

ICT and Pharmaceutical Innovation Trajectory: The Challenge of Maghreb Countries

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Abstract— The pharmaceutical firms are witnessing structural changes related to, among other things, the high costs of Research and Development (R & D), the extinction of patents, the growth of generics, the high risk of failure and the return on investment which is not always guaranteed. Faced to these constraints, the world's leading pharmaceutical firms have worked hard to improve their innovation potential by designing new molecules that are difficult to imitate. They tried to enhance the market access barriers for other molecules in order to preserve their dominant positions. Thus, the trajectory of innovation has changed and the technological revolution has not been limited solely to the chemical drugs whose manufacture is based on "trial and error" techniques. It has moved to personalized and "tailor-made" treatments, resulting from biotechnology. However, the manufacture of these latter requires an extreme use of knowledge and know-how in biology and Information and Telecommunication Technology (ICT) and a new reorganization of the whole sector. The objective of this paper is firstly, to present through a large literature review, the trajectory of innovation in the pharmaceutical industry and the reasons for the technological transformation that the industry is witnessing. Then to study the role that ICT plays in this revolution, and by the end to present the case of the pharmaceutical firms in Maghreb countries.

Index Terms— Biotechnology, Information and Communication Technology, Innovation trajectory, Pharmaceutical industry.

1 INTRODUCTION

With the patent extinction and the rise of generics, the world's leading pharmaceutical firms named "big pharma" have worked intensively to improve their innovation potential by designing revolutionary molecules that are personalized and outcome from biotechnology [1], [2]. The objective is to introduce molecules that are difficult to imitate in order to strengthen the market access barrier for other molecules and to preserve their dominant positions. Firms in this sector are undergoing a technological revolution that allows them to go beyond the chemical paradigm whose manufacturing process is based on "trial and error" techniques, and go further by offering its patients tailored biotechnology solutions [2], [3].

The sector slips from a supply of medicines to a therapeutic offer better adapted to the health needs of each patient. This technological progress needs information contained in the patient body and in his environment. The use of ICT and their implementation in order to build up databases is necessary to orientate the R&D in this field [3], [4]. The interactions between biology and other fields, especially informatics, drive change in technological paradigm and in business model of companies operating in the sector.

The objective of this paper is to analyze in the first section the technological change that the pharmaceutical industry is ongoing and presenting the effect of ICT in this technological pro-

gress. The second section of this paper focuses on the situation of pharmaceutical firms in Maghreb countries. Are they following the same steps as pharmaceutical firms in industrialized countries in terms of technological innovation or not? How the use of ICT can enhance their involvement in the innovation development? Finally, we present measures that we consider necessary for developing countries, to become actor in innovation process instead of consumer of imported innovation.

2 BACKGROUND

2.1 Pharmaceutical Innovation Trajectory

Pharmaceutical industry is ongoing a technological progress in order to bring solutions to the untreated diseases. The appeal to biotechnology and its emerging is not newly revealed in the literature devoted to the pharmaceutical sector. Ghabowski and Vernon [5] presented in 1993 a historical background about biotechnology emerging and the changes that drive in both R&D and innovation structure in pharmaceutical industry. Their study shows that the share of biotechnology continues to increase and its implementation influences not only the technological paradigm but also the organization of the sector itself. In fact, the sector knows consolidation among the pharmaceutical firms, which has not remained limited to companies within the same sector, but it concerns also other companies from diverse disciplines [6].

Biotechnology medicines are taking more and more place. As shown before, biotechnologies are often manufactured to respond to diseases that are still untreated. As a result, the market share of this category of medicines is starting to grow. See Fig. 1 [7].

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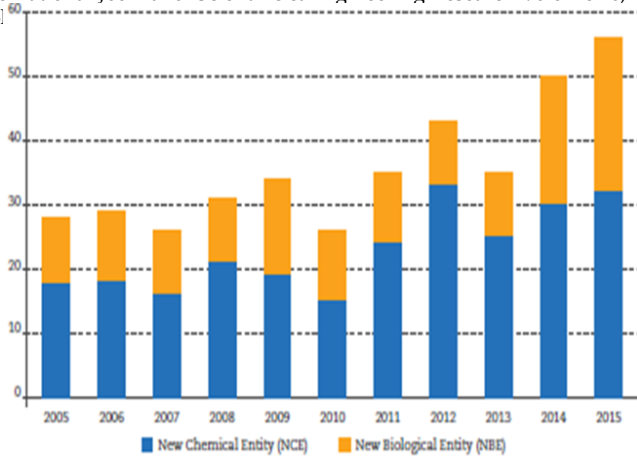


Fig. 1 Number of New Chemical and Biological Entities

Approved by the US Food and Drug Administration, 2004-2014

Other factors are mentioned in the literature as a change driver in the pharmaceutical sector. Malerba [8] is one of the authors that outline that the demand is a key element of sector change and evolution. Other authors explain that the increase of biotechnologies is a result of the fact that the majority of innovations enclosed most of the therapeutic needs. Searching for new molecules in areas of research already explored has become more complex and difficult [9], [10]. Firms have to explore new areas in order to stay competitive and to continue in the progressing trend of innovation in this sector. An article published by the journal McKinsey & Company shows that the leading firms in pharmaceutical sector are shifting to "biopharma" because "investing in biotech R&D has yielded better returns than the pharma industrie" [11]. Furthermore, it should be noted that the biotechnology is "the applied knowledge of biology, it seeks to duplicate or change the function of a living cell so it will work in a more predictable and controllable way" [12].

It means that the manufacturing of biotechnologies needs instruments that can allow the control of a living cells and the prediction of changes, which can undergo. It requires an extreme use of knowledge and expertise in different fields such as biology, molecular genetics, and computer science [13].

2.2 The Role of ICT in Pharmaceuticals Progress

It is largely demonstrated that the ICT plays an important role in facilitating the organizational learning and in building a strong absorptive capacity within the organization [14], [15]. Other research shows that the use of ICT has a positive impact on innovation [16]-[20]. However, in this section we limit our focus only on the place that the ICT takes in the biotechnology development.

Scientists involved in biotechnology research need to have more access to the information contained in the cells of the living organism and in a broader way collecting information about the human organism, that contains this living organs. The ICT is the solution that allows scientists to be connected to these organisms. It allows the capturing; the transmission and the analysis of genetic information contained in the living mechanism and use it for the production of healing molecules:

« for the development of new powerful and selective drugs search has to penetrate deeply into the human organism to unravel the biochemical interactions at the cellular, infra-cellular and, most importantly, molecular levels.» [3].

Peter Tormay [4] explains that companies in pharmaceutical industry need to implement Big Data and to maximize the value of its initiatives in order to strengthen the R&D projects and to satisfy patient special need. Other authors point out that the appeal to Big Data in pharmaceutical firms continue to increase. It enforces not only sales and marketing functions but also other scopes in medicines pipeline such as R&D activities and clinical trials [6].

Hamdouch and Dominique [6] explain that the new biotechnologic methods such as "molecular modeling" and "rational screening" need to master the informatics knowledge and materials. It has led to the development of new IT service providers. Moreover, Biology is no longer limited to the manipulation of cells of the living organism, cells and proteins because even the representation of the human body has changed, it is now perceived as an information warehouse [21]. *opy exactly! The quality and accuracy of the content of the electronic material submitted is crucial since the content is not recreated, but rather converted into the final published version.*

2.3 Need of partnerships between "Bio" and "Info"

As explained in previous sections, biotechnologies are multidisciplinary output. Their development needs synergies among several competencies. This synergy increases not only innovation but also it changes the pharmaceutical sector structure. In fact, the collaboration between biology "bio" and informatics "info" affects the organization of the sector and creates new organizational forms called "network firms". The change in paradigm leads companies to change their business model and seek for more collaborative network. They are moving from the large integrated firm to the firm with many inter-firm relations. The R&D activities have expended into a large mixture of players. This is because companies in pharmaceutical sector are moving from in house R&D to external partners, which are specialized, among other things, in patient's Data processing in order to bring medicines that better meet patient's needs [6].

It is important to mention the example of United States giants such as IBM Corp., Sun Microsystems Inc., Compaq Computer Corp and Motorola Inc., which each has several agreements with biotech companies. A partnership between Verily, an organization owned by Alphabet (Google) with GlaxoSmithKline, Sanofi, Novartis and Johnson & Johnson is to "implement new technologies in areas ranging from diabetes to robotic surgery. Another example of "bio" and "info" reconciliations is the announcement in June 2017 of Google's commitment to the Swiss company Novartis to invest in a \$ 300 million fund dedicated to the manufacture of new medicines [22], [23].

In summary, the development of biotechnologies necessitates the "big three" components, which are Big- pharma, Big-technologies and Big data. Big-pharma provides financial assets, biological experience and detain markets; Big-technologies master informatics tools that allows the capturing and the processing of information and Big-data, which can

centralize the information generated from different sources such as “the R&D process itself, retailers, patients, and care-givers” [24].

After presenting the role of ICT in leading pharmaceutical firms, on the process of the drug manufacturing, on the conception of personalized treatments and on the capturing of relevant information from the human body, and on the sector organization, we therefore, ask whether it conserves the same role in pharmaceutical firms located in developing countries.

3 CASE OF PHARMACEUTICAL FIRMS IN MAGHREB COUNTRIES

3.1 Pharmaceutical Innovation in Maghreb Countries

The main question that we seek to answer in this section concerns the degree of implication of pharmaceutical firms located in Maghreb countries in technological trend that the industry is ensuing in the world.

The development of biotechnologies is a complex process that necessitates important investments, sophisticated materials and “highly skilled experts” to operate cells, gens and living organs [11]. Generally, they are developed in the parent company and it is still too early to talk about biotechnology innovation in developing countries [13].

In Morocco, a program contract was concluded, in February 2013, between the government and the pharmaceutical industries, aiming the development of pharmaceutical industry as well as R&D activities. The government undertakes to set up an aid for the development of the R & D activity in the field of biosimilars [25]. These latter are drugs derived from biotechnology and which constitute a great benefit as well as for Moroccan patients and for the local pharmaceutical industry. Until now, the first and the only initiative of biosimilars manufacturing in Morocco was launched by the end of 2018 by a Moroccan laboratory named “Sothema” [26].

Another example to mention is Algeria where biotech drug manufacturing projects are under development, and they generally involve products whose patents are already extinct. These projects will not concern the cells that are the origin of the biotech drug manufacturing because the genetic engineering needs, among others, hundreds of control points that this country cannot actually afford [27], [28].

To assess the degree of the involvement of pharmaceutical firms located in Maghreb countries in innovative molecules manufacturing, we did not find any previous empirical work or sources generating gathered data about the new molecules that enter to the domestic markets. Therefore, in case of Morocco, we tried to do it from scratch by ourselves, as it is explained in the next section.

3.2 Methodology of Data Collecting

There are several definitions in the literature of innovative molecules in pharmaceutical industry. The Food and Drug Administration (FDA) distinguishes between “New Molecule Entry” and the “Update”: “It is considering as “New Molecular Entity (NME)”, an active ingredient that is commercialized for the first time”. In contrast, “a drug that is a new formulation, a new dosage of existing components, or commercialized

drug that has a new usage is considered as “Update”” [29]. In term of innovation, the “NME” is commonly considered in the literature review as the most innovative product while the “Update” is considered less innovative product [30]. In the present work, we consider both NME and Updates as innovative products titled “originators”. Our objective is not to study the intensity of innovation but the degree of involvement of firms in product innovation gloss over it is NME or Update. However, we did not consider generics as innovative products because they are operating on re-producing originators once their patents are extinct [31].

Therefore, we proceed in this way: we consulted specialized websites in health care and medicines launching in Maghreb countries. The information sought in these websites is the number of innovative molecules that entered these markets during the last five years, then we searched their origins (local manufacturing or imported). Unfortunately, as mentioned previously, we did not find any database that gathers the wanted information. So, and for the case of Morocco, we built it ourselves. First, we gathered information about innovative products entries available in National Official Bulletins (BO) published in the General Secretary of the Government website from 2014 until October 2018 [32]. Then, based on pharmacists help and on information available in pharmaceutical firm’s websites, we classify these products according to their origins, either imported or local manufacturing [33].

3.3 Result Discussion

Our findings show that the majority of innovative drugs that entered the domestic market are imported and less than 4 % are locally manufactured (see Table I).

TABLE I
Originators Entries to the MORROCAN Market

Year	Number of originators entries	part of originators locally manufactured	part of imported originators
2014	81	04	77
2015	70	01	69
2016	47	06	41
2017	72	0	72
2018*	74	02	72
total	344	13	331

In order to reach what is happening in other Maghreb markets such as Tunisia and Algeria, we proceeded in our primary analysis to summarize a number of websites related to the drugs information in these countries and we find almost the same results. The most innovative molecules commercialized in these countries are imported. Domestic firms are generally limited in manufacturing licensed drugs, and generics. In Tunisia, for example, 51% of local production are generics and 49% are under licensed manufacturing drugs [34].

Therefore, the industrial model in developing countries is based on the “license model”. The development of new molecule is an exception and concerns only few firms. Consequently, we can conclude that there is absence of product innovation in pharmaceutical firms located in these markets.

The literature review presents several explanations to the obstacles that innovation is facing in developing countries, especially in pharmaceutical sector. Sedkaoui [35] finds that the pharmaceutical firms in Algeria are suffering from the weakness of their financial assets, R&D cost, lack of competencies and regulation obstacles. Moreover, it is important to mention that pharmaceutical sector in developing countries is characterized by the predominance of multinationals affiliates. Unfortunately, these latter are limited on importing products from the parent company. Gabsi [36] emphasizes this finding and explains that the benefits of the flow of foreign investments in Tunisia is not systematic at "the technological level". He specified that the government should intervene in order to "encourage foreign firms to become more involved in the technology transfer process to local firms". The absence of partnerships between the university and industry spheres is also revealed in the literature as one of the most important obstacles to the innovation in developing countries [37].

To conclude, Maghreb countries do not have necessary resources nor an adequate ecosystem to undertake not only biotechnologies but also to manufacture innovative chemical molecules. In the next section, we explain how developing countries can enhance their involvement in the innovation process with the use of ICT, even if this innovation is done in developed countries.

4 ICT AS A SOLUTION ALLOWING MAGHREB COUNTRIES TO SHIFT FROM CONSUMERS TO PARTICIPANTS IN INNOVATION PROCESS

4.1 Use of ICT in Maghreb Countries: State of Play

The positive impact of the ICT use on the economic growth is largely demonstrated in econometric studies in both developed and developing countries [38], [39]. However, African countries did not discern yet how to take advantage from the development of ICT: "African countries have not been able yet to exploit their comparative advantages, such as proximity to the EU market and the availability of a multi-lingual and young population, to become integrated into the global value chains of different IT products and services" [40].

Several reasons behind the slow of ICTs adoption at firm's level are listed in the European Parliament report [40]. It includes, among other things, the policy framework and the constraining environment, the infrastructure weaknesses, education scarcity especially in rural zones and the access higher cost to the ICTs. Banji [41] develops similar arguments in his article about ICTs and industrial development. Healthcare sector, in general and more specifically the pharmaceutical industry does not come out of this scheme.

As explained before, pharmaceutical firms manufacturing model is based on under-licensed model and innovation is initiated in the parent firm. Firms in developing countries are limited in the scope of commercializing the products that they import or they manufacture under license. Therefore, the use of ICT is most useful in the marketing area in order to enlarge market share and to position in the domestic market. Unfortunately, it has not been extended to enclose R&D activities and production process.

4.2 Toward Other Perspectives of Innovation Development

As explained in the previous section, the use of ICT in pharmaceutical firms in developing countries is limited to the classical functions including, among others, information flow facilities within the firm, information capturing and storing, market surveillance and promotion activities. In order to be more resourceful, the use of ICT have to move to upper dimension, which is the constitution of collective databases integrating health data available in multiple sources. The collection of these vast sets of health data presents what is called nowadays "Big data". Much research presented the impact of big data on R&D activities and innovation in healthcare sector [42], [43]. However, what we seek to explain in this section is in which way the investment in big data can help developing countries to switch their situation from simple consumers to actors in innovation process.

Healthcare information in Maghreb countries, and generally Developing countries, is scattered all over different sources including among others, hospitals, clinics, doctors, pharmacists, industrials, retailers, and patients. There is an absence of health information system, on which companies can rely on to guide their R & D activities [44].

In the case of Morocco, the healthcare information systems that currently exist are content to convey a reduced flow of information from the periphery to the Ministry of Health without allowing access to other healthcare actors [44]. This system helps to understand, the human development, the body interactions with medicines and prevents the spread of diseases.

In addition to this, and in order to develop specific treatments to the context of developing or poor countries, multinationals needs to incorporate in their healthcare information system statistics related to the targeted context. As explained before, the development of biotechnologies depends on the patient and his environment information, and in order to take fully advantage from this situation, developing or poor countries have to be the providers of this valuable information to the multinationals.

It is important to mention that there are many initiatives launched by the United Nations "Global pulse" [45], the World Economic Forum [46] and European Parliament [40], in order to encourage policymakers in developing countries to develop big data. These reports issued by these organisms highlight many factors that help developing countries to set up big data tools, including among other things:

- Establishing legal framework for using open data
- Developing necessary Infrastructure
- Developing big data competencies
- Encouraging cultural and policy willing
- Facilitating patient's access to the ICT tools (data collected from mobile devices are relevant)

However, even if all these initiatives are important for developing big data systems in developing and poor countries they are not enough. It necessitates the engagement of multinationals to form partnerships with local technology players. These latter can set up software that collect information from different sources. The big data require different entities to work together to integrate health data from multiple sources

in one system named Health Information System.

5 CONCLUSION

Pharmaceutical sector is ongoing technological changes. Many factors participate in the emergence of the biotechnological paradigm, which in turn depends on the ICT uses and on the big data development. This latter offers a wide range of possibilities for Maghreb Countries to initiate innovation projects both at local and international level by providing multinationals with valuable information offered on one hand as an input of innovation process and on the other, as a mean of orienting their R&D activities.

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