ALGERIA IMPORT SUBSTITUTION POLICY: THE CASE OF THE PHARMACEUTICAL INDUSTRY

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ABSTRACT

This paper investigates Algeria's pharmaceutical industry import substitution issues and challenges. Algeria's pharmaceutical market, remains by far the largest existing market in the MENA region, and the reasons are, first, the country's universal health system, second, the country's rapid population growth, and third, the country's incentives to increase local production. However, eradicating supply shortages, and aligning supply with demand remain a challenge for policymakers. In fact in Algeria pharmaceuticals supply chain is characterized by a multiplicity of actors, ranging from local producers to government agencies, all engaged in products' pricing, quantities, stocks, and labeling policies. Supply shortages are also linked to the ongoing globalization of production and markets, which has driven prioritization of sales, first, to countries with comparatively advantageous prices, second, to countries with comparatively less severe penalties, third, to countries with unexpected rise in demand, and fourth, to countries with major production bottlenecks. In Algeria, the rising consumption pattern, exacerbated by population growth, epidemiological evolution, and innovative products, has led to much decisions crafted under conditions of high uncertainty.

KEY WORDS

Algeria, Healthcare, Industrial Development, Health Regulation, Pharmaco economics.

JEL CLASSIFICATION : I11, I12, L24, L65.

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LA POLITIQUE ALGERIENNE DE SUBSTITUTION AUX IMPORTATIONS : LE CAS DE L'INDUSTRIE PHARMACEUTIQUE

RÉSUMÉ

Ce travail examine les problèmes et les défis de la substitution des importations dans l''industrie pharmaceutique algérienne. Le marché pharmaceutique algérien reste de loin le plus grand marché existant dans la région MENA, et les raisons en sont, premièrement, le système de santé universel du pays, deuxièmement, la croissance démographique rapide du pays, et troisièmement, les incitations du pays à augmenter la production locale. Cependant, l'éradication des pénuries d'approvisionnement et l'alignement de l'offre sur la demande restent un défi pour les décideurs. En fait, en Algérie, la chaîne d'approvisionnement des produits pharmaceutiques se caractérise par une multiplicité d'acteurs, allant des producteurs locaux aux agences gouvernementales, tous engagés dans les politiques de prix, de quantités, de stocks et d'étiquetage des produits. Les pénuries d'approvisionnement sont également liées à la mondialisation en cours de la production et des marchés, qui a conduit à prioriser les ventes, premièrement, aux pays ayant des prix relativement avantageux, deuxièmement, aux pays ayant des sanctions relativement moins sévères, troisièmement, aux pays ayant une augmentation inattendue de la demande, et quatrièmement, aux pays ayant d'importants goulots d'étranglement au niveau de la production. En Algérie, la tendance à la hausse de la consommation, exacerbée par la croissance démographique, l'évolution épidémiologique et les produits innovants, a conduit à de nombreuses décisions prises dans des conditions de grande incertitude.

MOTS CLÉS

Algérie, Développement industriel, Pharmaco économie, Réglementation sanitaire, Santé.

JEL CLASSIFICATION : I11, I12, L24, L65.

سياسة إحلال الواردات في الجزائر: حالة الصناعة الصيدلانية

ملخص

تطرقت هذه الورقة البحثية للإشكاليات المتعلقة بسياسة الجزائر في مجال التصنيع من خلال سياسة احلال الواردات في قطاع الصناعة الصيدلانية. ان السوق الصيدلاني الجزائري هو أكبر سوق في منطقة الشرق الأوسط وشمال إفريقيا وهذا يرجع الى اسباب عديدة منها، أولاً، نظام التغطية الصحية والتأمين للجميع، ثانيا، النمو السكاني العالي، وثالثا، الإنتاج المحلي المتزايد. فإن السياسة المتبعة من طرف صناع القرار من اجل تماشي العرض مع الطلب وستظل ممارسة دائمة لان سلسلة القيمة تتميز بتعدد الاطراف من منتجين ووكالات حكومية وكلها تشارك في سياسة تسعير المنتجات وتحديد الانتاج. هذه الظاهرة راجعة لعدّة أسباب ومنها عملية عولمة الإنتاج و التسويق. أدت هده الظواهر المتشابكة للعولمة إلى اولا، بيع الأدوية في البلدان ذات الأسعار العالية، وثانياً، في البلدان ذات تسهيلات تنظيمية مشجعة، ثالثًا، في البلدان ذات الطلب العالي الراجع للتغييرات العلاجية، ورابعا، في البلدان التي تعاني من اختناقات انتاجية وندرة في المواد الاولية، أو نقص في جودة الادوية. أما في الحالة الجزائرية ان النمو السكاني العالي وتفاقم الاستهلاك وتضخم ميزانية الادوية ادى الى اتخاد قرارات متعارضة كونها اتخذت في ظل ظروف عدم تأكد بارز.

كلمات مفتاحية

الجزائر، الرعاية الصحية، الاقتصاد الدوائي، التنظيم الصحي، التنمية الصناعية.

تصنيف جال: I11, I12, L24, L65 .

INTRODUCTION

Since recent years, Algeria's pharmaceutical import trends have been steadily rising, for instance, they went up by 10.44 % in 2014, increasing the country's financial burdens by USD 2.6 billion compared to USD 2.34 billion in 2013. However, alongside rising trends, total imports volume were dropping from 34,142 tons in 2013 to 33,593 tons in 2014 (National Informatics & Statistics Bulletin, Algiers,2015).Even though import-substitution policies were seemingly progressing in magnitude, however ,the country was unable to decrease all financial pressure on its overly strained universal healthcare system .For the purpose of illustration, prescription drugs which represented then the substance of most expenditures, were estimated at 93.17 % of total pharmaceutical products imports .Antibiotics imports alone reached a value of USD 68.3 million in 2014, whereas in 2013, they only accounted for USD 56.8 million. This significant import cost increase in excess of 16 % was mainly attributed to seasonal products demand variation in a much volatile Algerian market. This costly pharmaceutical import dependency has created pressures for import substitution, localization, as well as a rational preference for generics over branded products. Algeria's local pharmaceutical production has been increasing three times along the last five years to reach a value of USD 1 billion, mainly due to the fact that more than 48 previously drug importers are now operating an excess of 75 local manufacturing units. Despite the bourgeoning of local pharmaceutical production actors, Algeria's drug import bills were not following the expected falling curve, despite the fact that the Ministry of Health planned for local suppliers to cover 70 % of the country's local demand by 2017, local suppliers have only met between 35 to 40 % of the country necessities .While the main reason for this discrepancy ,resided in the fact that local production remained quite unstructured and disorganized, it has also been observed that another reason was the increasing volume of reported unfair competition practices, e.g.; many local firms were just replicating the same standard products without significant variances. We could argue that Algeria's infant

pharmaceutical industry could have reached optimal gains from pricing deregulation, tax exemptions on imported equipment, which could have potentially favored local production of capital intensive investment complex products, and could have constituted the best alternative solution to counter unfair practices. Nonetheless, Algeria's public healthcare has still been characterized by a double-digit growth sector with market valuation reaching USD 3 billion in 2017, a consumer population segment sized at over 38 million, a guaranteed patient coverage, with however a state reimbursement budget strictly based on revolving oil and gas revenues. The country has always been searching for the best access and appropriate paths available to, *first*, redesign its health system and getting more advanced treatments, *second*, accommodate local players in a decentralized consumer base ever-expanding market, and *third*, promote Algeria's national manufacturing capabilities through fiscal and investment promotion policies. The country has nonetheless reached 70% local production by 2017 in a market, which was led by 314 private operators, 150 wholesalers-distributors, 9600 pharmacies, and was estimated at USD 3.7by the end of 2016.But then because 55% of Algeria population - accounting for 39.21 million people -are using 12.69 million *"Chifa"* social security cards which represent 68% of social security spending, hence pharmaceuticals imports bills have actually jumped by 2.4% in 2016 to USD 2 billion. High population growth, social security based free healthcare, and foreign exchange shortage conditions have obviously made out of Algeria's pharmaceuticals import bills a significant financial burden. Hence, controlling medicine expenditures, and promoting a local pharmaceutical industry became a top priority. This paper- based on a grounded theory qualitative case method design - has as objectives to contribute to current research on import substitution and localization of the pharmaceutical industry, to identify factors allowing for or hindering local production development.

The purpose of this qualitative grounded theory based–research paper is to investigate the effectiveness of Algeria's pharmaceuticals import substitution policies, obtain information from purposefully

selected local manufacturers, and explore these results using semi-structured interviews. The motivation for using a qualitative approach rather than a quantitative one, is that quantitative data and results only offers only a broad image of the research problem, e.g., a simple description for instance of '*what'* internal and external factors allow for or hinder local production development, while the qualitative data and its analysis provide a much enhanced explanations of '*why'* through an in-depth understanding of the research participants 'expert opinions *(*Creswell et al, 2002; Tashakkori et al, 1998*).* In this paper, the interview questions serve to explore - with the participants - import substitution issues and challenges, and propose appropriate business environment reforms.

The central research question would be stated as: which major business environment reforms are perceived by local drug manufacturers as necessary and sufficient prerequisites for satisfactory pharmaceuticals supply benchmarks effectively enabling them to carry out Algeria's decision makers import substitution policy plans?

1- THE CASE OF THE PHARMACEUTICAL INDUSTRY

1.1- Conceptual framework

Import Substitution Industrialization (ISI) is a Keynesian trade and economic policy incentive promoting import substitution with local production, the objective being to drastically reduce dependency*)* on imports. ISI policies works in fact by having the state lead economic development through nationalization, vital industries subsidization, increased taxation, and highly protectionist trade policies (Toye & Toye, 2003). ISI hence encourages governments to endow and arrange for substitutes products, set up protective trade barriers, adopt dual exchange rates, the first one, for importing capital goods and the second one, for importing consumer goods, with the sole goal to deter foreign direct investment. Consequently, protectionist inward-looking trade policies, using a simple supply-and-demand rationale, are geared to encourage consumers to purchase local products rather than expensive imports. A greater local output growth rate would enable local manufacturing attain a higher rate of technological progress, that

can be generated by a higher investment scale ,allowing local producers to take advantage of larger economies of scale (Goldar,1991), and simply put, whenever customs duties are levied on imported products, imports decreases, and local production increases, which positively affect trade balance .In Algeria the ISI model has been based on a tripod involving government, local manufacturers, and foreign partners, with the objective to progressively substitute imports by domestic production.

1.2- Research delimitations

Research delimitations would include: *1)* since our research paper is restricted to Algeria's on-going pharmaceuticals industry import substitution experience, and since originality is pegged to a particular time and space, it may be therefore hard to reproduce findings in different *environments* (Creswell & Maietta,2002); 2) since in qualitative in-depth semi-structured open-ended interviews, participants responses are based on personal experiences, they may also mirror personal opinions; *3)* since the time factor is significant, the country's import substitution experience is still an ongoing process, and the lack a comprehensive up to date national database, therefore research results may be skewed as well.

1.3- Significance of the research

This research paper may significantly contribute to the analysis of import substitution issues and challenges in general, and in the pharmaceutical industry specifically; it addresses a multitude of appropriate questions potentially helpful in pointing out to relevant future ISI research.

Moreover, the significant relevance of this research resides in the fact that no known previous research has already addressed the topic of Algeria's pharmaceuticals import substitution industrialization (ISI). Furthermore, the process of understanding and identifying Algeria pharmaceuticals industry ISI policies pertinent dynamics has the merit of offering insights to various industry actors, i.e., local government, industry policy makers, manufacturers, and potential

investors. Much of this research significance goes to public policy makers, academic researchers interested in comparative studies, but also to pharmaceuticals industry multinationals planning for joint ventures opportunities. Additionally, this research learning outcome may benefit qualitative methods research designers interested in the grounded theory based case qualitative methodology (Tashakkori, Teddlie & Teddlie, 1998).

1.4- Review of the literature

Import substitution industrialization (ISI) is an industrial development policy based on structuralist economics ,and implemented by some emerging-market nation-states interested to pursue self-sufficiency and lessening of imports dependency from developed countries .This theory promotes the protection and incubation of recently formed domestic industries to reach a fully developed state, so that locally produced merchandise become as quality competitive as the imported goods .Because this developmental theory is rooted in the infant industry economics argument (Toye & Toye,2003), therefore a functional industrial policy is supposed to subsidize and simultaneously establish simultaneously, *first*, a production unit of strategic substitutes, *second*, adequate trade barriers, i.e., tariffs, *third*, an overvalued currency that suits local manufacturers importing goods, and *fourth* ,disincentives for foreign direct investment .Adopting this ambitious form of economic integration and home grown import substitution industrialization policy can, in the short run, locally substitute imports, and, in the long run, turn to liberalization.

Whenever higher level of industrialization has been achieved, it has definitely helped many emerging economies catalyze the industrialization process, through convergent effects and effective responses .In the case of Algeria, just a decade ago, it was importing almost all of its pharmaceuticals, nonetheless, due to an ever-greater state protection of local manufacturing and the way new policies have compelled multinational drug developers to localize production, the country is nowadays supplying more than 50% of the national drug consumption .Given the state of Algeria large domestic production

capacity, the logical next step will be to question whether it can become a net exporter in future .In fact, Algeria is already now considered a production platform and launch pad for exports to other African countries regards to its production capacity, quality standards, and competitive pricing. For the time being, Algeria core mandate and current socio-economic responsibilities is to promote and foster domestic manufacturing of drugs, both through indigenous Algerian outfits and locally based international partnering companies. The pharmaceutical industry is indeed known to be responsible for the development, production, and marketing of medications, however, companies that operate in the industry are duly required - besides the routine patenting, testing, ensuring safety and efficacy, and marketing of drugs - to comply with laws and regulations governing production, distribution, and consumption of products (Harrigan, 1984). As for the pharmaceuticals industry in general, it can broadly be classified into two categories, *first*, patented medicines, and *second*, generic medicines (Kheir & al, 2008). Patented medicines are products developed by drug companies' laboratories research teams, and these drug companies range from very large multinationals to small and medium-sized enterprises.

Patented products allow for a long term guaranteed market monopoly, however, whenever amortization is over, and they enter public domain, these relatively cheap generics will go into mass production and marketing using alternative business models targeting mass-scale development of medicines identical or equivalent to patented medicines but under different brand names.

Given the strong dependency on innovation, some issues such as the high risks in R&D as well as supply chain (Jaberidoodst et al 2013), cause to decrease the attractiveness of the pharmaceutical industry compared to other industries (Gassmann et al 2008).

The development of a new drug is expensive, time consuming and the underlying process is extremely risky. Based on studies, an average cost of approximately $800 million is the cost of bringing a new drug to the market (DiMasi 2002 & 2003). Moreover, it is estimated that an average of 12 years have been passed from the

synthesis of the new active pharmaceutical materials to launch a new drug to the market (Matías-Reche, 2010).

Thereby, on average, out of every 10,000 ingredients synthesized in the laboratories, only one or two will successfully pass the steps to become marketable medicines (Festel et al. 2010). Meanwhile, international competitiveness is becoming more crucial for the pharmaceutical industry Given the strong dependency on invention ,some issues such as the high risks in R&D as well as supply chain (Jaberidoost, 2013), cause to decrease the attractiveness of the pharmaceutical industry compared to other industries (Gassmann, 2008). The development of a new drug is expensive, time consuming and the underlying process is extremely risky. Based on studies, an average cost of approximately $800 million is the cost of bringing a new drug to the market (DiMasi, 2003). Meanwhile, international competitiveness is becoming more crucial for the pharmaceutical industry.

2- OVERVIEW OF ALGERIA'S PUBLIC HEALTH CARE POLICY

When reviewing Algeria's evolving epidemiological profile, comparative studies appear to demonstrate a significantly higher prevalence of non-communicable lifestyle diseases such as diabetes, than in nearby Sub-Saharan Africa. This noticeable evolution of the prevalence of diabetes – a non-genetic acquired pathology - in Algeria compared to the scenarios encountered in Sub Saharan Africa has to do, *first*, with the transformation of the country economic and health profile, and, *second*, to a confluence of factors, such as urbanization, industrialization, eating behavior pattern, obesity, sedentary lifestyle, absence of a sound preventative healthcare strategy, all of which have triggered a surge in non-communicable diseases in Algeria .These diseases now account for 76 % of all deaths in this North African nation, however, infectious disease have not gone away for good, as demonstrated by recent outbreaks of cholera in and around Algeria capital city, Algiers, in 2018.While on the one hand, there have been a number of successes such as the profound decrease in infectious disease and very visible advancements in child health, on the other hand, incidence of non-communicable diseases, such as

cardiovascular maladies and diabetes are definitely exponentially increasing .A health economics approach, can hence be leveraged as an invaluable tool for Algeria to appropriately respond to and adapt to this shifting paradigm. Algeria is therefore striving to forge consensus in building a new order of public healthcare provision, i.e.; a sustainable model of national care that neither destabilize the financial integrity of the national welfare system, nor jeopardize the health needs of citizens.

In such a case, the Algerian Social Security system - given the sheer cost of certain innovative drugs - would have to forego many inclusion on the list of reimbursable drugs because additional costs would simply exceed the system current payment capacities .The envisioned Algerian healthcare, is to be based on public-private partnerships, and would incorporate all relevant pharmaco-economic health research findings, into a national drug development and local market development strategies, to deliver a much more patient-centric offering than it currently is.

It should be noted that a large part of the escalating drug bill in Algeria - and elsewhere - also relates to international drug development administrative authorities ,requiring to follow an increasingly exorbitant registration process in terms of number of patients and length of follow-up, e.g., in the 80s a 200-300-patient study was enough, now 10000-20000 are required to get a product on the market, in addition to 3-5 years of follow-up, pre or post-marketing authorization to verify the cardiovascular safety of a new molecule. Obviously, these constraints would have heavy consequences on the overall costs - ultimately reflected in the drugs face value price - which ultimately is a matter of achieving the optimum balance between competing objectives, taking into account the national specificities that need to be factored into the equation of financing national social security. Also, the deployment of class reference rates remains an important mechanism in Algeria social security apparatus toolbox for enforcing cost containment and best price-value ratios, so as to make therapeutic access for as many of citizens as possible ,under conditions of quality and minimization of

costs for the payer. The current privileging of generics and biosimilars, and deploying class of molecules reference rates, constitute therefore important cost control levers in the hands of the Social Security System. Indeed, much has been achieved to date in Algeria, life expectancy has risen for males to 75.4 and females to 77.4 (WHO, 2018), communicable diseases have fallen considerably, and the country is now facing the characteristic diseases of developed countries, such as diabetes and hypertension.

This is not unexpected, but it does necessitate the urgent adoption of a fresh approach to public healthcare, injecting greater rationality into decision making and spending to generate a commensurate value in terms of end outcomes.

2.1- The Algerian pharmaceutical industry

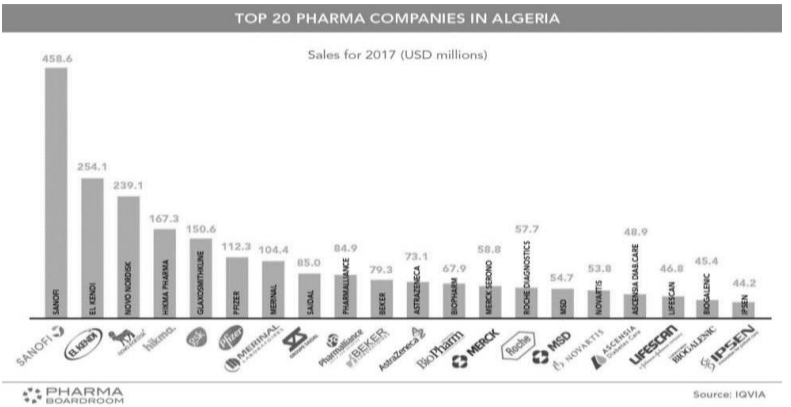
In addition to transforming the economy and its infrastructure to support knowledge-based industries, building a life sciences industry has been one of Algeria top economic priorities, hence Algeria is supporting its life sciences industry development through a variety of direct and complementary investments. Because, Algeria domestic production supplies only 15 % of the market need, 85% of it is imported, and Algeria consumes about 80 % of innovative medicines, and the remaining 20 % goes intogeneric medicine, the situation provides enough good reasons for the development of pharmaceutical investments.

Figure n° 1. Top 5 Algeria's Local Pharmaceutical Companies

Source: Algeria Ministry of Health, 2019. Local pharmaceutical companies

However, the increasing pressure exerted from the entrance of global pharmaceuticals giants into the Algerian market - coupled with Algeria agenda to regulate and push for low-cost generics is changing the future face of Algeria pharmaceutical industry – is calling both local manufacturers and public health decision-makers to collaborate ineffectively addressing current ISI issues and challenges.

Table n° 1. Top 20 Pharmaceutical Companies in Algeria



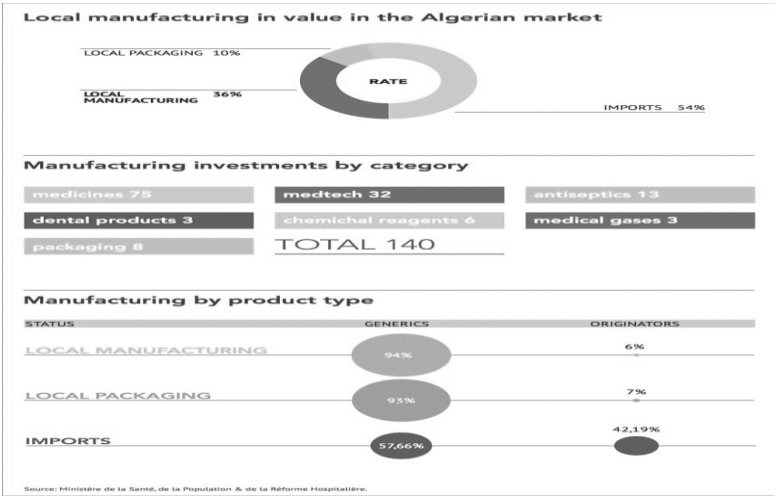
Source: IQVIA, 2018. Pharmaceutical Companies in Algeria, pp.30-42.

Among the several issues and challenges, questions to be addressed by Algeria local producers and public health decision makers could be as follow:*1)* How should players position themselves along the value chain e.g. development, production, marketing, sales, distribution, and retailing?*2)* How should companies optimize their business model in dealing with global pharmaceuticals companies inside the Algerian market? *3)* How should they leverage their in-depth knowledge of the Algerian market and in turn ensure their survival and prosperity? *4)* What is the best approac h to optimize operational efficiency (e.g. strategic sourcing strategy, inventory management, logistics)? *5)* Which activities (core vs. non-core) should be kept in-house and which should

be outsourced/offshored? *6)* What is the value proposition provided by local players? In order to address the potential challenges posed by the penetration of global pharmaceuticals players and low-cost generics, domestic players need to orchestrate a multitude of key strategic levers to sustain a competitive value proposition .Being squeezed on the top-line -mainly by locally produced branded generics of global pharmaceuticals companies, and on the bottom-line, mainly by pure generics of volume-focused and low-cost competitors -will therefore require a re-evaluation and adjustment of the entire business and value creation architecture. In fact, manufacturing might not be the core business for domestic players in the future, e.g.; outsourcing production to low cost countries, while in-country operations could solely focus on repackaging.

Also, domestic players could make use of their deep knowledge and understanding of the market as well as of the favorable regulatory situation, granting them exclusivity in most downstream segments of the value chain to tighten their grip over the marketing, sales and distribution activities of the industry.

Figure n° 2. Local Manufacturing in Algeria



Source: Algeria Ministry of Health, 2019. Local manufacturing in value in the Algerian market.

Likewise, domestic players could turn potential market challenges resulting from the penetration of global companies into opportunities by actively pursuing mutually beneficial partnerships. On the one hand, domestic players possess superior knowledge and influence in the local market, mainly through their solid understanding of the local market dynamics, long-term connections with the authorities and strong relationships with key stakeholders.

On the other hand, global companies have an edge mainly through their deep technical know-how, advanced research and development capabilities, strong brand equity as well as economies of scale. In fact, by complementing the capabilities of international players with the value proposition of domestic players through joint ventures, strategic alliances or in-licensing agreements, a win-win situation could be created, turning a potentially challenging scenario into an attractive business opportunity. Also, because pharmaceutical industry players are increasingly focusing on building their brand equity driven by the rise ofprice-focused generic players and the intensifying struggle to identify new blockbuster drugs, these established players are investing in strengthening their brand equity as one of the key levers of sustaining their firms' long term success, even though, the nature of the pharmaceutical industry poses unique complexities in terms of brand management and consumer targeting .Moreover, even if temptations are intense to invest in patent-expiring drugs ,the benefits should be carefully weighed against the risks of the penetration of low cost generics which are as follows:1) The regulated environment will increasingly fragment the market with recent drug approvals encompassing more specialized therapies targeted at smaller sub-groups of patients. The branding and marketing of niche products strains most feasibility studies and should hence be assessed on a case-by-case basis ;2) Because of diverse target groups, and beyond addressing patients, prescription products in particular involve a diverse set of stakeholders including healthcare professionals, manufacturers and insurers. These stakeholders influence and even make decisions on behalf of patients, hence a comprehensive branding strategy should therefore target the entire landscape of stakeholders

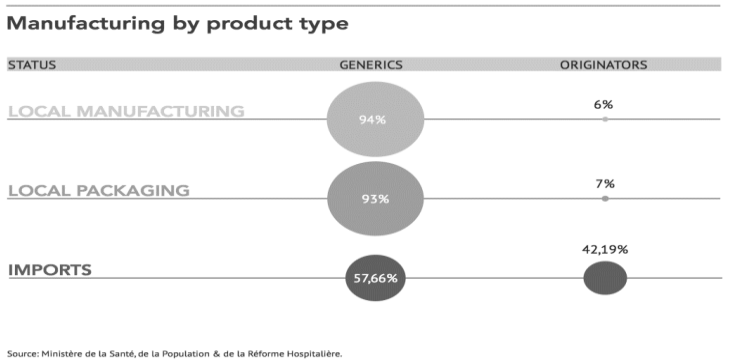
to achieve an optimal outcome. As a matter of fact, while the Algerian pharmaceutical market expands in line with the increasing healthcare needs of a growing population, and while foreign manufacturers are seeking to expand their domestic footprint, in parallel, the need to control spiraling healthcare costs will drive the trend towards more frugal pharmaceutical procurement in both the public and private sectors.

The net result of these trends will be a radical change in the Algerian pharmaceutical landscape, with domestic manufacturers struggling to compete with the brand strength of the traditional global pharmaceutical companies or the low cost-base of LCC manufacturers. In order to survive, domestic manufacturers in particular, must assess their market strategic positioning, and consider how best to capitalize on new opportunities in this rapidly changing environment.

Possible strategies include a reassessment of the value creation architecture and adopted business model as well as the building-up of a strong brand equity, and ultimately, the best-positioned players will be those who will understand their respective strengths and weaknesses and hence, possess the strategic agility to navigate the changing landscape .In fact, a core element of Algeria pharmaceutical industry are local entrepreneurs who started as sole importers and distributors of pharmaceutical products, and gradually developed their capabilities, ultimately establishing their own local manufacturing facilities.

This development - still in its infancy - has not yet alleviated drugs shortages, whereby 244 drugs are still reported to be out of stock in the Algerian market (Algerian National Union of Community Pharmacists - SNAPO, 2019). However, this challenging situation is not unique to Algeria, as drug shortages are still a growing issue affecting many other countries around the world.

Figure n° 3. Local Manufacturing by Product Type



Source: Algeria Ministry of Health, 2019. Local manufacturing by product type.

While Algeria is actively supporting the growth of local value chains, encouraging joint ventures and sponsoring non-tariff barriers in the form of price control mechanisms, global pharmaceutical players are therefore left in a position whereby top-line optimization is of fundamental importance, forcing many to turn to emerging markets for solutions, and their shifting focus is already evident, they have started to build and enlarge their footprint in emerging countries such as Algeria .In this context, Algeria still offers significant potential for global pharmaceutical companies due to habitual strong consumer preference for branded drugs, whereby, branded pharmaceutical products account for around 80% of the total pharmaceutical sales in Algeria.

In order to address the potential challenges posed by foreign players, domestic players needed to orchestrate a multitude of key strategic levers to sustain a competitive value proposition. Again, by synergizing the capabilities of global companies with local companies' value proposition via joint ventures, strategic alliances or in-licensing agreements, a mutually profitable situation could be created. At any rate, a major deterrent that global pharmaceutical exporters to Algeria will increasingly have to face, are the regulatory obstacles imposed by Algeria authorities attempting to protect local manufacturing.

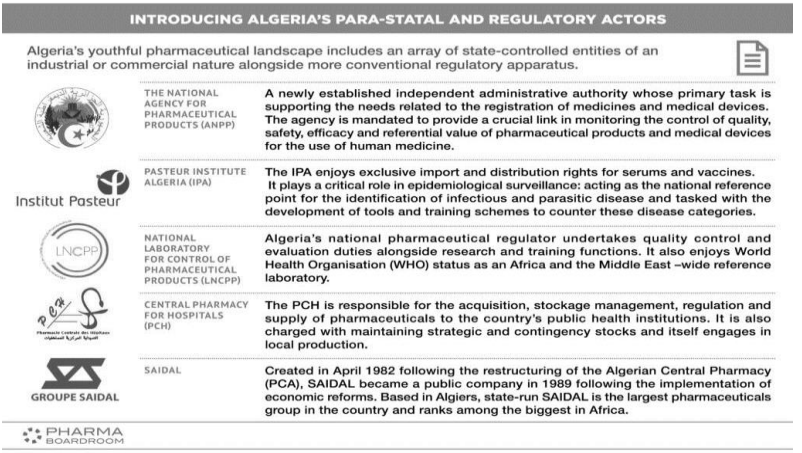
These may include - and not limited to - protracted registration procedures for foreign drugs, requirements for recertification and stringent price control mechanisms on certain drugs. As a result, global pharmaceutical companies have to date only established limited direct presence in Algeria in the form of joint ventures with local firms.

2.2- The rise of low cost generics

In an effort to curb the exploding cost of healthcare provision, governments in both developed and emerging markets are seeking to contain spending on pharmaceuticals. This increasing need to curtail spending on pharmaceutical products as Algeria transitions towards a market-driven model, will contribute to the growth of generics in both the public and private sectors.

Algeria curtailing of pharmaceutical expenditure has been achieved through the adoption of several measures including the introduction of regulations aimed at promoting and favoring local production, the establishment of regulatory agencies, which has also allowed the government to channel healthcare funds towards front-line operations, e.g.; addressing bed capacity shortages.

Table n° 2. Algeria Parastatal and Regulatory Actors



Source: Algeria Ministry of Health, 2019. Algeria parastatal and regulatory actors

In fact, the penetration of the national health insurance card "Chifa" has also played in favor of generics, as patients were channeled towards private hospitals and healthcare facilities, and once national insurance secured a stronger foothold in the market, their increased leverage over healthcare providers allowed them to drive private healthcare prescriptions towards cheaper forms of generics.

2.3- Algerian market attractiveness

Despite the complexities of the local market, multinational pharmaceutical companies are increasingly choosing Algeria as a base for their regional headquarters, and in order to survive foreign competition, domestic players, and manufacturers in particular, must assess their strategic positioning in the market and consider how best to capitalize on new opportunities in a changing environment. Possible strategies include a reassessment of the value creation architecture and adopted business model as well as the building-up of a strong brand equity, but ultimately, the best-positioned players will be those who understand their respective strengths and weaknesses and possess the strategic agility to navigate the changing landscape .Even though ,Algeria is geographically the largest country in Africa, it has not traditionally been considered the obvious location for situating a regional office, but in spite of a multitude of administrative and logistical hurdles remain, the logic for doing so is becoming ever-more apparent .Indeed, as soon as we start to factor in the rapid population growth and the epidemiological shift, then the envelope of opportunity to get involved with this market is immense, *first*, the market is growing at a rapid pace, which is certainly not the case in either Maghreb countries, Morocco or Tunisia or even much of Europe for that matter, *second*, Algeria is also very much an outlier within its Maghreb region when it comes to the willingness to engage in public-private partnerships , e.g.; the fact is that there is no public-private partnerships on issues such as patient and practitioner education in the other North West Africa cluster states is a testament to Algeria vision.

But, envisioning to make Algeria the sub-regional hub has its advantages and disadvantages, *first*, many MNCs have regarded the comparatively open and liberalized economies of Tunisia and Morocco as more welcoming to foreign investment and more aligned with international norms and therefore have preferred to place their headquarters there; *second*, the sheer size of the Algerian market, the volume of entrepreneurial opportunities and maturity of the public health system all render it strategically and commercially interesting and present a compelling business case. From a business strategy standpoint, it would be obvious to build the greatest presence in the largest market, as Algeria today represents some 45 % of French African market sales alone with a turnover surpassing USD 35 million and is the uncontested mega-market in the region, not only in terms of size, but also in terms of strategic relevance as the interface between north and south .Then there is also the argument that Algeria requires a more embedded presence precisely because of the country's intricacies and complexities, and technically difficult marketplace, e.g.; Algerian market access issues take up approximately 75 % of the entire regulatory affairs workload, therefore it is logical to want to base the area's regulatory affairs resources in Algeria rather than in Tunisia or Morocco.

Figure. n° 4. Arab Pharmaceutical Companies Presence in Algeria

Source: Algeria Ministry of Health, 2019. Arab pharmaceutical companies presence in Algeria

2.4- Multinationals localization strategy

A sudden imposition of import restrictions on pharmaceuticals in 2017 has pushed several multinational companies to establish local production facilities in Algeria. However, the localization process can be fraught both for companies that establish direct manufacturing footprints via joint ventures and those that employ the services of local contract manufacturers. Algeria's overtly protectionist pharmaceutical manufacturing policy has long proven troublesome for international drug developers. Matters reached a crescendo in 2017 when Algeria, unexpectedly imposed sweeping import restrictions on any incoming pharmaceuticals and medical devices for which there was some sort of domestically manufactured substitute, ostensibly with a view to preventing currency flight at a time when national economy was deteriorating. This policy prompted many MNC's, keen to protect their market positioning, to begin to engage in some form of local production, however, embarking on a localization strategy is no small matter, especially for innovative drug companies with international reputations to maintain, and while in-country manufacturing in Algeria is extremely developed for basic drugs, it is markedly less so for high potency products, e.g., oncology drugs. To overcome this, MNC's had to invest heavily in technology transfer, and there were essentially two alternatives, *first*, signing a commercial agreement, where an opportunity is given to update their facilities and integrate fresh know-how and technology in the short to mid-term, *second*, investing directly in establishing plant in conjunction with an indigenous joint venture partner .Some companies, not possessing enough Algerian market demand to justify setting up proprietary manufacturing facility, had to optfor the contract-manufacturing pathway, however, the limitation with Third Party Manufacturing is that companies can only be in control of the entirety of the other parts of the value chain when factory is registered under company name .Identifying a suitable partner can be difficult, e.g., Biopharm, however, there are a multitude of smaller players with questionable quality standards that would be way too risky to enter into partnership with. There are only 10 to 15 sites that possess the requisite high-quality standards, and they therefore tend to

be keenly sought after by the MNC's seeking to localize, and this minority indigenous contract manufacturers that have managed to attain international quality standards can select partners from arecord number of MNC's business proposals .Also, opting to establish a proprietary plant, however, carries challenges for MNCs, as there are a lot of parameters and variables to consider in such a project beyond securing the requisite financing and the physical construction of the facility. One key consideration will be how to source the human capital needed to staff the site plus identifying an appropriate indigenous joint venture partner under the obligatory 49/51 percent ownership rules. As a matter of fact, indigenous joint venture partners are more interested in technology and know-how transfer than in pure financial investment which they can easily source locally. In the pharmaceuticals sector, indigenous joint venture partners main objective, is often to scale the manufacturing value chain and therefore to acquire the capabilities and the competencies to produce ever more complex molecules. It is quite a common trend nowadays within the Algerian market for international drug developers to begin by teaming up with a local producer, before seeking to build up the infrastructure for independent local production. A rather distinctive approach, is to deploy parallel strategies, maintaining longstanding local partnerships, while, at the same time, acquiring own facility. In Algeria, collaborating to transfer knowledge and technologies, is a significant time and money investment, this partnership need to unfold as a more concrete collaboration for local manufacturing for the Algerian market as well as to export to neighboring countries - the 400 million people Greater Maghreb market - and becoming a hub for Africa.

Even though, there is a perception of Algeria from outside that there is an implicit obligation to produce coupled with a market access environment that seems to be very challenging for innovation, multinationals are however expected before all to develop infrastructure, improve education, and developing clinical trial sites in Algeria .Even though, the amount companies invest in manufacturing is miniscule compared to the investment that goes into R&D, investing in manufacturing might means ending up with production facilities that do not manufacture cutting edge drugs, all

locked in tight competition with one another and with other countries .An additional incentive for manufacturing locally – at least a list of essential medicines - is that the prices of products manufactured domestically receive a 27 % markup. The only way to earn return on investments today is to invest in research, and Algeria cannot do this on its own, it can only do it with real partnerships and with real researchers. Indeed, the more research developed, the more value added, however before setting up a cluster, Algeria need to have a talent pool to recruit from, which requires developing a strong academic environment.

3- RESEARCH DESIGN, METHODOLOGY AND DATA COLLECTION

The case study research we used in this investigation is a grounded theory qualitative research method design, a form of exploration of a time bounded system, with a detailed in-depth interviews information collection from a variety of participants .The procedure used was fundamentally based on in-depth semi-structured telephone and face to face interviews of local producers, accompanied by a triangulation of different data sources (Creswell & Maietta, 2002).The interview protocol included a three round of fifteen pilot tested open-ended questions. The protocol was pilot tested by selecting four producers from the target population, who were then omitted from the research. The exploratory debriefing with these four initial participants was aimed at securing feedback on the appropriateness of the interview questions and their significance to our research objectives.

The participants were sent the interview questions ahead of the arranged calling time or meeting, and were informed the interview will be tape-recorded and transcribed verbatim. Respondents had the chance to review and, eventually, corrected the interview contents after having been transcribed.

3.1- Grounded theory methodology (gtm)

Grounded theory is an inductive, comparative methodology for gathering, synthesizing, analyzing, and conceptualizing qualitative

data for theory construction purposes. Glaser and Strauss - founders of grounded theory - offered a codified statement of how to analyze qualitative data. While Glaser – objectivist - brought survey research, Strauss - constructivist - brought field research to grounded theory (*Charmaz, 2008)*. The techniques involved in the three major grounded theory strategies are coding, memo making, and theoretical sampling. We began with a broad query in our particular research area and then collected relevant information about our topic. As the process of data collection continued, each piece of information was reviewed, compared, and contrasted with other information. From this constant comparison process, commonalities and dissimilarities among categories of information became clear, and ultimately a theory explaining observations was inductively developed. Grounded theory is used to modify existing theory, develop or reveal differences from what is already known, as it is structured to address current theory from a new inductive perspective.

3.1.1. Questioning

Because grounded theory studies are generally focused on processes, grounded theory studies begin with open questions. Accordingly, we sought to learn from participants how the ISI process worked and how they made sense of it; hence we wanted to answer practical problems, i.e., which major business environment reforms were perceived by local drug manufacturers as necessary and sufficient prerequisites for satisfactory pharmaceuticals supply benchmark?

3.1.2. Coding

Coding being the first phase of analysis, and rather than applying extant concepts to data, wehave created codes as we studied the data and, concisely, defined what we see. Coding helped us begin to conceptualize what basic ISI processes occur in our research setting. Whenever we are coding we do not merely carefully read and label materials, as coding continues, we start identifying categories that are interesting or relevant to our research question. When we produce such a collection, we focus on the differences in the use of this

category according to the setting and actors involved, which is referred to as the method of constant comparison. In the course of such comparisons the category system are reworked, and some categories are merged together and others broken up, as the close reading of the data allows us an increasingly refined understanding.

3.1.3. Theoretical Sampling

Grounded theory studies are characterized by theoretical sampling, which requires data to be collected and analyzed, and thus sampling began purposively as in any qualitative study. We interviewed all consenting industry professionals who had been involved in the ISI process in Algeria, and we then recruited 14 public and private pharmaceutical professionals, and this purposive sample was designed to provide maximum variation.

Evolution of theoretical sampling and interview questions

Important core focused codes were identified, including practical ISI dimensions of the process. We also changed our interview questions based on the analysis we were doing. We confirmed and enriched our understanding of ISI processes and further clarified our concepts. This is an example of the openness of grounded theory studies subtly shifting focus aiming to confirm or disconfirm the broader reach of emerging theory and complete inductive development of key concepts.

Theoretical sampling had7 face to face interviews and 7 telephone interviews, and a total of 14 participants were recruited. Telephone interviews were of comparable length, content and quality to face to face interviews, as reported in the relevant methodological literature.

Concept Mapping and Theoretical Memoing

At time of writing, we have reached theoretical saturation, as we have become increasingly certain about our central focused codes, and we have re-examined the data to find all available insights regarding those codes. We have drawn diagrams and written memos, and looked rigorously for events or accounts not explained by the emerging theory so as to develop it further to explain all the data. Our

theory, is expressed as a set of concepts cohesively related to one another, accounting adequately for all the data we have collected. We have presented the developing theory to professional audiences and to the participants, the model included relationships among concepts, consequences of process, variations in the process, and found it was accepted by and resonated with these audiences.

3.2- Interviews

One hour in-depth interviews were conducted, we travelled to the various cities where interviews took place, and participants were interviewed in places convenient to them, i.e.; workplace, home, public space. Interviews were semi-structured and based loosely on our research questions. Interviews were digitally recorded and professionally transcribed, we wrote memos, and then took a month for data analysis in which coding and memo-writing occurred.

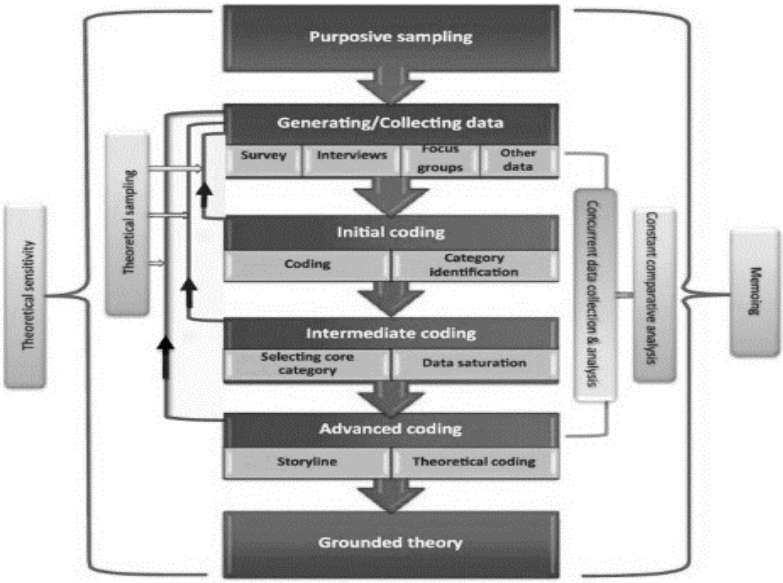
3.3- **Data Analysis**

3.3.1 Coding & Constant Comparative Methodology

While coding is the core process in classic grounded theory methodology, there are two types of coding in a classic grounded theory study, *substantive coding*, which includes both open and selective coding procedures, and *theoretical* coding. While in substantive coding, we work directly with raw data, fracturing and analyzing it ,axial coding being the breaking down of core themes during qualitative data analysis ,theoretical coding emerge through the data analysis process. *Theoretical saturation* is achieved through *constant comparison* of incidents, i.e.; indicators in the data to elicit the properties and dimensions of each category, i.e.; code. This constant comparing of incidents continues until the process yields the *interchangeability of indicators*, and no new properties or dimensions are emerging from continued coding and comparison. The coding of data in grounded theory occurs in conjunction with analysis through a process of *conceptual memoing*, capturing our ideation of the emerging theory. Coding is essential to the development of a grounded theory, coding being the pivotal link between collecting data and developing an emergent theory to explain these data (Charmaz, 2008). Through

coding, we define what is happening in the data and begin to grapple with what it means. Coding occurs in stages, *first*, in initial coding, we generate as many ideas as possible inductively from early data; *second* ,in focused coding, we pursues a selected set of central codes from inside all the generated research data. Because initial coding identifies many different processes, after the first few interviews, we had a large amount of data and many initial co. In the case of qualitative analysis, data collection and analysis always proceed simultaneously *(Merriam, 1998).* Qualitative data obtained through the interviews, documents and materials are duly coded, analyzed for themes using qualitative data analysis software, in vivo.

Figure n° 5. GT Research Design Framework



Source: Gale, N.K., Heath, G., Cameron, E., Rashid, S. and Redwood, S., 2013. Using the framework method for the analysis of q ualitative data in multi-disciplinary health research. BMC medical research methodology, 13(1), p.117.

Qualitative analysis entails the following steps *first*, a preliminary data exploration reading through transcripts and memos; *second*, data coding, segmenting, and labeling text; *third*, codes are used to develop

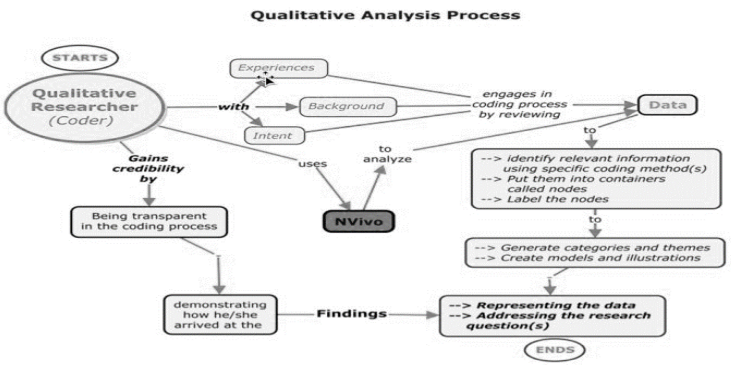
themes aggregating similar codes together; *fourth*, connecting and interrelating themes; and *fifth*, constructing a narrative (Creswell & Maietta, 2002).

NVivo visual data display indicates the evolving factorial conceptual framework and data relationships *(Miles&Huberman,1994).* All along the analysis, the case keep being contextualized, hence its description and themes remain relevant to the case activities and situations (Creswell & Maitta, 2002; Merriam,1998).

Based on all these analysis, we can provide a detailed case narration, a trustworthy insightful description, and a credible case interpretation mentioning all coherent and useful lessons learned.

To this end, our qualitative investigation has consequently used in fact, *first*, triangulation, i.e.; congregating various information sources, i.e.; interviews, documents; *second*, member inspection ,i.e., getting feedback from participants on categories and themes accuracy; *third*, richly described findings; and *fourth,* external audit ,i.e., third party conducting research review and feedback (Creswell & Maitta, 2002).

Figure n° 6. Qualitative Analysis Process



Source: Gale, N.K., Heath, G., Cameron, E., Rashid, S. and Redwood, S., 2013. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC medical research methodology

3.3.2. Memoing

Throughout the research, we wrote extensive case-based memos and conceptual memos. After each interview, we wrote a case-based memo reflecting on what we learned from that interview. They contained our impressions about the participants' experiences, and our reactions; they were also used to systematically question some of our pre-existing ideas in relation to what had been said in the interview. After a few interviews, we began making and recording comparisons among these memos. We also wrote conceptual memos about the initial codes and focused codes being developed (Charmaz, 2008).

In these memos, we made comparisons between data, cases and codes in order to find similarities and differences, and raised questions to be answered in continuing interviews.

4- RÉSULTS

4.1- Overview of the Research

The main aim of the research paper was to investigate import substitution issues and challenges in the Algerian pharmaceutical industry. The basic research question was formulated as follows, how pharmaceuticals import substitution policies effectively decreased imports and increased local production.

4.1.1. During Data Collection

The aim of this stage was: *1)* to record digitally all interviews, professionally transcribing in detail and checking transcripts against the recordings; *2)* to analyze the interview transcripts after each round of interviews, allowing for theoretical sampling process to occur;*3)* to write case-based memos after each interview in the field, allowing us to capture initial ideas, making comparisons between participants' accounts, comparing reflections, enriching data analysis, and guiding further data collection; *4)*to include phone interviews given research participants' preference; phone interviews had similar length and depth compared to physical interviews.

4.1.2. During Data Analysis

The aim of this stage was: *1)* to keep detailed analysis records, making possible the writing of this paper; *2)* to use constant comparative method, enabling the analysis to produce not a description, but a model, in which related abstract concepts and process were explained; *3)* to contextualize emerging interpretations, introducing a wide range of disciplinary perspectives, and developing a detailed model of ISI process, and analyzing cases of process variation.

4.2- Major Findings of the Research

In terms of evaluating future successes of Algeria's import substitution, we think that the lack of local experience in pharmaceuticals manufacturing, the lack of overt competition and politico-economic power concentrated in the hands of a few corrupted government bureaucracy officials, the weak entrepreneurial development incentives, the closed system reduced innovation and efficiency, the lack of regulatory processes, all constituting local hazards restraining local consumers and medical community trust in the quality of locally produced pharmaceuticals, and incentives for illegal imports from neighboring countries, of whom Tunisia and France mainly.

5- RESEARCH LIMITATIONS

Research limitations include: *1)* Since qualitative research use purposive sampling, we cannot state that our sample will be representative of the local manufacturers population; *2)* Since the qualitative research nature of the data acquired, we may be subject to our personal interpretations; *3)* Since the interpretative nature of the qualitative research, we may bring our own analysis biases in the findings. This research sampled only a small part of Algeria pharmaceutical manufacturers. Indeed, it sampled only a small part of the country producers, however that part of manufacturers was one that was well-known in the industry. The sample of producers

remained therefore relatively small, so that generalization of the results cannot be easily justified.

CONCLUSIONS AND RECOMMANDATIONS

Assuming that interview based qualitative data results can be used as a basis for noteworthy conclusions, we conclude that our main findings have to do with import substitution issues and challenges in general, and possible with Algeria pharmaceutical industry in particular.

In spite of all the limitations, this research conclusions do suggest consensual and practical measures that industry policy makers could implement to support domestic enterprises-producers of finished drugs and substances, speed the ISI process and improve pharmaceutical production localization: *1)* joint venture agreements should clearly state a foreign technology transfer clause, the relevant key performance indicators, and comply with international good manufacturing practice standards; *2)* specific product groups to be produced by domestic manufacturers should result from prior sector gap analysis; *3)* government based incentive system for local import-substituting manufacturers should be thoroughly reviewed ; *4)* national social security reimbursement policy should involve private third party insurers and should be accordingly revised ; *5)* current universal public healthcare system categories coverage should be revised. These are the kind of stakeholders agreed upon strategies that need to be reflected in national health policies, and they are certainly worth putting on the agenda of meetings where policymakers come together to make suggestions and implement decisions. There are also suggested good practices in terms of management and communication regarding disruptions and tensions in medicine supply, which should be recommended to stakeholders across the Algerian medicine supply chain. These measures could be described as follows:*1)* developing sufficient availability of drugs is the responsibility of the local pharmaceutical producers subjecting it to agreed upon profitability ratios.

A global solution to this major problem at national level, is the maintenance in the local market of cheap molecules sometimes not economically profitable, but essential for patient treatment; *2)* developing an anti-shortage roadmap with targeted actions should be tailored to each of the players along the value chain; *3)* advocating pharmacist intervention to replace the unavailable initially doctor prescribed drug by another; *4)* developing a national guide outlining the essential elements for a harmonized approach to detection, notification and management of disruptions, as well as underlining that early notification to competent authorities is a key aspect in the prevention and solving of supply shortages. Developing a guide underlines the responsibilities in the notification of current or future shortages due to regulatory problems, quality defects and other causes. this include issues related to compliance with good manufacturing and distribution practices, non-compliant batches and recalls of drugs on the market; *5)*developing a continuous national monitoring system of the supply and demand situation on all products, and shortages planning systems for public health sensitive ones, and maintaining open and uninterrupted communication with all stakeholders in the distribution chain, such as producers and wholesaler-dispatchers. The availability of timely relevant information, is necessary to plan and rationalize the remaining stocks, as well as to prevent the creation of overstocks. For drugs that have a significant impact on patients, specific shortage press releases are also required. In addition, the listing must include the start date of disruption, the estimate of the end date, the reasons for it, and the actions taken to deal with it. Therapeutic alternatives, where they exist, should also be communicated to health professionals and patients, as well any conditional reimbursement and restrictive indications;*7)*obliging domestic producers to ensure the availability of essential medicines within three months of their production, otherwise import programs will be initiated, and coercive measures for defective producers and importers who do not honor their commitments will be enacted;*8)*revising the very low prices of some locally produced medicines in order to dissuade local producers from abandoning them because of their negative margins.

Further research obviously need to be much more broadly based; the better to aid generalization. Refining the research questions used in this research and replicating of the research, involving a larger sample of respondents, seems necessary.

CONCLUDING REMARKS

At the methodological level, this paper provided a detailed explanation of how a research evolves using grounded theory methodology, one of the most commonly used methodologies in qualitative social sciences. It has been stated that the "use of grounded theory, at least as much as any other research method, only develops with experience. Hence the failure of all those attempts to provide clear, mechanistic rules for grounded theory. It is based around heuristics and guidelines rather than rules and prescriptions *(Charmaz, 2008).* Our detailed explanation of our experience in this grounded theory study is intended to provide, the kind of experience that might help other qualitative social science researchers to apply and benefit from grounded theory methodology in their research. We hope that our explanation will assist others to avoid using grounded theory as an approving body and instead use it as a resource that can greatly improve the quality and outcome of a qualitative study. We may conclude that the country is in fact in need of a bigger and radical rethink, *first*, of the becoming of the Algerian universal health care system as a whole, *second*, of the social security system in particular, and *third*, of the pharmaceuticals as a backbone industry. From this research the most significant finding is that the smooth operation of the drug distribution chain in Algeria was compromised by the multiplicity of actors, from individual firms to the various ministerial departments and agencies involved in pricing, quantities, stocks and labeling. In a nutshell, Algeria - under its currently difficult economic conditions - ought to involve the transition to a system-strategic approach to import substitution, a reevaluation of macroeconomic policy and the rejection of certain liberal principles, our benchmark countries are currently technological leaders in global value chains and this can similarly help Algeria develop its

pharmaceutical industrial base. Also, while the Middle East and North African region's pharmaceutical market is projected to reach a value of around USD 60 billion by 2025, the most impressive growth and significant contribution will be coming from this North African giant which is Algeria .Indeed, the healthcare sector in Algeria - Africa's largest nation by landmass - has seen plenty of upheaval in recent years including the economic fallout from the global oil price slump of 2014 and the imposition of import restrictions on pharmaceuticals and medical devices, nevertheless, the USD 3.8 billion Algerian pharmaceutical market remains a high priority for multinationals investing in the Arab region, with many companies choosing to base regional functions in the country. From a business point of view, Algeria has a great deal to offer, not only is this the second largest market on the African continent, but it is also a real heavyweight when compared to other Middle Eastern markets, an one of the characteristics that immediately stands out in Algeria is the sheer importance that the authorities place on securing access to healthcare for its sizeable population, and factors accounting for this, are the greatest prioritization of healthcare services and the highest life expectancy in the Arab region.

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