that complete its wide portfolio in primary care or specialty care³⁷.

China: is a big opportunity for earlier-stage products, especially in oncology, vaccines, nephrology, CNS, dermatology and respiratory³⁸.

C Enhance Digital Technologies And Artificial Intelligence

Sanofi aims to make patients' lives better, through developing and innovating medical advices, and enhancing the digital technology, which represents new way to improve care at a reduced cost with improved patient or customer experience³⁹; through 7 prior digital health sectors: digital clinical trials, digital factory, multi-engagement channel, consumer precision marketing and ecommerce, data and analytics, drugs and solution, diabetes solutions. We will focus on the two first ones:

Digital Clinical Trials

Clinical trials concerns the put of new drug on human use, and study its efficiency, dosage, side effects...etc. Before digitalizing the clinical trials, the phase of finding patients for these trials was difficult, and has many constraints, like the geographic ones, so patients should be close from the study centres; and they have to go there regularly for tests and observation. Now, the digital technology has created the "mobile nurse", it is an Apple iPhone that helps patients to be monitored from distance and send their data for researchers in real time. This technology has facilitated the patients recruitment, so as, the collection and analysing of data, therefore, putting the drug in market a lot sooner⁴⁰.

Digital Factory 4.0

"The ambition for Sanofi is to create a fully-fledged and disruptive biotechnology sector, answering the demand for customized and high quality products. A patient-oriented, digital and sustainable ecosystem, this is Sanofi's vision for its factory of the future!" says Jakob Harttung, Head of Factory 4.0 Manufacturing Excellence⁴¹. This is the future factory in Sanofi vision, equipped with intelligent advices and sensors able to treat thousand of production information, and generate thousands

data to monitor, advanced analyse and control manufacturing of drugs, paperless manufacturing process^{*42}.

D Managing The Relationship With Investors And Society

Sanofi aims to build a good relationship with its investors and its environment as whole, through 3 main axes: opening contact channel between Sanofi and its investors and society, committing to corporate social responsibility and citizenship, making financial information available and easy to reach.

This contact channel uses the internet website as a main tool to match sanofi with its environment; through “publication” to deliver the information to the different users. Consulting Sanofi website may provide enough information for investors, students, researchers and society as whole, through displaying the company Strategy for the next years, the future projects, the company vision in which concerns the digitalization operation...etc.

Sanofi believes by the corporate citizenship⁴³ concept, and the corporate social responsibility is in heart of its commitment towards society; we will find in this website the different reports and initiatives that Sanofi leads, the different efforts to protect environment and reduce the negative impacts of its activities; by putting various policies to⁴⁴: reduce green gas emissions, streamlining water consumption and pharmaceuticals in the environment, waste management, climate change and health.

Besides that, Sanofi had created the Ethics & Business Integrity (E&BI) Department, and developed the “Code of Ethics” that is available in 29 language⁴⁵, in order to enhance integrity and transparency in its daily activities.

The right of reaching the information is respected according to Sanofi, by publishing the financial reports⁴⁶ for the actual and previous years, with day-to-day shares⁴⁷ details, movement, prices, indexes, to keep the investors aware about their investment.

Dividends value is increasing slightly from year to another, but it keeps increasing without any decrease in the last 10 years at least, it was €2.20 in 2008 and reached €3.07 in 2018⁴⁸, moreover, the dividends payment is done every year and takes 5 days as maximum⁴⁹ between the

record day and payment day, which makes investors comfortable and encouraged to still invest in this company.

VII WHAT COULD THE ALGERIAN COMPANIES LEARN FROM THIS EXPERIENCE?

The Algerian companies are working in undeveloped market, known by its volatility especially from regulations side, the low drugs quality... in the other side it knows ascending demand for drugs and able to accommodate huge quantities of them, and this encourage the dealers in this field to move on. However, it needs to be more developed, which makes the collaborations with international companies necessary to get knowledge, bring manufacturing technology, keep up with the updates in the pharmaceutical industry.

At the same time, it is very important to encourage the Algerian companies collaborations between each other, to build strong ground for solid Algerian pharmaceutical industry, and making conglomerates to face the international competition.

The next important point is to focus in the research and development centres to find solutions for the widespread diseases in Algeria, Africa and the third world in general, as they are the main markets to sell and export the Algerian drugs. Besides that, the research and development collaborations should be enhanced by creating local and national initiatives to attract competences, and relying on start-ups.

VIII CONCLUSIONS

This research seeks to highlight the pathway for a successful company, by taking the experience of Sanofi pharmaceutical company as example. First, we tried to present the main challenges are facing the pharmaceutical companies in general. Then, explaining the main successful keys led Sanofi company to grow up, continue and build a strange position in the market. After this, we focused on the main Sanofi's strategy axes to face these challenges and adapt with the changing environment it lives in. In the end of this research, we could extract the following results:

Merger-acquisition policy is inevitable for companies to stay existing, the key of success of this policy is to know what company to choose and when, this requires having far view for future and expecting the industry trending;

Research and development function should match out of the traditional vision that imposes companies to be closed on themselves. However, being opened on the others, getting and enriching the company knowledge through partnerships and collaborations;

Keep up with technology by digitalization of the different pharmaceutical functions like research and development, relationship with patients and all the dealers, and drugs manufacturing, represent a big challenge facing the companies, that have to win it.

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