Moving towards a North African pharmaceutical market

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WARNING

The opinions expressed in the present document are those of its authors and not of the departments they are attached to. This report does not reflect the position of IPEMED. The objective of IPEMED is to set off an open debate as part of a smart complementarity between the different stakeholders. All potential mistakes are only attributable to the authors.

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THE IPEMED "HEALTH IN THE MEDITERRANEAN" APPROACH

In 2011, IPEMED put health at the centre of its reflection on the Mediterranean economic integration, in order to lay the groundwork of an open debate on health in North African countries (Algeria, Morocco and Tunisia). The choice was made to make a first assessment of health systems with the collaboration of recognized public health specialists of these countries. A work team was constituted, country-monographs were created and a diagnosis was established and shared.

This first report allowed to underline the common possibilities and challenges these countries are confronted with. It offers lines of evolution in terms of public health policies that could be the object of North-South cooperation, but also with the countries of the northern shore of the Mediterranean. It is about offering solutions allowing each country that would want to start reforms to find elements of reflection and methodological axis to support their efforts.

It was the object of a meeting, in the presence of the representatives of the Algerian, Moroccan, Tunisian, Spanish, French and Italian Ministries of Health, as well as the General secretariat of the Union for the Mediterranean (UFM). The objective of this meeting was to favour a work dynamic on tangible South-South cooperation and with the North as well. It was also a political approach aiming at making the different ministries aware of the relevance of the implementation of a "5+5 Dialogue" dedicated to health.

At the end of this meeting, it was decided to constitute a technical and informal work group by associating the voluntary "5+5 dialogue" countries, the UFM as well as other players (European Union, World Health Organisation, partners of the regional development, national and international private sector, etc.). Common interest themes were identified, among which that of pharmaceutical policies, medical information, vaccination policy, executive and manager training.

The first meeting of this technical and informal work group will take place in 2014.

In order to accompany this work dynamic and relying on the conclusions of the first report, IPEMED launched, in 2013, a study on the North African pharmaceutical market. Even though it is not exhaustive, this report explores the situation of North African pharmaceutical markets. It aims at identifying the obstacles and assets of a greater North African integration and at offering encouraging orientation for action (North African marketing authorization, development of the industry, etc.). Not all of the stakeholders have been consulted in the framework of this report.

The report, which approaches the pharmaceutical question under a restricted angle and which falls within a long-term reflection aiming at a better access to cheaper quality care, is a first step. Later, it must allow to launch an open debate at a larger scale on North-South and South-South cooperation and on the possibilities of coproduction in the region. This cooperation must come from a collective reflection and be shared by all the stakeholders. Therefore, the report is to be presented and debated with all the stakeholders (concerned ministries, national and international representatives of the pharmaceutical industry, local players, regulation agencies, etc.).

Macarena NUÑO, IPEMED project manager

TABLE OF CONTENTS

ACRONYMS

MA	Marketing authorisation
CNAS	National Social Insurance Fund
DMEAICO	Drugs Medical Equipment and Appliances Importing CO
EMA	European Medicines Agency
ENAPHARMA	Algerian National Society for Pharmaceutical Products
ENCOPHARM	Constantine National Society for Pharmaceutical Products
ENOPHARM	Oran National Society for Pharmaceutical Products
EDQM	European Directorate for the Quality of Medicines & HealthCare
FDA	Food and Drug Administration
LNCPP	National Laboratory for the Control of Pharmaceutical Products
MENA	Middle East and North of Africa
MSO	Medical Supply Organization
ONS	National Office of Statistics
PCH	Hospitals Central Pharmacy
PCM	Central Pharmacy of Morocco
PCT	Central Pharmacy of Tunisia
SIPHAT	Society of Pharmaceutical Industries of Tunisia
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UNOP	National Union of Pharmacy Operators
WHO	World Health Organisation
WTC	World Trade Organisation

FOREWORD

Towards what medicines policy for North Africa?

By Pr Farid Chaoui
IPEMED co-project officer on Health

Medicines are not industrial and commercial products like others, they are the "elixir", the balm that tears you away from disease and suffering. Thus, it bears not only a scientific, industrial and commercial problematic, but also an important social dimension that weighs as much, or maybe even more, on southern countries' pharmaceutical policies.

Current situation

By 2020, North Africa will have about 100 million inhabitants, among which more than 12% will be more than 60 years old and 25 to 30% will be aged 0 to 14 years old. This characteristic of an incomplete demographic transition will impose on this region the double burden of specific infan-to-juvenile health problems and those more complex, heavy and expensive of non-communicable diseases prevalent in the senior population.

This sanitary situation is emphasized by the epidemiological transition. Beside the morbidity linked to not completely eradicated communicable diseases, the amount of non-communicable diseases keeps increasing, in particular cancers, cardiovascular diseases and diabetes.

In the last few years, these two transitions have met a third one, putting health problems in the list of political priorities: the democratic transition.

Compared with these sanitary challenges, the means, and especially the financial ones, are not adapted, since the National Health Expenditure (NHE) in the three central North African countries is estimated today at less than US$400/inhabitant/year (against 6 to 10 times more in OECD countries). The share of medicines is estimated at less than US$80/inhabitant/year which is both little and a lot: it is very little compared to the OECD figures (more than US$500 in average) but it is a lot when we measure the share of medicines in the NHE that varies according to the countries from 20 to 50% [1] (12% in the United Kingdom, 16% in France and 7% in New Zealand). Given these figures, the medicines consumption of North African populations can be put into perspective. It could increase, but to do so, a better health cover must be implemented. Purchasing power must be improved because populations consider that medicines are not accessible enough.

1 See country monographs: in Algeria, according to the Ministry of Health, the share of medicines in the NHE went from 20% in 1995 to 34% in 2006. For Tunisia, it went from 30% in 2001 to 44% in 2010 (Ministry of Health).

Besides, and this is more serious, we know how much we spend for medicines, but the qualitative information regarding them is limited.

Key issues to promote a national and North African pharmaceutical dynamic

The medicines policy is only a segment of the health national policy. Without this essential policy that allows to set sanitary priorities and, therefore, strategic choices for the development of the national pharmaceutical industry, the pharmaceutical policy is likely to be taken hostage by particular interests. The challenge is to implement a relevant and realistic policy according to the population's needs, and taking into account the available resources. It is also about developing national policies by exploiting the existing complementarities between North African countries and by taking advantage of the existing South-South cooperation as well as with partner-countries of the northern shore of the Mediterranean.

In order to do so, the main stakes must be debated. They represent many action axis than can be supported.

■ What pharmaceutical strategy should be implemented?

This question refers to that of the choice of health national policy, health-care cover, etc. but also to the choice of medicines available on the territory (according to the WHO less than 200 international non-proprietary names (INN) are necessary to cure more than 90% of human pathologies) and those produced locally. Therefore, we should support the definition of a list of essential medicines that would constitute the basis of the development of the North African pharmaceutical industry as well as the realization of a treatment guide, dedicated in priority to general practitioners, serving as a basis for their prescriptions according to medical progress and to the rational use of medicines. Let's not forget the importance of developing sanitary information campaigns for the population regarding the good use of medicines to fight against self-medication and waste.

■ What national or North African industries to develop to ensure the local production of medicines?

The three North African countries develop strategies aiming at promoting the production of generic medicines. Realistic North-South co-production logics could be implemented, allowing a balance between local production and importation, given the current industrial weaknesses of southern countries. In the long term, know-how transfers could allow, for some medicines, to overcome the current situation and tend to local fabrication.

The implementation of industries raises the question of industrial and technological capacities of North African countries and of the strategy to develop in order to obtain the skills that are not available locally. This reflection leads to the necessity of developing a modern industrial basis capable of absorbing this know-how and ensure a reliable and quality production of active substances.

Unfortunately, necessary medicines cannot all be made generic. Some innovative molecules are irreplaceable in the treatment of some heavy

pathologies such as AIDS or hepatitis, or non-communicable diseases like cancers, metabolic and cardiovascular diseases. These molecules are quite costly and are protected by patents. Some countries like South Africa, India, Brazil and Thailand decided to copy any molecule considered necessary to their sanitary needs by using the rule of "compulsory licensing[2]". Given the increasing cost of non-communicable diseases in the NHE, could this path be considered for North African countries? Is it realistic and feasible regarding the skills and means they have at their disposal?

■ What about the training of specialized health-care workers? What role for innovation and research?

In order for this ambitious policy to succeed and to improve healthcare quality, we must ask the question of the actions that could be carried out regarding prescribers in order to improve the level of their academic and post-university training. What should be the implication of public authorities? What regulations with the private sector? The training policy to implement does not only concern health-care workers. Reinforcing and developing the training of specialised legal experts in North Africa is also necessary for all these transformations imply a high level of legal expertise.

The development of a research and innovation policy in the pharmaceutical field is also essential so that North African countries get the technological skills necessary to the implementation of an efficient pharmaceutical industry. This research and innovation policy must be organized around clear priorities. A particular attention must be paid to the diffusion and promotion of research results towards the production system.

■ Relevance of a Mediterranean cooperation

The implementation of this ambitious policy implies a process in the short and medium terms implying heavy structural reforms, a high financial and human investment, etc. In order to succeed, it is desirable to promote a regional cooperation, among North African countries first, to work on a larger market, estimated at more than 100 million consumers by 2020. However, it would be a mistake not to exchange experiences and implement tangible cooperation with partner-countries of the northern shore.

For southern countries, this is a great challenge: being able to develop a clear strategy in terms of pharmaceutical policy aiming at "healing better at a lesser cost". In the current context, they will not be able to make it without a better integration in this key sector.

2 WTO agreement on TRIPS (Trade-Related Aspects of Intellectual Property Rights) and Doha Ministerial Declaration of November 2011.

ABSTRACT

In April 2012, IPEMED published a report on the situation of healthcare systems in three North African countries (Morocco, Algeria and Tunisia). This report showed that the issue of medicines, which remains essential in the political reflection on the organization of healthcare system, is identical in these three countries. This report recommended to *"implement an increased regulation of the pharmaceutical market encouraging more convergence and integration at the North African level"*, and encouraged collaboration between the three countries as well as with the northern shore of the Mediterranean.

IPEMED therefore ordered the realization of an assessment of the pharmaceutical market in these three countries. This work focuses on the study of regional pharmaceutical markets through the monographs of each country, the emphasis on existing complementarities between these markets and the identification of structuring elements allowing a better integration.

In North Africa, the pharmaceutical sector is evolving. Even though organization and development vary from one country to another, the three countries managed, in just a few years, to develop a pharmaceutical industry that allows them today to cover a large part of the local consumption. However, it is in Morocco that one can see the most significant results in terms of national cover and exportation. Today, the pharmaceutical industry, independent from the state, allows to ensure the cover of 65% of the national market needs (against 49% in Tunisia and 30% in Algeria) and exports towards African, Middle-Eastern and European countries.

Moroccan and Tunisian pharmaceutical industries respect international standards. They are now registered in the European zone for their quality standards. As for Algeria, it mainly applies the ISO standards but not international pharmaceutical norms.

Besides, the three North African countries gave the pharmaceutical market a specific legislation as well as important regulatory basis. They all have procedures in terms of registration, distribution and control of these highly sensitive products. They also have a system of centralized medicine purchase ensured by different institutions (Ministry of Health, Central Pharmacy, etc.).

What is more, North African countries encourage the local production of generic medicines in order to reduce healthcare costs and give people easier access to medicines. However, in spite of the different measures carried out to favour their fabrication (setting of prices, exemption from VAT, reduction of custom duties), the development of generic medicines remains limited for several reasons (absence of right of substitution, prescription and patients trust issues, multiplicity of fabrication units, dependence for raw material supply, etc.).

Another issue that can be pointed out concerns the absence of research and technological innovation activities, especially in Algeria. Morocco and Tunisia have implemented legal and financial measures to promote research and development.

In order to develop a better integration of the pharmaceutical market and of the production industry at the North African scale, one can take a look to some examples of integration regarding:

- common purchase of medicines and vaccines: an experience that dates back to the 1980's and that is the result of cooperation efforts between the member states of the Arab Maghreb Union (Algeria, Libya, Mauritania, Morocco and Tunisia);
- standardization of registration and marketing authorization (MA) procedures and their mutual recognition by North African countries, following the model adopted by the countries of the European Union (EU) and that of the member states of the West African Economic and Monetary Union (UEMOA);
- cooperation in terms of medicines production to face the consequences of the development of new non-communicable diseases, improve medicines supply in the region and reinforce its accessibility by the population.

Finally, based on the pharmaceutical monographs of the three countries as well as the obstacles and assets linked to the integration of the three markets, recommendations are provided in order to encourage the pharmaceutical sector in the region. It is mainly about:

- implementing, at the regional level, supranational professional organisms capable of ensuring a standardization of the regulation joint purchase procedure for medicines, vaccines and serums; of controlling the good quality of local productions; of drawing up a development plan for basic infrastructures for the industrialization of medicines;
- implementing a permanent secretariat in order to ensure a regional coordination for medicines joint purchases and a better development of the pharmaceutical industry;
- reinforcing the link between the different North African pharmacy universities, orders of pharmacists, learned societies and all the professionals of the pharmaceutical sector;
- standardizing the regulatory framework of medicines registration and control and implementing a network of quality control laboratories;
- developing North African cooperation in terms of medicines production (especially of generic ones);
- starting the regional integration with the production of vaccines, oncology products, serums and medicines derived from biotechnology;
- implementing an independent association of medicines manufacturers so that the pharmaceutical industry can benefit from a scientific, commercial and industrial exchange space in North Africa;
- organizing workshops, meetings and conferences on standardization procedures of medicines registration and control.

INTRODUCTION

In 2011-2012, a group of North African public health specialists[3] assessed the healthcare systems in three North African countries (Morocco, Algeria and Tunisia). This assessment shows that pharmaceutical and health products issues are identical in these countries. It remains essential in the political reflection on the organization of the healthcare system.

The share allocated to medicines and health products represents more than a third of these countries' global healthcare spending. It represents a much more important share for households and health-insurance managing bodies.

The report also highlights that the situation of pharmaceutical markets varies from one country to another. In Morocco, since the independence, the pharmaceutical sector underwent undeniable evolutions and can ensure, today, the cover of 65% of the local market needs thanks to the Moroccan industry and exports a good share of its products towards African, Middle-Eastern and even European countries[4].

In the last few years, the Ministry of Health made efforts regarding the setting of prices, fiscalisation of some essential medicines, exemption from VAT and reduction of custom duties for others, as well as encouraging the fabrication of generic medicines.

In spite of all these realizations, some problems remain and are linked, partly, to the weak production of generic medicines, to the multiplicity of fabrication units, to the dependence on raw material supply and to the dysfunctions linked to medicines supply management in the public sector.

In Tunisia, the pharmaceutical sector presents specificities requiring the intervention of public and private players, with the main following characteristics: the sector is regulated and supervised by the Ministry of Public Health and by some public institutions depending from it, such as the National laboratory of medicine control, the National centre of pharmacovigilance, the Central Pharmacy of Tunisia (the only organism authorized to import medicines and vaccines acting as a national purchasing body) and the Pasteur Institute of Tunis. Up to now, this monopoly allowed to manage the costs (medicines are acquired through bids) as well as the prices uniformity and control, the supply regularity in the country and the support to health programs via the self-compensation mechanism, the principle of which is to increase the prices of non-indispensable medicines and to use these profits to balance the medicines used in health programs.

Over the last fifteen years, the medicines local production registered a high growth. From 1987 to 2008, the consumption covered by the local fabrication went from 8% to nearly 50%.

3 Notes IPEMED n°13, April 2012, "Health systems in Algeria, Morocco and Tunisia: national challenges and joint issues" available at www.ipemed.coop/fr/nos-projets-r16/sante-c89/chantier-sante-sc89

4 The Moroccan pharmaceutical sector manufactures a large range of products in compliance with the international standards. Therefore, the WHO classified the Moroccan pharmaceutical industry in the European zone for quality standards.

As for Algeria, the market analysis underlines that this market remains highly dependent on importations, but that the national production has more than doubled. Besides, the will of public authorities to promote generic medicines and the local fabrication favoured the consumption of generic medicines in citizens.

Besides, even if some regulatory texts show that there is room for improvement in the pharmaceutical sector, a lot remains to be done in terms of market regulation, reinforcement of technico-administrative control, security for the supply of public health structures and encouragement of national production.

The report shows that there are also similarities between North African countries. They all have an obvious desire to develop their medicines production, and especially of generic ones. They all have a multiplicity of small, non-competitive, production units as well as supply issues especially in the public sector, etc.

The report advocates *"a reinforcement of the cooperation between the three countries to face the consequences of the development of non-communicable diseases that are likely to inflate the medicines costs. Not only will these countries have to manufacture or import medicines in quantity and quality, but they will also have to consent to the pressure of their populations who will demand to benefit from the last treatments available."*

Thanks to this study, propositions were made, such as *"implementing a better regulation of the pharmaceutical market encouraging more convergence and integration at the North African level"* and encouraging collaboration between countries. A better convergence of marketing authorization procedures, the implementation of a scientific committee common to the concerned countries for the scientific evaluation of MA request, policies of support to complementary national productions, etc. could be tangible actions that could lead to a more integrated pharmaceutical market in North Africa.

This document aims at a better understanding of national pharmaceutical markets in North Africa (Morocco, Algeria and Tunisia). In particular, its objectives are:

- assessing medicines demand and its characteristics, medicines offer and market offer (country monographs);
- underlying existing complementarities between countries;
- identifying obstacles and assets for a better North African integration of the pharmaceutical market (MA, others) and for a North African pharmaceutical industry.

Therefore, this report presents examples of integration through the market and through production, as well as recommendations or potential solutions allowing this integration.

This work was realized thanks to a document review, existing collections and the gathering of relevant national and international data. One must point out that some data date back to the early 2000's. It was almost impossible, via the available documentation and websites, to collect more recent data.

The pharmaceutical market in North Africa

The pharmaceutical market in Algeria

A reminder of a few general economic and socio-demographic data is necessary to better understand the reality of the pharmaceutical market as well as the constraints weighing over it and over the country's health system.

According to the annual report of the Bank of Algeria, in 2012 the GDP growth reached 3.3% against 2.6% in 2011. In sectorial terms, the Algerian economy is witnessing a return of industrial activities – except for hydrocarbons (6.9% in 2012 against 7.2% in 2011). After the 2011 decrease, the added value of the construction industry grew of 8.2% (that is 3 points more than in 2011). According to the Bank of Algeria, this improvement is mainly due to the increase in State equipment spending (+13.1% compared with 2011) and to the boosting of the household construction program.

Regarding the revival of the Algerian industry, the action program of the Ministry of Industry and Investment Promotion comes from the orientations of the "Strategy and policies of industrial revival and development" which encourages industries linked to assembly and conditioning such as electric and electronic industries, food-processing, capital goods, pharmaceutical and veterinary industries. In the Algerian pharmaceutical industry, the Group Saidal has the monopoly. Several other Algerian and foreign private laboratory-companies are active in this sector, especially through joint enterprises between the Group Saidal and foreign groups.

From a sanitary point of view, Algeria, like developing countries, is currently in a transitory phase both demographically, especially with the increase in old people (over 60 years old) and epidemiologically with the eradication of some communicable diseases and the apparition of diseases such as hypertension and diabetes for example. In Algeria, between 1970 and 2010, the birth rate almost doubled while the death rate was nearly stable, which led to a quite important surplus of population. Life expectancy at birth also improved from 52.6 years old in 1970 to 75.7 today. As for mortality, the rate did not vary much (about 4.5‰) since the beginning of the 1970's. The same goes for the cause of these deaths. Cardiovascular diseases come first with a rate of 26.1%, followed by perinatal illnesses (13.5%), cancers (9.5%) and traumas (8.6%).

As for the health expenditure, it represented 5.8% of GDP in 2009. It grows regularly because of the combination of several factors, especially population growth and evolution of age pyramid, aspiration to well-being, rapid increase in modern diseases as well as the important social cover and the standardization of third-party payer. Medicines consumption follows this tendency and importations keep increasing every year, in spite of an increasingly present local production. Indeed, the Algerian pharmaceutical market

is, and will remain for a long time, the most important and the most creditworthy in the region thanks to a very generous social protection system.

In spite of the progress registered in the Algerian healthcare system, the development of healthcare services remains uncontrolled. Since the beginning of the opening up of the economy and the application of liberalization reforms, the Algerian health system has been characterized by the dualism of the public/private sectors, at the cost of coordination and complementarity.

Besides, regarding human resources, one must point out that as well as being insufficient, they are badly allocated over the national territory. Big cities in the North of Algeria have more practitioners and especially specialists. This poor allocation is due to the fact that practitioners who are located elsewhere, especially in the South of the country, after their academic course, go back to the North at the end of their local contracts to set up their private practice.

Following the liberalization reforms carried out by the public authorities, the pharmaceutical sector in general, and of medicines in particular, is undergoing deep evolutions. Still today, it is the object of several reforms linked to the healthcare system and aiming at, among others, reorganizing medicines financing modes and reimbursement mechanisms; or regarding agreements with the European Union[5] and the adherence to the WTO.

Organization of the pharmaceutical market

The national pharmaceutical sector evolved along with the healthcare system by adapting progressively to the evolution of the level of the national demand in pharmaceutical products. However, it also underwent all the difficulties of the national economy management, those linked to a centralized and procedure-oriented management until 1990, those linked to the liberalization and to an opening-up that was too fast and insufficiently controlled.

■ The pharmaceutical sector actors

Currently, one can distinguish four categories of actors at the scale of medicines production and distribution circuit. They are the public sector actors, private manufacturers, wholesaler-distributors and, finally, public and private dispensaries in charge of retail distribution.

Actors of the public pharmaceutical sector. Based on a functional separation of the different bodies (production, importation, wholesale and retail), public actors are present at the four following steps:

- The production body, represented by Saidal: a public company founded in 1982 that started by taking over the production units of the former Central Pharmacy of Algeria. Saidal has now started to diversify its production in particular through partnership agreements with foreign companies.
- Wholesale distribution: represented by Digromed that took over, from 1997, the network of former importation public companies. For several

5 Currently being assessed for a coming adherence.

years, Digromed started to diversify its activity by manufacturing generic medicines[6] before being dissolved in 2009[7].

- Retail distribution: represented by the company Endimed, in charge of managing the network of former public retail pharmacies. This network that represented nearly one thousand pharmacies through all the national territory, was also dissolved and let its pharmacies to qualified pharmacists[8].
- Public pharmacies in charge of delivering for free a list of medicines financed by the National Social Insurance Fund (CNAS) for underprivileged and/or chronically ill people with a very low revenue.
- The Hospitals Central Pharmacy (PCH) which is a public institution with an industrial and commercial character implemented to coordinate and rationalize public hospitals supply programs.

One must point out that apart from the PCH, which was given a clear and precise function towards public hospital structures, the public network is made of companies that are completely submitted to the commercial code just like any other private company.

Private manufacturers and importers and private retail pharmacies. From 1963 to 1990, the pharmaceutical market was exclusively under state control. Since, the suppression of the State monopoly allowed the emergence of private operators in importation, production and distribution.

Private wholesalers-distributers. They are in charge of the wholesale supply of the different retail pharmacies over the national territory. Their activity is controlled by the dispositions of the decree n° 59/MSP of 20 July 1995 setting up the terms of pharmaceutical products wholesale distribution activity. These wholesaler-distributers ensure an essential regulatory function and represent an important media to pass on economic information on the market, products and consumption habits[9].

Private sector actors witnessed a large and fast growth both regarding medicines importation and distribution (wholesale). While they did not exist at the beginning of the 1990's, in 2011, they are 135 importers (against 4 in 1991) and 67 manufacturers[10] (against 1 in 1991). Registered wholesalers are 360 (against 6 in 1991) and the network of retail pharmacies is animated by more than 8,600 pharmacists.

6 National Union of Pharmaceutical Operators, « L'organisation du marché national des médicaments : Difficultés et perspectives annoncées face aux échéances de l'application de l'accord d'association avec l'Union européenne et à l'entrée de l'Algérie à l'OMC », ["Organization of the national pharmaceutical market: Announced difficulties and perspectives faced with the deadline of the association agreement application with the European Union and the adherence of Algerian in the WTO"] September 2005.

7 Belhacene O. & Ferfera M. Y., Les effets contrastes de l'implication des laboratoires étrangers dans l'industrie pharmaceutique algérienne. Colloque International-Algérie : Cinquante ans d'expériences de développement. [Contrastive effects of foreign laboratories implication in the Algerian pharmaceutical industry. International Algeria-Symposium: Fifty years of experience in development.]

8 Belhacene O. & Ferfera M. Y., Idem.

9 National Union of Pharmaceutical Operators, Idem.

10 Of which 20 conditioners.

■ Supervisory and regulatory administrations

The Algerian pharmaceutical market is regulated by several administrative departments with a considerable and determining influence on the different market levels. One can cite, for instance, the Ministries in charge of Public Health, of Social Protection and of Industry. The Ministry in charge of Health actually remains, in spite of the huge progress made by liberalization over the last twenty years, the core of the pharmaceutical market as a whole. It exercises essential regulation and intervention prerogatives regarding the organization and operating of the pharmaceutical market. They are constraining but regularly revised procedures that rigorously supervise importation, the price setting of the Algerian public price (PPA), banking, custom and tax mechanisms on the one hand, and quality control regulations on the other hand. Most of these rules refer either to regulatory texts or to specifications.

Besides, the implication of the Ministry of Health and of social Security in the national pharmaceutical market fundamentally comes from its position of supervisory administration of the CNAS. This institution takes part in the reimbursement to patients of medical care costs as well as medicines prescribed via the Reimbursement technical committee (CTR) deciding, since April 2006, of the products to be reimbursed according to a reference price.

Given the importance of health insurance coverage, legally extended to all registered workers and their families, the CNAS is potentially the ultimate buyer of most medicines marketed on the national territory. As such, it benefits from a significant negotiation power towards the distribution and supply system and constitutes a potentially efficient regulation tool.

Finally, the Ministry in charge of Industry, SMBs and investment promotion, concerned by the development of the Algerian pharmaceutical industry[11], has actually no significant influence on the market and does not apply a specific policy regarding pharmaceutical companies.

■ Regulatory framework applicable to the pharmaceutical market

The pharmaceutical market is highly regulated because of imperatives linked to public health protection and promotion. The Algerian regulation applied to the sector of pharmaceutical products for humans is rather developed and deals with all the aspects linked to the product's environment. However, this regulation lacks legislative authority because of clauses that have long been considered obsolete and out of date[12]. Therefore, and after the deep changes undergone since the beginning of the 1990's, with an opening process of the pharmaceutical sector directed to private capital both national and foreign, important organization measures (on registration, price setting, generic support, protection of national production, etc.) were taken via circulars, notes or instructions. This had negative consequences on the regulation coherence and transparency and probably also on the conditions of its implementation.

From registration to marketing authorization. Pharmaceutical products designed for the market must be registered. This phase constitutes the entry

11 In the case of public companies acting in the pharmaceutical sector.

12 Clauses regarding medicines from the act 85-05 of 16 February 1985 on health modified by act 90.17 of 31 July 1990 and act 08-13 of 20-07-2008 announcing the "National agency of pharmaceutical products".

point of all the regulatory architecture that regulated medicines before they can be prescribed, sold or administrated in Algeria[13].

Like in any other country, medicines requesting a marketing authorization are assessed by the Ministry and evaluated by the National Laboratory for the Control of Pharmaceutical Products (LNCPP) and the MA is delivered in the name of the manufacturing laboratory.

The decree 92-284 of 6 July 1992 and its amending texts plan all the registration steps of a product, as well as the conditions in which the decisions made are managed, in the respect of public health objectives. And yet, much remains to be done to improve efficiency and make it an efficient, rigorous and transparent tool. It mainly concerns: case processing delays, traceability of the different processing steps, buyers response delays, mastering of expertise phases, follow-up and information of decisions taken, etc.[14]

Besides, the decree 80-142 of 17 May 1980 setting the attributions, composition and operating mode of the national commission in charge of the classification is inadequate and out of date regarding the central role of this commission in the regulation of medicine registration. This decree was amended by an order of the Ministry of Health (n°47 of 10 July 1995) that modified the composition and organization of the commission.

Regulation of quality control. With the liberalization introduced in the 1990's, three decrees were adopted in 1992, 1993 and 1996 regarding the quality control of pharmaceutical products. Beside the precautions taken regarding the prior approval of concerned laboratories, we must point out specifically:

- The executive decree 92-65 of 12 February 1992[15] regarding the conformity control of locally manufactured or imported products. It organizes the modalities of the law application, for manufacturers, importers, distributors as well as for State services, to ensure the quality and conformity of the products they put on the market.
- The executive decree 93-140 of 14 June 1993 about the creation, organization and operation of the National Laboratory of pharmaceutical products control. This text is essential for this public organism regulates the whole pharmaceutical market. Its role is all the more so important as it applies before all the process starts. Therefore, no pharmaceutical product can be marketed without having been controlled first.
- The executive decree 96-355 of 19 October 1996 about the creation, organization and operation of the network of tests and quality analysis laboratories. This network, gathering the laboratories created at the level of various ministerial departments, aims at creating the necessary synergy to reinforce the capacities of analysis and quality control at the national level.

13 Some medicines can be prescribed and administered in hospitals without MA for they benefit from a special authorization delivered by the Ministry of Health, Population and Hospital Reform.

14 National Union of Pharmaceutical Operators, op.cit.

15 This regulatory text concern all the products, including pharmaceutical products, and was implemented with Act 89-02 of 7 February 1989 on consumer protection general rules.

Importations regulation. Medicines are one of the only mass consumption product that remains submitted, to this day, to an administrative authorization prior to importation (Order 03-04 of 19 July 2003). Therefore, this legal disposition gave a legal base to importation regulation measures that already existed and that had been gradually implemented by the sanitary administration for about ten years. One can distinguish three categories of measures: those aiming at controlling importation operations, those aiming at a quality development of generic products on the Algerian market and those regarding the protection of national production.

Development of generic medicines. Given that in Algeria most of the national consumption comes from importations, supporting generic medicines starts with the implementation of importation regulation. Therefore, three types of measures regarding medicines importations were implemented:

- registration of a brand name medicine will only be authorized in the absence of a generic medicine and in the limits of a potential additional cost compared to the reference price of the INN at a maximum of 25%;
- the local fabrication of brand products, under their generic form, will be supported and made easier by the public authorities. In the same context, the importation of products manufactured locally will no longer be authorized;
- the authorities clearly support the local production of medicines through an explicit exemption of rights and taxes on inputs and the implementation of favourable reference price for reimbursement.

We must point out that these measures, aiming at promoting generic medicines, have never been applied (see section about generic medicines production).

■ Public policies and support measures

Medicines have always benefited from custom duties and VAT exemption for importation of inputs and raw materials destined for local production in order to favour the development of this economic activity. However, the management of this system is submitted to meticulous and heavy controls by the three administrations (Ministry of Health, Customs and tax authorities).

■ Institutional framework linked to Euro-Mediterranean, North African and bilateral economic and technical cooperation agreements

Between 2009 and 2010, Algeria concluded several cooperation and partnership agreements with the United States, France, Cuba, Jordan, Poland, Italy, Russia and Tunisia. The main cooperation and partnership actions and projects in the pharmaceutical sector consisted in:

- reactivating, consolidating and reinforcing the partnership between the different actors for the production of generic medicines against cancer, chronic diseases and intensifying the cooperation in terms of technology transfer;
- identifying the pharmaceutical market needs in Algeria through the provision of medicines at a reasonable price, especially for those for people suffering from chronic diseases and broadening the investigation field

in Algeria by integrating biotechnology and investment in the sector of generic medicines for the treatment of different forms of cancers;
- modernizing and broadening the capacities of the Group Saidal;
- making a fabrication technology transfer for vaccines and biopharmaceutical products, assisting the conception of pharmaceutical products new units and implementing research and development in biotechnology;
- reinforcing the cooperation in paediatric and cardiac surgery, medical equipment as well as training and sharing of experience.

Medicines demand and its characteristics

The consumption of pharmaceutical products in general, and of medicines in particular, represents the first item of expenditure in the health sector. It represents a serious problem for health policies and systems, especially with the increased growth of the pharmaceutical market (medicines offer constituted by the national production and importation significantly increased in the three countries), with the evolution of healthcare demand in general and of medicines in particular through the rising living standards, the epidemiological and demographic transition as well as the improvement of medical care for some pathologies and medical insurance.

Therapeutic and medical needs evolve towards recent treatments, innovative and more costly products; for instance: anticancer medicines, analog/pen-injection insulin, monoclonal antibodies and interferon, triple therapies, prosthesis and sophisticated exploration equipment. The only data authors could access to show that in 2008, 18% of medicines consumption was linked to cardiac troubles, 17% to metabolic and digestive troubles, 15% to anti-infectious medicines and 12% to the central nervous system[16], etc.

In Algeria, the average consumption per inhabitant (constituted of purchased medicines and of others supplied for free) was evaluated at US$ 14 in 1992 to reach US$21.4 per inhabitant in 1995, US$ 63 per inhabitant in 2000 and US$ 165 per inhabitant in 2006.

As for the average spending per inhabitant per year for medicines in Algeria, it reached € 34.7 in 2006 against € 28.2 in 2004. By comparison, this amount is estimated at € 440 in France while in Morocco and Tunisia, the estimations reach an average spending of €16.6 and € 27.5 respectively.

Out of the total health spending, the share of medicines expenditure represents 30% in 2006 against 20.3% in 1995.

Medicines offer

With an average growth of 10% a year, the Algerian pharmaceutical market is the third market in Africa (US$ 3.45 billion in 201217). However, it remains structurally importer; local production units focus on generic medicines and on the same pharmaceutical forms that only cover one part of the needs (essentially under the form of liquids, pastes and dry pills).

16 Semmoud M., "The pharmaceutical sector in Algeria: Datas and perspectives", 13st class of RESSMA, Marrakech, from 30 May to 09 June 2011.

17 According to a recent study of IMS Health reported by Algérie-Focus on 30 May 2013: www.algerie-focus.com/blog/2013/05/251-medicaments-toujours-interdits-dimportation-en-algerie.

Besides, whatever its investments in local production, Algeria remains highly dependent on the global medicines market, as it imports in average 70% of the consumed medicines.

■ Size of the pharmaceutical market

In 2011, the national pharmaceutical market represented US$ 2.0 billion, of which US$ 1.85 billion were imported medicines and US$ 1.05 billion of local production, of which 84% goes to the private sector and 16% to the public sector[18].

According to the data of the customs National Center of Computer and Statistics (CNIS), Algerian importations of pharmaceutical products[19] reached US$ 606.26 million during the first four months of 2013, decreasing by 13.2% compared with the same period of 2012 (US$ 698.3 million).

Algerian importations of pharmaceutical products reached a total of US$2.3 billion in 2012, with an increase of 24% compared with 2011 (US$ 1.85 billion), representing the 2nd place of consumption goods after cereals and the 7th place for importation in absolute terms. Thanks to the National Office of Statistics data available and to the UNOP survey, one can make an approximate estimation of the national market values and its evolution since 2000.

The measures imposing pharmaceutical operators to invest in local production and forbidding the importation of medicines produced locally allowed to reduce the medicines bills. Indeed, they decreased (see **TABLE 1**) by 6% and 4% going from US$ 1,845 million in 2008 to US$ 1,734 in 2009 and to US$ 1,665 in 2010. However, they started increasing again by 11% and 24% respectively over the period 2010-2011 and 2011-2012.

18 National Union of Pharmaceutical Operators, op. cit.

19 In average, over the last decade, medicines represent nearly 95% of the total of pharmaceutical products bills.

TABLE 1 Evolution of the size of the Algerian pharmaceutical market (in US$)

Year	Local Production	Importations	Estimation of the national market	Evolution (Base 100 : 2000)			Share of local production (%)	Share of importations (%)
				Local prod.	Importations	National market		
2000	111,442,500	457,094,380	568,536,880	100	100	100	20	80
2001	93,043,200	492,396,377	585,439,577	83	108	103	16	84
2002	106,585,600	619,804,810	726,390,410	96	136	128	15	85
2003	100,843,800	615,483,659	716,327,459	90	135	126	14	86
2004	225,000,000	877,425,980	1,102,425,980	202	192	194	20	80
2005	232,400,000	1,068,678,140	1,301,078,140	209	234	229	18	82
2006	455,000,000	1,185,492,173	1,640,492,173	408	259	289	28	72
2007	586,574,000	1,445,652,495	2,032,226,495	526	316	357	29	71
2008	533,900,400	1,844,557,869	2,378,458,269	479	404	418	22	78
2009	771,324,400	1,734,367,374	2,505,691,774	692	379	441	31	69
2010	800,000,000	1,664,703,324	2,464,703,324	718	364	434	32	68
2011	1,050,000,000	1,850,000,000	2,900,000,000	942	405	510	36	64
2012	1,150,000,000	2,300,000,000	3,450,000,000	1,032	503	607	33	67

Sources: ONS, UNOP and CNIS-DG Douanes

As for local fabrication, it increased by 44% between 2008 and 2009 before slowing down and reaching 10% between 2011 and 2012. The objective of Algeria is to produce locally 70% of its medicines consumption by the end of 2015 with the help of foreign laboratories. In order to reach this objective, the State took important measures to settle a pharmaceutical industry especially by encouraging investments and settling industrial partnerships.

Besides, in 2011, the share of generic medicines[20] represented 35% of the global consumption of registered medicines against 48.5% in 2009 and about 38% in 2006 (see **TABLE 2**).

20 They are generic medicines with a specialty name ("Brand generic") and are different from generic medicines presented under their INN.

TABLE 2 Evolution of the share of generic medicines (production, conditioning, importation) in the global medicines consumption

	2004	2005	2006	2009	2011
Generic	31.99%	33.60%	37.92%	48.5%	35%
Brand	78.01%	66.40%	62.08%	51.5%	65%

Source: Ministry of Health

As for local production, it is mostly oriented (75%) towards the fabrication of generic medicines in 2011, against 81% and 80% respectively in 2008 and 2009.

■ Main manufacturers and importers

In terms of medicines production in Algeria, SAIDAL takes up the greatest share (39.8%), followed by Sanofi Aventis (26%), while Pfizer only represents 11.5% of medicines manufactured in 2005[21]. However the group SAIDAL loses shares when it come to the pharmaceutical market (importation and fabrication) since they went down to 8.7% in 2007. Indeed, the Algerian pharmaceutical market is mostly controlled by foreign groups. The most important investors in the pharmaceutical sector in Algeria are, in order of importance: Sanofi Aventis (14%), Bio Pharm (10%), LPA (4.6%), Pfizer (4.4%), Laboratoire Salem (4.3%), Hikma pharma (4.2%) and Prodiphal (4.2%)[22].

■ Types of produced medicines

In order to face these needs, Algeria has production units capable of producing all the required dosage forms. They are the following pharmaceutical forms:

- non-sterile liquid oral forms (syrups and oral suspensions): 16 units (of which 8 are exclusively dedicated to this form);
- oral dry forms (capsules, pills, powders in packets): 11 units of which 4 dedicated to these forms only, 4 where another form is produced (non-sterile oral liquid) and 3 more versatile;
- non-sterile liquid forms for external use (antiseptic): 10 fabrication units, of which 7 units dedicated to this form only or associated with pasty forms for external use;
- pasty forms: 6 fabrication sites, associated with other forms of fabrications;
- semi-solid forms: 5 production sites, of which 4 are dedicated to this form (suppository);
- injectable medicines (sterile): 1 site and 1 project of site. These site produce other forms;
- other sterile liquid forms: 5 producers, of which 3 for large solutes and 2 for collyrium.

■ Access to active substances to produce medicines

In Algeria, the LNCPP created, in its technical structures, a chemical service specialized in the quality control of the active substance. It aims at:

21 Boutouchent Z. & Lejeune A., « Analyse de la filière industrie pharmaceutique en Algérie » [Analysis of the pharmaceutical industry in Algeria], Ministry of Small and Medium-sized Enterprises and Crafts & European Commission, SMB Euro-Development main report, Algiers, October 2007.

22 Dahmane L. « Le marketing pharmaceutique : Case complexe Saidal » [Pharmaceutical marketing: the complex case of Saidal], PhD thesis, University of Economics and Management of Dely Ibrahim – Algeria. Management department, Academic year 2009-2010.

- making the Direction aware of its responsibilities by testifying the authenticity of the supplier/producer;
- vouching for the existence of a quality insurance system;
- mastering the conception with a conformity certificate of the European pharmacopeia (EPC), a Drug Master File (DMF) or International Comitee of Harmonization (ICH);
- identifying all the ingredients used in the fabrication of the raw material (active substance).

■ Exportations

According to the data of the CNIS-DG Douanes, the exportation of medicines in Algeria was at its best in 2001 and 2009 (**TABLE 3**). During these years, they evolved respectively by 61% and 50%. In 2010, their value decreased by 52% compared to 2009. Since 2007, even though their importance varies every year, pharmaceutical products are mostly exported towards Libya, Morocco, France, Jordan and Saudi Arabia. In 2010, more than 85% of exportations are of benefit for these countries (TABLE 4).

TABLE 3 Evolution of medicines exportations in Algeria (in US$)

	2000	2001	2002	2003	2 004	2005*	2006	2007	2008	2009	2010
Exportations	289,419	465,421	563,690	749,850	978,744	–	4,729,430	2,916,413	1,746,961	2,625,872	1,271,019

Sources: CNIS-DG Douanes
*: No data available

TABLE 4 Evolution of the breakdown of pharmaceutical products exportations in Algeria per country (%)

Year / Country	2000	2001	2002	2003	2004	2005*	2006	2007	2008	2009	2010
Saudi Arabia	0	0	0	0	17.5		0	10.6	1.2	3.2	6.4
Spain	0	0	0	0	0.3		78.3	0	0	9.1	0
France	8.7	73.4	61.2	9.3	22.6		0.9	36.7	40.6	32.9	20.3
Italy	0	0.1	0	50.1	19.9		0.5	0	0.2	0	0
Jordan	1.4	0	0	0	0		0.5	0	2.5	3.1	7
Morocco	88.6	18.4	1.8	0.3	1.8		4.8	18.9	0	5.5	22
Nigeria	0	0	0.2	15.1	10.5		2.8	3.7	6.4	9	1.7
Libya	0	0	0	0	4.7		3.4	15.1	27.6	21.6	29.7
Senegal	1.1	1.9	17.4	17.9	0.2		1.3	0.4	3.6	2.3	2
Yemen	0	0	10	1.2	11.6		0	1.9	3.7	0.6	0
Others	0.2	6.2	9.4	6.1	10.9		7.4	12.7	14.3	12.7	10.9
Total	100	100	100	100	100		100	100	100	100	100

Sources: CNIS-DG Douanes
* : Non-available data

■ Importations

Over the same period (2000-2010), and according to the Customs Directorate, importations of pharmaceutical products are as described in **TABLE 5**. Even though they keep decreasing, the most important share is that of medicines conditioned for retail (about 90%). This decrease was realized at the expense of importations of human or animal blood, serums and vaccines.

TABLE 5 Evolution of pharmaceutical product importations in Algeria by category (in million US$)

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Glands and other organs	5.776	3.611	3.341	4.068	3.848	5.733	3,711.894	5.901	6.163	5.992	551.439
Human or animal blood, serums, vaccines	12.182	15.836	18.994	24.446	33.451	32.111	38.351	75.183	105.424	126.601	128.565
Medicines non-conditioned for retail	1.560	3.840	9.360	7.027	13.632	26.994	23.541	25.815	38.865	58.239	34.575
Medicines conditioned for retail	427.387	457.780	573.916	565.280	807.843	980.480	1,092.393	1,307.642	1,650.990	1,508.415	1,456.405
Waddings, Gauzes, Strips and similar items	2.042	2.444	2.210	3.057	5.501	5.955	3.809	5.316	8.054	7.583	7.034
Preparations and other pharmaceutical items	8.147	8.885	11.983	11.606	13.151	17.406	23.688	25.795	35.061	27.538	37.573
Overall total	457.094	492.396	619.805	615.484	877.426	1,068.678	1,185.492	1,445.652	1,844.558	1,734.367	1,664.703

Source: DG Douanes – CNIS

The evolution over these ten years (from 2000 to 2010) of each of these pharmaceutical product categories of importation also shows the fast growth of the category of medicines conditioned for retail until 2005. This growth slew down in 2008 and 2009, with other decreasing peaks in 2003, 2006 and 2010.

In 2010, the category that underwent an important evolution is that of preparations and other pharmaceutical items (36%). This increase was also present in 2006 and 2008.

Research and innovation

THE IGNORANCE of the patents system and of patent protection procedures is at the origin of the low rate of patent registrations in Algeria (1st registration in 2005). Until April 2010, the Algerian national institute of industrial property registered 181 patent applications, of which 98 about medicines.

The first observation in scientific research is the total absence of companies (public and private) from research, while it constitutes the core of any

industrial development, which explains the absence of technological innovations. The second observation is that the research issue in Algeria does not lie in the allocation of means (human, material and financial) but in the implementation of a real innovation national policy making the concerned actors interact. Research in Algeria also suffers from the absence of collective will, of communication between researchers, of team-work, of relations between universities and research centres, between research centres and the industry, and between official structures and researchers.

Considered as a qualitative and quantitative measure indicator of the research and development activity, scientific publication reflects the efforts of researchers and remains a good way to highlight innovations. Even though Algeria is making progress, the publication rate remains incomparable to that registered in other countries and even in neighbouring countries. The available data only concern publications in general. Publications on the pharmaceutical industry are included.

As for innovation in companies, even if the designation is used, the R&D structure does not exist. Instead, one can find other entities under the form of laboratories, centres, engineering office, etc. Their main activities concern the realization of conformity tests and quality control. However, these entities may sometimes be at the origin of activities leading to modifications/improvements. Indeed, for almost all companies, the innovations realized are incremental; they improve the taste, the conditioning or the presentation of the product. Technological innovation does not exist.

In order to meet the new needs in innovative products coming from the Algerian population and from the Middle-East and Africa region, the Algerian government undertook a large project of creation of a biotechnological centre (including production and R&D sites). The project is starting with the support of large companies, American academic centres and some major European companies. This project represents a significant challenge in terms of development of new scientific training, skills and expertise. It should encourage the modernization of biomedical and scientific Algerian academic trainings that have difficulties renewing themselves, especially to integrate a R&D and management dimension that currently lacks in local health industries. Finally, this project can complete the development of a biopharmaceutical industry currently too oriented on chemical products while the international drive for competitiveness in health concerns biotechnologies and advanced technologies.

The pharmaceutical market in Morocco

A reminder of a few general economic and socio-demographic data is necessary to better understand the reality of the pharmaceutical market as well as the constraints weighing over it and over the country's health system. In spite of an unfavourable international environment these last three years, Morocco keeps showing encouraging results, characterized by the strengthening of the macroeconomic framework and a progressive diversification of the productive basis of the national economy. The implementation of strategic reforms allowed to maintain the basic principles of the economy.

In 2011, in spite of the crisis, the GDP growth rate reached 5% against 3.7% in 2010 and 4.8% in 2009, thus reflecting a lesser volatility of the economy thanks to the efforts of the secondary sector (industries, construction industry, transports and telecommunications) and tertiary sector (banks, insurance, other services) that are progressively driving growth.

Since the independence, Morocco engaged in large investments to develop and give the country basic industrial infrastructures. The industrial sector represents nearly 28% of GDP. Dominated by food-processing, textile and leather industries for a long time, Moroccan industry rapidly diversified thanks to the development of various sectors such as chemistry and parachemistry, paper and cardboard, car equipment and vehicle assembly, services to businesses, computers, electronic and aeronautic industry.

The Moroccan pharmaceutical industry is the third in Africa in terms of revenue after South Africa and Algeria. This industry generates a revenue of Dhs 9 billion per year, or € 900 million per year.

In this macroeconomic context, the country's sanitary situation is characterized by the reduction of mortality and fecundity rates, announcing the demographic transition and a change in the morbidity structure, resulting in the emergence of chronic diseases due to the epidemiologic transition.

The gross mortality rate decreased from 19‰ in 1960 to 5.6‰ in 2010, however it remains much higher in rural areas (7.2) than in urban areas (4.4). Infant mortality went from 91‰ in 1979 to 37‰ in 1997 and to 28.8‰ currently. The index of maternal mortality dropped from 359 deceases for 100,000 live births at the end of the 1970's to 227 at the end of the 1990's and to 112 currently. As for life expectancy at birth, it rose from 47 years old in 1962 to 74.8 in 2012. The total fecundity rate dropped from 4.5 in 1987 to 2.6 in 2011.

Even though these various indicators confirm the efforts made by the Ministry of Health, many issues remain to be tackled.

■ A strengthened but underused infrastructure

In Morocco, the basic healthcare network greatly developed. The same goes for the hospital network, but at a very low pace. The country thus went up from 0.58 basic healthcare institutions for 10,000 inhabitants in 1980

(1/17,000 inhabitants) to 0.83 for 10,000 inhabitants (1/12,000) today. In spite of the efforts of the Ministry of Health to reinforce the sanitary network, nearly 20% of the population still live at more than ten kilometers of a basic sanitary infrastructure and the level of use of public curative services remains remarkably low with 0.6 new case per person per year.

■ Health-care workers shortage

One of the most striking characteristics in the Moroccan health system is the staff shortage, in spite of the slight improvements made in the last few years. The density of doctors, both private and public, rose from 0.43 to 0.62 for 1,000 inhabitants between 1999 and 2012, while the density of nursing personnel oscillated between 0.89 and 0.97 for 1,000 inhabitants. Besides, more than 40% of Moroccan specialists exclusively work in the urban private sector.

■ A funding that is still too dependent on direct payments

Morocco progressively increased the amounts dedicated to healthcare. The total spending rose from Dhs 18.9 billion (US$ 1.7 billion) in 2001 to Dhs 47.8 billion (US$ 5.8 billion) in 2010, that is an average increase of 12.2% per inhabitant per year.

The greatest share of this spending (53.6% in 2010) is ensured by households' direct payments. The high rate of direct payments deepens inequalities between the different categories of population and puts households at high risks of financial disaster and impoverishment.

The resources collected by the national healthcare system are dedicated, for a rather important part (31.7% in 2010 against 33.6% in 2006), to the purchase of medicines and medical items as final consumption goods for the patient and not as inputs used by health professionals for healthcare.

■ Medicines remain expensive

The prices of medicines are twice to three times higher in Morocco than in most neighbouring countries, mainly because of the supply fragmentation and the absence of competition by quality generic medicines, the penetration of which does not go beyond 30%.

One must point out that the pharmaceutical market in Morocco, as everywhere else in the world, keeps evolving. Every day, new specialties are created, while others are drawn back from the market or have their instructions modified. The promotion of generic medicines by the public authorities, as part of their policy to give citizens better access to healthcare, and the competition between the different pharmaceutical companies intensify this phenomenon.

The growth of the pharmaceutical market increased both in value and in volume, especially after the introduction of the compulsory health insurance and more recently of the Assistance Scheme for the Economically Underprivileged (RAMED).

Organization of the pharmaceutical market

■ Actors of the pharmaceutical sector

The Moroccan pharmaceutical market is entirely controlled by the private sector from importation to retail distribution, production and wholesale distribution. There is a supply service of the public healthcare institutions (Central Pharmacy).

Wholesalers-distributors find themselves between the pharmaceutical industry and retail pharmacies. Their main activity consists in buying and selling medicines, therefore it is a service provision activity. They supply 80% of manufactured medicines; the rest is supplied directly by pharmaceutical companies themselves.

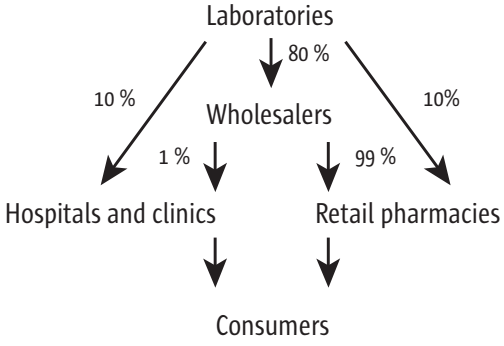
The second category of actors implicated in the supply chain of pharmaceutical products concerns retail pharmacies. They are managed by the owner and pharmacist, helped by pharmacy-technicians or assistants.

As for the public sector, it covers about 10% of the national market needs and it is in charge of supplying sanitary establishments under the authority of the Ministry of Health. The current supply system of the public sector is entirely ensured by the Supply division. Medicines are distributed freely to patients. However, the four CHUs (establishments with an administrative autonomy) get their supplies independently (except occasionally for urgent supplies, in such case the products are "lent"). By the same token, programs of the Direction of the population, with for example vaccines and contraceptives, and of the Direction of epidemiology and disease control, with for instance products against tuberculosis, AIDS and vaccines, buy directly their medicines and medical items and stock them in the warehouse of the Supply division that also ensures supplies. The division supplies health provincial delegations (which in turn supply health centres) and semi-autonomous hospitals (SEGMA).

The supply organization implemented allows a marketed product to access in one day the different points of sale present over the whole national territory.

Schematically, one can represent the organization of pharmaceutical products supply networks in Morocco as shown in **FIGURE 1**.

FIGURE 1 Organisation of the medicines supply circuit



Source: AMIP

For a long time now there has been an Order of pharmacists. The National council of the Order of pharmacists comes from four regional councils. The members are elected. Industrial companies are mostly represented by the Moroccan Association for Pharmaceutical Industries (AMIP). It gathers 25 laboratories. Almost all multinational companies are members of Health Innovation Morocco (MIS). Some multinational companies are also members of the AMIP.

The Moroccan association for generic medicines (MAG) is the 3rd professional association in this sector. It was created in 2010. It gathers exclusively generic medicines industrials, some of which are already members of the AMIP. This association mostly aims at developing generic medicines in Morocco.

Currently, the Moroccan pharmaceutical sector is, in size, the second on the African continent, after South Africa. It is constituted of 40 industrial units, 50 suppliers and more than 10,000 retail pharmacies[23].

Besides, the pharmaceutical industries are geographically located in the region of Greater-Casablanca with a total of 32 companies[24].

■ Supervisory and regulatory administrations

The Ministry of Heath ensures sanitary security in general and medicines security in particular. On the one hand, it must ensure the availability of vital products through regular supply, for all the citizens, by traceable circuits. On the other hand, it must ensure the quality, efficiency and safety of these medicines. Therefore, medicines and pharmacies are highly regulated and controlled by the Ministry of Health[25].

There are legal dispositions establishing the powers and responsibilities of the Pharmaceutical regulatory authority represented by the Direction of Medicine and Pharmacy (DMP). The DMP is part of the Ministry of Health and is a semi-autonomous organism. It performs a certain number of functions, described in **TABLE 6**, following the clauses of decree n° 2-94-285 of 17 joumada Il 1415 (21 November 1994) regarding the attributions and organization of the Ministry of Public Health[26].

23 Ministry of Health – WHO, « Rapport des travaux de la commission consultative du médicament et des produits de santé » ["Report of the works of the medicines and health products consultancy commission"], January 2013.

24 Competition Council, op. cit.

25 Competition Council, « Etude sur la concurrentiabilité du secteur de l'industrie pharmaceutique » [Study on the competition of the pharmaceutical industry sector], 2011.

26 WHO – Ministry of Health, "Morocco Pharmaceutical Profile", 2011.

TABLE 6 Functions of the Direction of Medicine and Pharmacy

Functions	
Marketing authorization / registration	Yes
Inspection	Yes
Control of importations	Yes
License grant	Yes
Market control	Yes
Quality control	Yes
Promotion control, control of advertisement for medicines	Yes
Clinical trials control	Yes
Pharmacovigilance	Yes

Source: Morocco Pharmaceutical Profile. MS – WHO, 2011

The DMP is a technical, expertise and support tool for the decisions taken by the Ministry of Health regarding medicines, health products and the management of the sanitary risk linked to these products. Its main objective is to guarantee the security of medicine and health products use via a scientific assessment in order to ensure the quality of these products as well as to meet the legitimate expectations of the public and of health professionals with quality reliable information. Its security approach has been expanded to other health products such as medical devices, laboratory reagents for in vitro diagnosis, foodstuffs and beverages for special diets, childcare items and biocides.

The DMP has a National Laboratory for the Control of Pharmaceutical Products (LNCM) playing an essential role in the quality, technical evaluation and expertise processes. It refers to and applies the international quality control standards and technical references of: the European Pharmacopeia (PE), the American pharmacopeia (USP), the directives of the World Health Organization (WHO), the guidelines of the European Agency for the Evaluation of Medicinal Products (EMEA) and of the European Directorate for the Quality of Medicines (EDQM), the guidelines of the Food and Drug Administration (FAD), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), the guide to Good Manufacturing Practice (GMP) and national standards.

The National Laboratory of medicines control is recognized at the regional and international scales since it is a WHO collaborating laboratory. A laboratory approved by the Arab League, accredited by the European Directorate for the Quality of Medicines in 2007 and renewed in 2011, prequalified by the WHO in 2008, associated member of the European Pharmacopeia and of the American Pharmacopeia in 2010[27].

27 Doctinews, n°40, January 2012.

Since 1960[28], in order to better control pharmacy activities, Morocco had implemented an industrial policy based on the model of import substitution. Five years later, the Ministry of Health imposed the gradual local fabrication of some medicines, except products representing small amounts consumed or requiring a sophisticated and costly technology. The result was the development of a pharmaceutical industry composed of 40 production units today, against 8 in 1965. Three of these companies are the leaders of the private Moroccan market (outside of the hospital sector).

■ Regulatory framework applicable to the pharmaceutical market

Morocco adopted very strict regulations[29] in comparison with countries with a developed and structured industry. These regulations, which define precisely the operating conditions and modalities for each of the different operators, from industrials to retail pharmacies, are made of natural barriers impeding anything that could represent a potential danger for citizens since they precisely aim at protecting them. Besides, these regulations also aim at a free access, for all citizens, to healthcare in general and medicines in particular[30].

As regards the registration procedures for medicines, the MA request files are submitted to the Direction of Medicine and Pharmacy. The assessment of the administrative file is made at the Pharmacy division while the assessment of the technical file is made at the National Laboratory for medicines control. The results are then submitted to the national commission of MAs, composed of experts and medicine professors working in the four university hospitals (CHUs), who give their opinion on the therapeutic relevance of the medicine. If they are in favour, an agreement in principle is delivered to import (3 months) or manufacture (12 months) the medicine and submit samples to the National Laboratory for medicines control for an analytic expertise. The MA is then accepted if the results of the analysis comply with the regulations. In other cases (postponed or refused files, non-compliant analysis), further information or changes are required to re-examine the MA request files.

There are two types of MA requests: the MA requests for new products and the requests for the extension of already authorized MAs (an MA is delivered for five years). There are no systems of mutual recognition of the delivered MAs between the DMP and other foreign authorities.

The entry into force, in 2005, of a law on intellectual property led to a peak in MA requests at the DMP in 2004. In total, 831 requests were submitted, of which 748 for generic medicines, against half less the following year.

In 2010, 469 MA request were submitted for new products (a request is for a form, a presentation and/or a dosage) and 252 for MA extensions[31]. Over the 469 requests on new products, 342 MA were given, that is nearly 73% of the requests accepted. One request out of four has however been refused[32].

28 Dahir of 1960 defining medicines operating conditions.

29 Act 17-04 on the code of medicines and pharmacy, announced by the Dahir n°1-06-151 of 30 chaoual 1427 (22 November 2006), is the first major reform of the pharmaceutical sector.

30 Competition Council, op. cit.

31 National Observatory for Human Development, « Les disparités dans l'accès aux soins au Maroc : Etude de cas » [Disparities in healthcare access in Morocco: Case study], 2011.

32 National Observatory for Human Development, op. cit.

■ Public policies and support measures

Beyond the obvious economic issue, the development of the pharmaceutical sector could improve the health of all Moroccan citizens, through a broad and accessible offer of medicines and healthcare, while contributing to the independence of the national health system. In this respect, Morocco implemented, in February 2013, a program for the pharmaceutical industry sector aiming at supporting a promising sector both on the national and international markets. This program is the result of a strategy built with all the public and private stakeholders. By favouring a targeted approach, and by mobilizing the concerned partners as well as the necessary resources, it must give this sector optimal conditions for development. It formalises the commitments of the partners implied over the period 2013-2023[33].

This project was born from the combination of two strategies:

- one exportation strategy focused on three major lines: development of R&D activities, reinforcement of Moroccan manufacturers, setting up of foreign manufacturers;
- one strategy of development of the national market focused on three major lines: development of generic medicines, improvement of access to medicines, improvement of access to healthcare.

One must also note that Morocco is the only Arab country to impose VAT payment on medicines. Custom duties and taxes are imposed on the importation of several pharmaceutical products.

■ The institutional framework linked to commercial as well as technical and economic cooperation Euro-Mediterranean, North African and bilateral agreements

In the context of its liberalization and global opening-up strategy, over the last decade Morocco updated the legal framework ruling its commercial relations with its partners through free-trade agreements both with its main partner – the European Union – and with a certain number of Arab countries of the European Free Trade Association (EFTA) and Turkey.

Therefore, in the framework of the Barcelona process (November 1995) aiming at the creation of a Euro-Mediterranean free trade zone by 2012, Morocco concluded a certain number of agreements with its European and Mediterranean partners. The most important are the association agreement signed in February 1996 between Morocco and the UE, that came into force in March 2000, and the free trade agreement with the EFTA signed on 19 June 1997 and in application since March 2000. These agreements aimed at, among other things, the gradual implementation of a free trade zone and planned many cooperation areas on political, economic, social, scientific and cultural issues.

In the same context, Morocco engaged in a free trade process with a few Arab countries in regard to the new relations of these countries with the EU. Therefore, bilateral free trade agreements were signed with Egypt in May 1996, and entered into force on 29 April 1999, and with Tunisia in March 1999. At the regional scale, it signed in February 2004 the quadripartite

33 Ministry of Industry, Trade and New Technologies, « Contrat programme pour le développement du secteur de l'industrie pharmaceutique » [Program contract for the development of the Pharmaceutical Industry sector], February 2013.

agreement between Morocco, Egypt, Tunisia and Jordan thus implementing the Agadir declaration of May 2001.

As for other Arab countries, Morocco diversified its outlets and strengthened its relationships with its commercial partners, be it at the bilateral level (United Arab Emirates) or at the regional level in the context of the Arab free trade area that came into force in January 1998. It also signed a free trade agreement with Turkey and then with the United States in June 2004[34].

Since December 2004, Morocco is a member of the World Trade Organization and has therefore reviewed strictly its regulations on intellectual property[35].

The international agreements concluded by Morocco with various countries threw the pharmaceutical industry into a new environment where competition is harsh. It will now have to face an increasingly fierce competition in order to keep its markets or conquer new ones.

Medicines demand and its characteristics

In 2009, the private pharmaceutical consumption (medicines bought in pharmacies, excluding hospital consumption) in Morocco was of Dhs 372 per inhabitant per year, or nearly US$ 44 per inhabitant per year, which represents a volume of 8.6 boxes. It remains quite low (France[36]: US$ 524 per capita in 2004) because of a very weak social coverage, of a low purchasing power and of the high price of medicines.

The cumulative change in consumption in terms of value, over the period 1991-2005, was of +104%. That is a yearly average of +7.5% (**FIGURE 2**). This evolution goes down to +44% over the period 2005-2009. That is a yearly average of +11%. This can be explained mostly by the impact of the implementation of the compulsory health insurance on medicines consumption[37]. Besides, while the WHO advises to dedicate at least 10% of GDP to medicines, this rate does not reach 5% in Morocco.

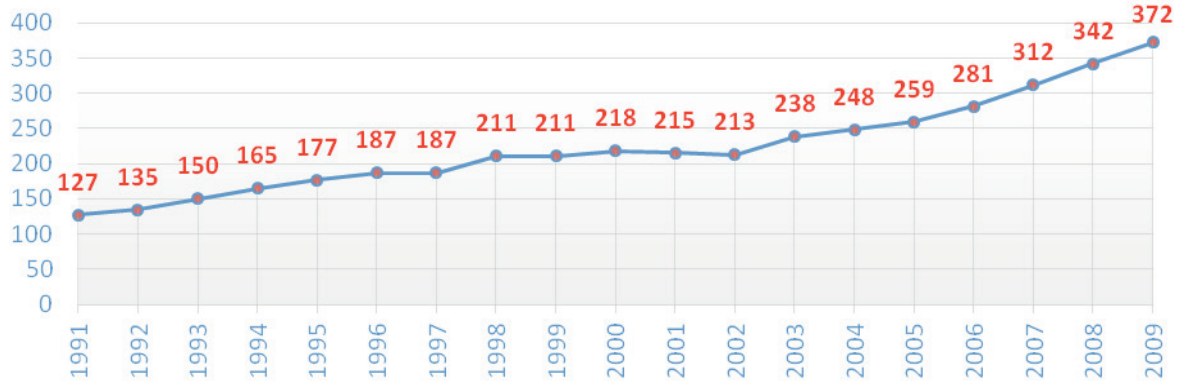
34 Moroccan Pharmaceutical Industry Association, "Morocco and international agreements", www.amip.ma/dynamicdata/Secteur_Accords.aspx?langid=5

35 Act 17-97 of 18 December 2004 amending preexisting texts and ensuring the conformity of Morocco with the WHO; Act 31-05 amending and completing the previous legislation in order to introduce some of the requirements imposed by the Trademark Law Treaty of the World Intellectual Property Organization (WIPO) and by the free trade agreement signed with the United States in March 2004.

36 LEEM, « Consommation pharmaceutique et indicateurs de santé publique » [Pharmaceutical consumption and public health indicators], Study report, May 2009.

37 Competition Council, op. cit.

FIGURE 2 Evolution of medicines consumption per capita in Morocco (in Dhs)



Source: Belaïche, 2010

Medicines offer

In Morocco, the pharmaceutical industry is young but is rapidly evolving. It developed very quickly over the last twenty years. Indeed, the World Health Organization confirms that it has a proven experience and expertise and places it in the "Europe zone".

■ Size of the pharmaceutical market

In 2012, the market generated a revenue of about Dhs 11.5 million (including hospital products and public bids), of which Dhs 8.2 million generated by the private pharmaceutical market. The share of brand-name medicines represented nearly 70% of the sales on the private market, against 30% for generic medicines, that is Dhs 2.5. In volume, the consumption of medicines reached 289,345 units consumed over the same period against 172,000 units in 2000[38].

Morocco produced nearly 65% of its pharmaceutical needs and exports 10% of its production, especially to African countries[39]. The remaining 35% are ensured by the importations of low consumption volume and mostly come from European countries[40].

There are currently over 5,000 pharmaceutical specialties covering nearly all the therapeutic classes[41]. According to the therapeutic classification of medicines consumed in 2010 (**TABLES 7** & **8**), medicines for the digestive system and metabolism are ranked first with 18% of market share and nearly Dhs 1.4 billion. Anti-infectious and cardio-vascular medicines are ranked second and third and respectively take up 16% and 11% of the market[42].

38 BMCE Capital Research Flash, « Tour d'horizon : Industrie pharmaceutique » [Overview: Pharmaceutical industry], March 2013.

39 National Observatory for Human Development, op. cit. & L'Opinion, « Industrie pharmaceutique : Jeune et à développement rapide » [The pharmaceutical industry: young and fast-developing], 14 July 2012.

40 Moroccan Pharmaceutical Industry Association, « Le Médicament au Maroc : Couverture du marché intérieur » [Medicines in Morocco: covering the national territory], www.amip.ma/dynamicdata/Secteur_Couvert.aspx?langid=5

41 Competition Council, op. cit.

42 Moroccan Pharmaceutical Industry Association, op. cit.

TABLE 7 The first ten therapeutic classes in value (2010)

	Values (Dhs)	Market share (%)
Digestive system and metabolism	1,442,612,761	18
Anti-infectious v general	1,265,798,997	16
Cardio-vascular system	884,681,417	11
Nervous system	878,476,765	11
Respiratory system	649,810,252	8
Somatomotor system	609,844,261	7.3
Genit-urin-horm-sex system	581,702,077	7.3
Others	424,129,146	5.3
Dermatology	407,355,122	5.1
Sensory organs	310,723,451	3.9
Total	7,934 048,145	100

Source: AMIP/IMS-Health

TABLE 8 The first ten therapeutic classes in units (2010)

	Units (thousands)	Market share (%)
Digestive system and metabolism	55,758,334	19.8
Central nervous system	49,377,400	17.5
Respiratory system	31,439,569	11.1
Anti-infectious v general	23,922,804	8.2
Genit-urin-horm-sex system	23,115,894	8.2
Dermatology	21,065,689	7.4
Somatomotor system	20,022,919	7.1
Cardio-vascular system	14,974,985	5.3
Sensory organs	14,673,929	5.2
Others	10,269,427	3.6
Total	281,869,540	100

Source: AMIP/IMS-Health

Today, the private market ensures 80% of the production of these companies, while the public and foreign markets ensure 10% each. The forty production sites spread over the territory allow to cover 65% of the population's needs and covers all therapeutic classes[43].

As for medicines exportations, they concern Moroccan generic medicines as well as European industrial series relocated by foreign groups, be they brand-name or generic medicines. They rose from Dhs 241 million in 2005 to 475[44] million in 2011 with a sustained growth reaching over 10% per year. Between 2005 and 2008, these evolutions reached 26%[45]. In spite of

43 Competition Council, op. cit.

44 Morocco in figures in 2011 & Currency board, « Rapport du commerce extérieur » [Report on external trade], Final edition, 2011.

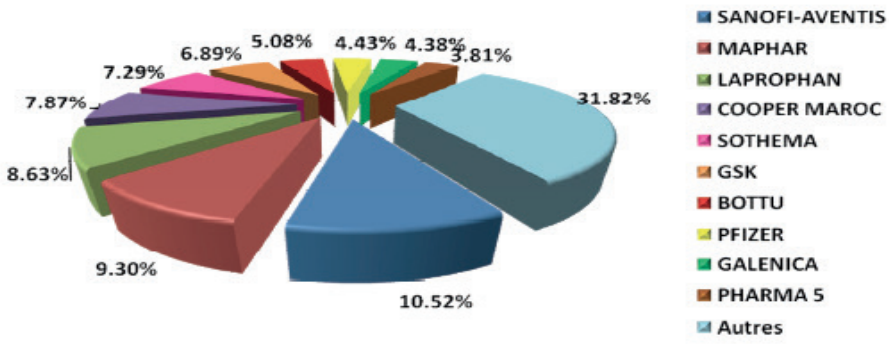
45 Competition Council, op. cit.

this performance, Moroccan exportations remain under that of some countries in the MENA region, such as Jordan, Turkey and Egypt.

■ Main producers and importers

For the year 2009, Sanofi Aventis comes first with market shares in terms of value reaching 10.52%, followed by MAPHAR with 9.30% and by LAPROPHAN (8.63%)[46] (**FIGURE 3**).

FIGURE 3 Market shares in value (Dhs) of pharmaceutical industries



Source: AMIP

■ Access to active substances to produce medicines

The Moroccan pharmaceutical industry is a formulating and packaging industry, as the WHO regularly points out. Therefore, it highly depends on foreign suppliers who know about production and marketing of a strategic good in this sector: the active substance later introduced by the manufacturers to obtain syrups, capsules, pills, ointments, etc.

The low production volumes and the dependence on foreign suppliers of raw materials have direct consequences on the price of medicines. On the one hand, short series have consequences on prices in an industry where economies of scale are essential and represent a significant competitive advantage beside patent ownership or high marketing expenses. On the other hand, the Moroccan pharmaceutical industry depends on raw materials price fluctuations according to their origin and quality. Besides, since Moroccan companies produce under license, a consequence is that very often commercial agreements require the license holder to get his raw material supply to the company that granted it the license[47].

■ Exportations

Morocco mainly exports towards Europe (**TABLE 9**) with Dhs 733 million in 2012, against Dhs 447 million in 2011 (evolution of +54.6%). The main client of the Moroccan pharmaceutical industry is France with exportations reaching up to 71% of exportations towards Europe.

Exportations towards Africa represent 31% of total Moroccan medicines exportations. The main importing countries are those of Arab Maghreb

46 Competition Council, op. cit. & National Observatory for Human Development, op. cit.

47 National Observatory for Human Development, op. cit.

Union (AMU). The Moroccan industry is trying to reach new markets, especially in sub-Saharan countries like Senegal and Ivory Coast[48].

Table 9 Medicines and pharmaceutical products exportations (2011)

Country	Value (Dhs 1,000)	Weight (Tons)
European Union, including:	316,172	1.743
France	306,497	1.637
Belgium	4,896	89
Portugal	2,825	7
Arab Maghreb Union	66,833	246
Other countries*	91,076	380
Total	474,081	2.369

Source: Report on external trade – Final edition 2011.
*: By deduction

■ Importations

The importation of medicines is strictly regulated and controlled by the administration. Indeed, any importation of medicines is subject to the prior approval of the Ministry of Health. They did not cease to increase over the period 2005-2011, to reach Dhs 4.9 billion in 2011[49] (**TABLE 10**). In 2012, they slightly decreased by 6% to reach Dhs 4.6 billion[50]. Through the analysis of importations, we can make out a strong tendency to import medicines of French origin followed by far by the United States and Germany[51].

TABLE 10 Medicines and pharmaceutical products importations (2011)

Main countries	Value (Dhs 1,000)	Weight (Tons)
France	1,461,748	2,917
United States	444,396	148
Germany	359,856	206
Great Britain	292,350	732
Italy	217,301	221
Spain	196,163	505
Belgium	172,610	168
China	85,260	645
Portugal	37,837	67
Saudi Arabia	19,560	130
Brazil	6,174	5
Algeria	1,639	10

Source: Report on external trade – Final edition 2011.

48 Currency board, 2011, op. cit. Currency board, « Rapport du commerce extérieur » [Report on external trade], Provisional edition, 2012, Competition Council, op. cit.

49 Currency board, 2011, op. cit. Currency board, 2012, op. cit. Competition Council, op. cit.

50 Currency board, 2012, op. cit.

51 Currency board; Report on external trade, Final edition 2011.

Besides, the high ratio of the relation between the imported amount and volume finds its origin in the predominance of brand-name medicines in Moroccan importations, either because they all are protected by patents or because of costly technologies or fabrication processes[52]. They are mostly the so-called high-tech medicines, the local fabrication of which remains impossible. This category is mostly dedicated to serious and chronic diseases, especially to anti-cancer and cardiovascular diseases treatments.

■ Production of generic medicines

Between 2003 and 2007, generic medicines, which represent 30% of medicines global market, increased by 65% in volume and by 51% in value. More than 50% of the sales of these medicines are constituted by antibiotics[53].

Generic medicines are necessary for underprivileged people to access healthcare and are an unavoidable means to balance the accounts of health insurance systems (compulsory health insurance, RAMED, etc.)[54]. Currently, the greatest share of generic medicines consumption in Morocco is ensured by the State's public markets. In 2011, generic medicines represented 78% in volume of medicines public purchases and 65% in value[55].

In 2012, a decree[56] regarding the bioequivalence of generic medicines came into force in the context of the clauses of the act 17-04 on the code of medicines and pharmacies. This text defines the bioequivalence and sets up the scientific exemption criteria of the bioequivalence studies for some categories of pharmaceutical forms. It establishes the obligation, for any laboratory, producer or importer, wishing to market generic medicines, to prove by clinical tests that the generic medicine is bioequivalent to the brand-name one. This is a step required by the Ministry of Health to obtain marketing authorization.

Research and innovation

For over fifty years, the Moroccan pharmaceutical industry has been a pillar of the Moroccan economy. Over the last few years, this sector went through a sustained development, with a high level of performance and expertise recognized by the WHO. Indeed, the production conformity of the sector to the international quality standards, and especially the GMPs, allowed to export 10% of its production towards European, Arab and African countries[57]. In order to give more visibility for the ten coming years, the Moroccan Government concluded, in February 2013, a program contract with the representatives of the industrial pharmaceutical sector, aiming at developing the

52 National Observatory for Human Development, op. cit. & L'Opinion, « Industrie pharmaceutique : Jeune et à développement rapide » [The pharmaceutical industry: young and fast-developing], 14 July 2012.

53 « Industrie pharmaceutique : Jeune et à développement rapide » [The pharmaceutical industry: young and fast-developing], L'Opinion of 14 July 2012.

54 National Observatory for Human Development, op. cit. & L'Opinion, « Industrie pharmaceutique : Jeune et à développement rapide », [The pharmaceutical industry: young and fast-developing] 14 July 2012.

55 Ministry of Health – Supply division, « approvisionnement en produits pharmaceutiques : état des lieux et perspectives » [Pharmaceuticals supply: overview and perspectives], 2011.

56 Decree n° 2-12-198 of 21 rejeb 1433 (12 June 2012) regarding the bioequivalence of generic medicines.

57 Ministry of Industry, Trade and New Technologies, « Secteur industriel – Autres secteurs industriels – Pharmaceutique » [Industrial sector – Other industrial sectors – Pharmaceutical industry]. www.mcinet.gov.ma/Industrie/Secteurs%20industriels/AutresSecteursIndustriels/Pages/Parachime.aspx

Moroccan pharmaceutical industry, while covering all production activities, as well as R&D activities.

The program plans the creation of an integrated industrial platform (P2I) that should benefit from the network created in the context of the Emergence Plan for industry in Morocco. The government committed itself to create a P2I combining several possibilities, especially the rental or sale of land, of ready-to-use buildings or of customized premises.

1,017 patents for invention were submitted to the Moroccan Office for Industrial and Commercial Property (OMPIC) in 2012 against 1,022 in 2011. Almost 200 requests of invention patents were of Moroccan origin and nine of the accepted ones concerned pharmaceutical products[58].

The pharmaceutical market in Tunisia

A reminder of a few general economic and socio-demographic data is necessary to better understand the reality of the pharmaceutical market as well as the constraints weighing over it and over the country's health system.

After the revolution of 2011, Tunisia underwent a serious recession along with national and regional unrest. The GDP contracted by 1.8% in real terms, because of a strong drop in tourism and foreign direct investments. As a result of the economic recession and the return of Tunisian workers who worked in Libya, unemployment increased to reach 19% in 2011, unemployment among young people reaching 42%. After a deceleration of 3.5% in 2011, inflation increased and reached 5.7 year-on-year in April 2012.

This macro-economic instability led to the recession of the Tunisian economy as well as to the worsening of commercial, financial and tax imbalances.

The signs of an economic recovery appeared in early 2012. According to the preliminary results of the National Institute of Statistics (INS), the GDP at constant prices increased by 1.2% in the first quarter of 2012 compared to the fourth quarter of 2011. The national economy thus registered a growth of 4.8% for the first quarter of 2012 compared to the same period of the previous year.

The recovery of economic growth in 2012 comes from a good agricultural campaign and a reinforcement of activity in services (+5.3% against - 3.6% in 2011) and in manufacturing (+1.8 against -4.2%). Over this period, tourism and foreign direct investments also progressed with a respective growth of 51.8% and 21.1% compared to 2011.

Even though in 1950 the industrial sector was almost non-existent, preventing local production from developing, Tunisia created the necessary infrastructures and also tried to develop the sector of new technologies,

58 Moroccan Office for Industrial and Commercial Property activity report, 2012.

among which the site of Sidi Thabet for biotechnologies and pharmaceutical industry.

Tunisia has unquestionably an unusual history, standing out from all African Arabo-Muslim countries. The abolition of polygamy, as soon as the independence (1956), associated to a policy of family planning and to the progresses of the healthcare system explains, mostly, the transition model followed by Tunisia.

The infant mortality rate, averaging 200‰ in 1956, reached 17.8‰ in 2009. This decrease in infant mortality resulted in an increase in life expectancy at birth that went from 37 years old at the end of the 1940's to 52 years old at the end of the 1960's and to 74.5 years old in 2009 (72.5 for men and 76.5 for women). The demographic transition was followed by a multifactorial epidemiological transition: a sanitary, social, economic and cultural transition.

The epidemiological profile of Tunisia is characterized by:

- a sharp decrease, an even the elimination, of "traditional" communicable diseases (malaria, bilharziasis, trachoma, tuberculosis, infectious diarrhoea...) and childhood diseases (poliomyelitis, tetanus, neonatal, diphtheria...);
- apparition of chronic and degenerative non-communicable diseases, with a multifactorial etiology and with a costly medical care;
- an increase in road accidents with significant consequences in terms of mortality and morbidity.

The healthcare system is no longer adapted to this new context. Several challenges must be taken up.

■ Healthcare provision

Personal healthcare provision is ensured by a predominant, dense and decentralized public sector (95% of the population lives less than four kilometres away from a basic health centre) and a private sector with increasingly decentralized ambulatory premises and a growing number of hospitals.

There is a high concentration of hospitals in coastal regions (52% of public hospitals and most of private ones). Most of this hospital capacity is located in third-line structures. The same goes for heavy equipment and healthcare personnel. The medical density varies for general practitioners, from 96 for 10,000 inhabitants in Tunis to 36 for 10,000 inhabitants in the Centre-West region. For specialists, it varies from 111 for 10,000 to 12 for 10,000 inhabitants for the same regions.

■ Mobilization of human resources

Tunisia developed important capacities of health-care workers training in various categories. However, the evolution of the healthcare system requires the integration of new professions, especially professions linked to management, engineering and computers.

The development of medical technologies encouraged the public authorities to adopt a "sanitary map of heavy equipment" as a regulation

tool for the installation of this equipment. However, the fast development of private hospitals led to a multiplication of this heavy equipment, faster than in the public sector, without any assessment of this equipment use.

■ General administration and governance

Tunisia implemented a powerful legal and regulatory arsenal to manage the health sector, especially the public part. However, the regulation of private sector healthcare provision remains low, favoured by the absence of intervention levers, such as public funding.

■ Funding system

The health insurance system contains many schemes added up over the years according to the needs of certain occupational categories. Most of the Tunisian population benefits from a health insurance coverage (98%), according to different systems : compulsory social security schemes[59] (68%), free medical assistance (28%) 8% of which benefit from free healthcare[60] and 22% from reduced prices[61]. Beside the compulsory scheme, complementary private insurances can be subscribed to through public and private companies in favour of their employees and public sector employee mutual funds. Even though nearly all the Tunisian population benefits from social security and from total or partial gratuity, the share of household direct spending remains very high (40% of healthcare total spending) and remains inequitable in terms of healthcare access and impoverishment of certain categories of population.

Tunisia is progressively moving towards a payment scheme linked to the activity. A new sharing of healthcare financial costs is taking shape in order to reduce the spending of the Sate and of households and replace them by an increased contribution of compulsory healthcare coverage.

■ Medicines

Even though the pricing of medicines is under control[62] at all the stages and the homologation is homogeneous over the Tunisian territory (in particular for retail distribution), the share of specific medicines (anti-cancer medicines) in the spending is very high.

One must point out that since the adherence of Tunisia to the WTO in 1995, the Tunisian pharmaceutical sector has known deep changes. It is now in a quite dynamic transformation phase with the development of the pharmaceutical industry in general and by the generic medicines industry in particular. Initiatives and the implementation of an adapted legal and regulatory framework favoured, as soon as the 1990's, the privatization of this sector as well as its development.

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59 Social security schemes are open to employees and employers who must become affiliated. The compulsory social security covers pensions, family care, health risk and work accidents as well as occupational diseases. Until 2007, all services were provided by two agencies: the CNSS covering private sector workers and the CNRPS covering civil servants as well as local authorities and public institutions staff. Since then, the management of health coverage was assigned to one agency (the National Sickness Insurance Fund).

60 This category is defined according the poverty threshold and is constituted of families who benefit from a permanent help program. The decree N°98-1812 fixes the conditions and attribution or cancellation modalities of the free healthcare card. People who benefit from free healthcare cannot have access to private healthcare and sometimes have difficulty to obtain or renew their cards.

61 The attribution of reduced prices cards is granted to people with the minimum guaranteed interprofessional wage and according to the size of the family. The beneficiaries must pay flat-rate contributions to healthcare costs at every contact.

62 It is done by the PCT that submits the different prices to the Ministry of Public Health for approbation.

Organization of the pharmaceutical market

■ Pharmaceutical sector actors

The organization of the Tunisian pharmaceutical sector presents unique characteristics, in particular regarding manufacturing and importation control of medicines dedicated to both public and private sectors.

Public organizations of medicines importation. Importation is a State monopoly controlled by the Central Pharmacy of Tunisia (PCT). This organization gives the PCT the power to negotiate very advantageous prices for it acts as an unavoidable partner for foreign laboratories. Besides, the centralized management of medicines both at the national level and between the different sectors (hospitals and private sector) gives it room for maneuver in its management and, in theory, reduces its financial costs. The PCT represents a model for the different countries of the African and Oriental Mediterranean areas[63].

Thanks to the importation monopoly of the PCT, the support to local production and generic medicines, Tunisia controls the prices, availability and quality of medicines as well as their accessibility. This centralization of all importations is a particularity of the Tunisian system. By controlling the prices of imported medicines[64], it contains medicines supply costs in public hospitals and improves the financial accessibility of medicines sold in private pharmacies for most of the population.

Medicines supply through production. The second origin of supply is ensured by the local fabrication of medicines. This sector has known a very important evolution.

Supply. In Tunisia, wholesale distribution is partly ensured by the PCT regarding medicines of chemical origin but also by the network of private wholesalers-distributors. It exclusively supplies medicines for the public sector.

Wholesalers-distributors are intermediaries between importers (PCT) or local manufacturers and retail pharmacies. The official margin of wholesalers is of 8%. They are present in almost all regions of Tunisia, even though their turnover is very variable. A numerus clausus controls the installation of day and night retail pharmacies.

About 60% of the total pharmaceutical consumption is sold by retail pharmacies. The other 40% are consumed in hospitals. Retail pharmacies must be the propriety of a pharmacist, who can only own one pharmacy. The official margin of pharmacists decreases gradually according to the price of the medicine and varies between 24 and 30%.

63 Areas defined according to the WHO.

64 This price stabilization comes from two mechanisms. First, through a direct payment by the centralized supply organization of the potential increases of the purchase cost of imported medicines, and second, through joint purchase and the competition of suppliers in the context of international bids for substitutable medicines supply. The latter increases the negotiation power and reduces management costs.

At the international level, Tunisia stands out by the implementation, since 1976, of retail pharmacies open only at night with an effective and strict separation of night and day pharmacies. One must point out that the amounts of imported medicines are only determined by the prescription volumes and over-the-counter consumption. They are in no case influenced by the structures that centralize importations. This dual public/private model combines an efficient public control of the medicines chain with the flexibility of a private distribution system. Besides, by offering a mutual right of scrutiny between the public and private sectors, it prevents conflicts of interest that could damage the supply system operation.

In November 2011, the sector of medicines for human use gathered 47 laboratories against 30 in 2006 and 27 in 2003. Over the 45 laboratories registered in 2009, ten export their entire production. These laboratories work in the following activities:

- fabrication of medicines prepared for therapeutic or prophylactic use (23 laboratories);
- fabrication of medicines for medical, chirurgical, dental or veterinary use (9 laboratories);
- fabrication of other pharmaceutical products and single-use accessories, such as syringes (13 laboratories).

In 2003, there were 50 wholesalers-distributors employing 1,000 people against 49 private wholesalers in 2000. In 2006, the number of retail pharmacies was of 1,650 with 46 pharmaceutical stores (distribution structures under the responsibility of a retail pharmacy but without the actual presence of a pharmacist)[65].

■ Supervisory and regulatory administrations

In Tunisia, the pharmaceutical market is regulated by several administrative departments. They are the following control and regulatory public organizations:

- the Direction of Medicine and Pharmacy (DPM). It is a technico-administrative unit of the Ministry of Public Health. It is in charge of the creation and follow-up of the national pharmaceutical policy. It delivers all the necessary authorizations for pharmacy and medicines, especially marketing authorizations and clearance authorizations for imported stocks. It manages the installation of pharmacies according to a waiting list (numerus clausus). It organizes the collaboration between the different organizations of the Ministry of Public Health. It also plays the role of interface for all questions regarding medicines between the relevant Ministry and other Ministries (Trade as well as Finance and Industry);
- the National Pharmacovigilance Center (CNPV). It collects and operates, at the national scale, the pharmacovigilance data and gives the alert when it discovers sanitary problems. It also ensures activities of health monitoring at the international level and carries out researches in the literature on the undesirable effects of medicines;
- the Pharmaceutical Inspection Directorate (DIP). It manages all inspections regarding manufacturers, wholesalers-distributors, retail pharmacies and all sanitary establishments with a pharmacy service or simply in possession of medicines stocks;

65 National Council of the Tunisian Order of Pharmacists. www.ciopf.org/Fiches-des-pays/Tunisie

- the National Laboratory for the Control of Medicines (LNCM). This laboratory controls the quality of medicines, of medical devices and cosmetic, corporal hygiene and dietetic products available in Tunisia. It also takes part in the assessment of MA request files;
- the National Agency of the Sanitary and Environmental Control of Products (ANCSEP). This recently created agency coordinates the activities sanitary and environmental control of products of the different public organizations;
- Customs. They are the entry door of medicines in Tunisia. They check the legal character of all medicines and health products importations and only allow goods clearance after getting a unique and specific authorization for each delivery granted by the DMP (clearance ticket).

■ Regulatory frame applicable to the pharmaceutical market

In Tunisia, the regulation applied to pharmaceutical products is quite developed and concerns all the aspects linked to the product's environment.

Medicines registration. The DMP manages the registration procedures for medicines for human and veterinary use and delivers marketing authorizations for imported and locally produced medicines. It also deals with MA follow-up (renewal, cancellation, handover and modification), in accordance with the regulations in force.

The article 5 of the act n°85-91 regulating the fabrication and registration of pharmaceuticals dedicated to human medicine and amended by the act 99-73 of 26 July 1999 specifies that no medicinal products can be debited with or without charge, before prior marketing authorization delivered by the Ministry of Public Health after agreement of the Technical Committee for Proprietary Medicinal Products.

The technical committee that gives a consultative opinion on any MA request submitted to the DPM is a commission, the composition and operation of which are fixed by a decree, the first one dating back to 1987. One must point out that medicines imported in the context of firm orders do not need MA in Tunisia. They are an exception to article 5 of the act 85-91 of 22 November 1985 since it is a flexible mechanism adapted to the particular needs of some patients. Such medicines imported for compassionate use are generally innovative therapies for serious diseases or prescribed for the treatment of rare diseases.

Medicines control. According to article 2 of the act 90-76 of 7 August 1990, the National Laboratory for the Control of Medicines is in charge, among other things, of controlling the quality of medicines. It intervenes in two ways:

- automatic assessment of the pharmaceutical part of the MA file in compliance with a registration procedure managed by the DPM;
- control of medical samples supplied with the MA request or on units taken from the importation of a lot or on distribution or supply premises.

Medicines quality can thus be controlled before and after marketing.

The LNCM also created a guide helping people in charge of assessing the pharmaceutical part of the MA file to give a complete and precise assessment

report, making it easier to decide whether the MA request can be accepted or modified.

Control and assessment of activities of actors implied in the pharmaceutical chain[66]. The Directorate of pharmaceutical inspection is in charge of ensuring the application of laws and texts organizing pharmaceutical professions as well as pharmaceutical products for human and veterinary use. It performs the various necessary inspection, assessment and survey operations in order to guarantee the final quality of the prescribed medicine.

The regulatory framework of inspections mostly relies on the following legal texts:

- Act 61-15 of 31 May 1961 regarding the inspection of pharmacies and other pharmaceutical companies;
- Act 69-54 of 26 July 1969 on the regulation of poisonous substances;
- Act 73-55 of 3 August 1973 organizing pharmaceutical professions;
- Act 78-23 of 8 March 1978 organizing veterinary pharmacy;
- Act 83-24 of 7 March 1983 regarding quality control, marketing and information on the use of breast milk substitute and similar products;
- Act 85-91 of 22 November 1985 regulating the fabrication and registration of pharmaceuticals dedicating to human medicine;
- Act 91-63 of 29 July 1991 regarding sanitary organization.

Four types of inspections were defined depending on whether they are carried out before or after the opening of the establishment.

From a global system of pharmaceutical quality insurance to the implementation of a visa prior to the marketing of each medicines lots. The Act 99-73 of 26 July 1999 amending the brand-name Act n°85-91 regulating the fabrication and registration of pharmaceuticals dedicated to human medicine introduced a 16 bis article stipulating that, in order to be marketed, any medicine must obtain for each lot a visa delivered on demand of the manufacturer or importer, beside the (marketing) authorization.

The National Agency of the Sanitary and Environmental Control of Products is in charge of the procedure and makes sure that the visas of the different control organizations appear on the document, especially the signature of the DPM representative. It is a visa delivered after the analysis of documents issued by the manufacturer of the importer and the signatories may consider it as a purely administrative issue. Without counterfactual analysis, which is impossible to carry out on all lots routinely, the visa cannot really guarantee the quality of the marketed lots. Besides, it may vainly postpone the provision date of the imported or locally produced lots. It also puts into question the very function of the pharmacist in charge of the production site.

■ Public policies and support measures

In Tunisia, the public authorities have implemented incentives to this sector in particular. They are:

- exemption for the purchase of imported raw materials and packaging items;

66 They are health-care personnel and services (public and private), importation, fabrication and marketing units of medicines and products for therapeutic use, cosmetics and corporal hygiene and all other assimilated products for human and veterinary medicines.

- reduced VAT, 6% instead of 16.82%;
- possibility to take part in public market bids for more than two MA;
- margin of preference at 10% granted to national companies in the case of international bids.

■ Institutional framework linked to Euro-Mediterranean, North African and bilateral economic and technical cooperation agreements

Tunisia signed two major international agreements over the last decade: the adherence agreement to the WTO in 1994 and the association agreement with the European Union negotiated in 1995. These two agreements were concluded on principles of strong liberalization of goods and services international trade and more generally in a context of States opening up their economies. In the long term, they may have consequences on the availability and accessibility of medicines in Tunisia.

The consequence of the agreement on TRIPS, added to the adherence agreement to the WTO, are quite known to developing countries that must adopt more constraining regulations in terms of patent recognition for medicines[67-68]. Tunisia prepared for it. The existing legal framework that already allowed the recognition of certain types of patents, is now in compliance with the clauses of the agreement on TRIPS. The practical implementation of these new measures from the end of the transition period (1st January 2005) should not lead to substantial modifications of the operating mode of the Tunisian pharmaceutical system and in particular of that of the PCT.

Medicines demand and its characteristics

The studies carried out by the Ministry of Public Health allowed to evaluate the value of the pharmaceutical supply (importation price or sale price of local manufacturers) rather than the consumption. In that sense, the pharmaceutical consumption in Tunisia rose from about Dt 400 million in 2001 (US$ 278 million) to Dt 530 million in 2005 and to Dt 974 million in 2010 (**TABLE 11**); showing an average annual increase of 16.75% over the last period. This consumption is characterized by the important use of medicines dedicated to the treatment of infectious diseases, of diseases linked to the digestive and nervous systems as well as of cardiac diseases. In 2010, these medicines represented nearly 70% of the total pharmaceutical market (anti-infectious medicines: 40%, digestive system: 15%, cardiovascular system: 15%). Medicines linked to the central nervous system represented 10% of this market.

Besides, in 2010, the pharmaceutical spending in Tunisia reached Dt 1,293 million (US$ 895.43 million), that is 44% of the total health spending (against 30.2% in 2001) and 2.2% of GDP. Only 30% of this spending was allocated to the public sector. The pharmaceutical spending reached Dt 122.57 (US$ 84.88) per inhabitant in 2010, against Dt 70 in 2006 and Dt 30 in 1995.

67 World Trade Organization. Agreement on Trade-Related Aspects of Intellectual Property Rights. Geneva, WHO, 1997.

68 Velásquez G, Boulet P. Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement. Geneva, WHO, 1999.

TABLE 11 Evolution of pharmaceutical consumption in Tunisia (million Dt)

	1987	1990	1995	1999	2000	2001	2003	2005	2010
consumption	105.7	109.4	174	346	289	400	440	530	974

Medicines offer

■ Size of the pharmaceutical market

According to the data of the National Institute of Statistics, the pharmaceutical market in Tunisia represented Dt 896 million in 2010 against dt 620 million in 2006 and Dt 321 million in 1999. One must point out that the peaks took place in 2004 (15%) and 2008 (20%). 51% of this market is supplied by importations. This proportion of importations significantly decreased since it reached 61% in 2005. As for the national production, it registered peaks in 2006 and 2008 with respectively 24% and 29% increases (**TABLE 12**).

TABLE 12 Evolution of the pharmaceutical market size in Tunisia (million Dt)

Year	National production	Importations	Total	Evolution (Basis: 1999)			Share of National production	Share of importations
				National production	Importations	Total		
1999	144	177	321	100	100	100	45%	55%
2003	183	264	447	127	149	139	41%	59%
2004	209	307	516	145	173	161	41%	59%
2005	220	338	558	153	191	174	39%	61%
2006	272	348	620	189	197	193	44%	56%
2007	280	405	685	194	229	213	41%	59%
2008	360	459	819	250	259	255	44%	56%
2010	436	460	896	303	260	279	49%	51%

Source: National Institute of Statistics and Central Pharmacy of Tunisia

Since the mid-1990's, the prices of importation medicines have been increasing much more than the prices of locally produced ones, which are mostly made of former substances that fell into the public domain. In parallel, one can note a move towards the consumption of more recent importation medicines at higher prices. Therefore, the importation global volume decreased between 1990 and 1999 by nearly 14%, highlighting the increase of medicines local production, but this decrease in volume does not balance the increase in the cost of imported medicines (increase of 74% of the importations value over the same period).

Besides, the increase in the cost of imported medicines in dinars is very high. This evolution is not due to an increase in quantities since the volumes imported over the period decreased but they can be explained by the depreciation of the Tunisian currency compared to the main international

currencies, especially the dollar (the cost of importations in dollars remains almost constant) and by the strong increase in medicines prices on the global market, in particular for new treatments.

■ Main producers and importers

In 2009, the laboratories Adwa, Teriak, Saiph, Sanofi Aventis, Siphat, Galpharma, Unimed, Medis, Winthrop pharma, Berg Life sciences produced the twenty specialties taking up most of the pharmaceutical market turnover in Tunisia. As for importation, the Tunisian pharmaceutical market is largely dominated by foreign groups. The major importers of the pharmaceutical sector in Tunisia are: Novartis, Aventis pharma, Novo Nordisk, Roche pharma Schweiz, Norgine pharma, Serono pharma schweiz, BMS, Astra Zeneca.

■ National production

The major effect of the correlation system in Tunisia was that of an important growth in local production capacities. Indeed, in 2010, the national production covered 49% of the total consumption, against 45% in 1999, 14% in 1990 and 8% in 1987. This production is divided between brand-name medicines (39%) and generic medicines (61%). The number of MA delivered for local products is of 1,733 out of a total of 3,548 marketed MA.

Over the period 2004-2008, the investments realized in the pharmaceutical sector reached an annual average of Dt 27 million. They allowed the creation of 790 jobs in 2008.

■ Importations

Medicines importations progressed of 9% per year in average over the last decade. In 2008, 97% of imported pharmaceuticals were medicines prepared for therapeutic use. The pharmaceuticals imported come from 34 countries. France is the main supplier. In 2010, the share of medicines imported from France represented 75% of importations[69]. It was followed by Switzerland (13%), the United Kingdom (6%), Italy (4%), Denmark (3%) and Germany (3%).

This distribution between supply countries is not the consequence of a preference from the Tunisian sanitary authorities for there is no benefit for products according to their origin in the granting of an MA or in the importation process. One must point out that the data here above concern the country of origin and not the country of fabrication of medicines. These data can be explained by the fact that pharmaceutical laboratories, for practical reasons probably, tend to organize their importations towards francophone countries from their branches located in France.

Sorted by therapeutic class, the data available goes back to 2003. Out of the Dt 236 million of importations realized by the Central Pharmacy of Tunisia (out of a total of Dt 264 million of all importations), 16% represent anti-infectious pharmaceuticals, 14% concern cardiology, 13% the digestive system and 10% the nervous system.

69 The share of pharmaceuticals imported from France significantly decreased since it reached 70% in 2001 and 76% in 1993.

■ Production for exportation

In Tunisia, the exportations of pharmaceutical products reached about Dt 40 million in 2010 against 30 million in 2008 and 19 in 2004. They correspond to sales on bids rather than to regular exportations. Pharmaceutical exportations were divided as follows: 70% were destined for the North African market, 15% for Europe and 15% for African and Arab countries. In 2008, 93% of pharmaceutical industries' exportations were medicines for therapeutic use.

■ Access to active substances to produce medicines

The pharmaceutical industry presents an average rate of local integration of about 40%. Indeed, in Tunisia, there are no production units of active substances, which makes Tunisian laboratories dependent on the importations of this necessary input. Other raw materials of local origin are mainly primary packaging items – except glass packaging that are all imported – and cardboard printed packaging.

■ Types of marketed pharmaceuticals and products

The range of pharmaceutical and paramedicinal products marketed in Tunisia is similar to that marketed in developed countries. In 2008, it contained 13,117 articles and was divided as shown in **TABLE 13**.

TABLE 13 Distribution of pharmaceutical and paramedicinal products by product family

Product family	Number of articles
Medicines for human use	3,146
Veterinary products	504
Dental products	640
Biological reagent	321
Ligatures and dressings	513
Chemical products	1,614
Homeopathy products	127
Accessories	1,015
Pharmaceutical products	5,237

Source: PCT

Sorted by therapeutic class, the distribution of the pharmaceutical market shows that in 2003, nearly 20% was allocated to anti-infectious medicines, 14.5% to medicines for the digestive system, etc. As for the national fabrication of pharmaceuticals, it concerns a quite diversified range of products. It includes pills, capsules, powders, vials, syrups, creams, suppositories, injectable medicines, penicillin and sing-use syringes.

Pharmaceuticals in dry form (pills, capsules, powders) represent 44% of production, against 23% for pasty and semi-solid forms (suppositories, ointments) and 33% for injectable and drinkable liquids.

■ Production of generic medicines

For several years, Tunisia has implemented a policy to encourage the use of generic medicines via regulatory measures, sectorial encouragement to the local fabrication of generic medicines and international bids for the supply of medicines of interchangeable origin, including for retail pharmacies.

Therefore, Tunisia adopted measures at the beginning of the 1990's in order to favour local production:

- exemption of custom duties for raw materials and packaging items;
- reduction of custom duties for equipment, advantageous VAT rate, taxation of similar imported products;
- benefits granted to local producers in the framework of public markets regulation;
- correlation system. On demand of a Tunisian manufacturer, the importation of a pharmaceutical similar to a locally produced one can be suspended according to certain conditions (especially if the manufacturer commits himself to maintain a minimal stock equivalent to the stock that the PCT would have of the imported product);
- authorization of subcontracting, making possible the cooperation between companies and the optimization of production capacities.

This policy of encouragement to the local production of pharmaceuticals, and in particular of generic medicines, thanks to the correlation mechanism, contributed to the fact that in 1997 about two thirds of locally produced medicines were generic ones.

The market share in value of generic medicines even decreased quite significantly, and especially in hospitals. In 2001, 37.6% in value of medicines provided in hospitals were generic ones against 47.4 in 1997.

However, generic medicines have not, to this day, known the development whished by public authorities. Here is why:

- absence of substitution right by the pharmacist, even though it is legally recognized;
- mechanisms of price control that make the price difference between brand-name and generic medicines quite low;
- the culture of prescriptions of brand-name medicines instead of INN;
- the salary of wholesalers-distributors and retail pharmacists is a percentage of the sale price. It is therefore lower if the sale price is low.

Research and innovation

Tunisia implemented legal and financial measures to promote research and development. It now has 35 research centres, 147 laboratories and 610 units specialized in scientific research, of which 50% specialized in biotechnology. Orientation modifications linked to the regulation in terms of medicines patents were implemented. The national legislation came into force on 1st January 2005.

One must point out that, since the adherence of Tunisia to the WTO, the INNORPI started accepting inventions regarding medicines. From 1995

to the end of 2004, it received no less than 800 patent requests for pharmaceuticals. These requests were accepted and their delivery procedure was postponed until January 2005 in virtue of article 103 of the law on patents and in accordance with article 65 (TRIPS) stipulating that *"to the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years."*

For a better North African integration of the pharmaceutical market and of a pharmaceutical production industry

The previous section facilitated the understanding of the organization of the pharmaceutical market in the three North African countries. This section shows what are the main similarities, differences and complementarities between these markets and the various assets and obstacles regarding the possibility to create an integrated North African market.

Complementarities between pharmaceutical markets in North Africa

The importance of the pharmaceutical market in the three countries, regarding both local production and importation, encouraged local authorities to give it a specific legislation as well as an important regulatory framework. They all implemented procedures in terms of registration, distribution and control of these highly sensitive products[70].

■ The pharmaceutical sector is characterized by the intervention of public and private actors with a predominance varying from one country to another

Since their independence, the three North African countries built a real pharmaceutical industry in order to produce their own medecines, alone or in partnership with large multinational groups. They retained, for the pharmaceutical sector, the intervention of public and private actors with a predominance varying from one country to another.

Algeria works with both sectors but greatly favours the public sector. The pharmaceutical market was, until 1990, exclusively under the control of the State. Since then, the country targeted the development of its local pharmaceutical industry in order to reduce the important costs of importations and thus become a production platform of generic medicines. The cancellation of the state monopoly allowed the emergence of private operators that are now developing quickly[71].

Just after its independence, Morocco chose a pharmaceutical industry in which private initiative was the main development tool. The modalities of technological transfer in this sector were made possible through the association of the national private capital and the international capital (multinational). Since 1957, the public authorities chose to develop a pharmaceutical industry with a national production, distribution and marketing open to the private sector, in the context of a regulated liberal economy under the authority of the Ministry of Health.

70 Bouguedour R., « Conférence de l'OIE sur les médicaments vétérinaires en Afrique » [Conference of OIE on veterinary medicines in Africa], Dakar, 25-27 March 2008.

71 Ministry of Industry, Small and Medium-size Enterprise and Investment Promotion, op. cit.

Tunisia lies somewhere between these two countries. It made an effort to regulate the pharmaceutical sector, which presents specificities requiring the intervention of public and private actors. For many years, the pharmaceutical policy has been relying on a strong public sector. Public supply structures centralize importations of medicines destined for both public and private sectors. The PCT plays an important role and represents the main operator and regulator[72-73].

The liberalization of the sector also allowed the development of a private industry as well as the reinforcement of partnerships with multinational companies that entrusted Tunisian laboratories with the production and marketing of some of their products.

■ The sector is regulated by different public structures of regulation and control with a defined expertise

In the three countries the pharmaceutical sector is regulated by several administrative departments with a significant and determining influence on the market. The Ministry in charge of Health remains the department in charge of exercising the main regulation and control authority in accordance with rules determined by regulatory texts and via varied structures (Direction of Medicine and Pharmacy, Pharmacovigilance Center, Medicines control Laboratory, Directorate of Pharmaceutical Inspection, etc.).

Other departments intervene according to the cases in each country. For instance: the Ministry of Work and Social Security in Algeria, the Ministry of Trade and New Technologies in Morocco and Custom Authorities in Morocco and Tunisia.

Besides, the pharmaceutical market is highly regulated, be it in Algeria, Morocco or Tunisia. This regulation concerns all the aspects linked to the environment of pharmaceuticals and defines the conditions and modalities ruling the sector. The implementing texts are quite varied (decree, order, circular, resolution, etc.) thus illustrating the variability of their implementation level. The scope of application of these texts remains rather homogeneous and concerns all the pharmaceutical industry (importation, registration, use, etc.).

Indeed, the three North African countries have a registration procedure for medicines requiring the intervention of a technical commission placed under the authority of the Ministry of Health. The MA enquirer must supply technical and administrative files. The nature of the required documents varies from one country to another.

Besides, the MA enquirer must supply samples of the product as it is a compulsory part of the regulatory procedure in the three countries. The samples are analysed under all their aspects by national laboratories of pharmaceutical products control[74].

72 Chaoui F. & Legros M., "Les systèmes de santé en Algérie, Maroc et Tunisie : défis nationaux et enjeux partagés" [Health systems in Algeria, Morocco and Tunisia: National challenges and joint issues], IPEMED Notes – Studies and analysis, April 2012.

73 WHO, 2003, op. cit.

74 Bouguedour R. 2008, op. cit.

There are also control procedures for imported medicines, at the border posts of each of the three countries. They concern MA checks as well as the physical control of products. This control can also consist in random sampling to carry out analysis in laboratories[75].

■ Morocco and Tunisia apply international standards and technical references

The Moroccan pharmaceutical industry is known to meet the international standards. The industry is submitted to a very strict fabrication for companies must respect the Good Manufacturing Practices recommended by the WHO and by European medicines agencie. They are also subject to the direct control of the Ministry of Health via the Direction of Medicine and Pharmacy (Pharmacy inspection and National laboratory for medicines control).

The quality control refers to international standards and technical references, especially European and American pharmacopeias, WHO directives, European (EMA, EDQM) and American (FDA) guidelines, guidelines of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, the European and WHO Good Manufacturing Practices guides and international standards[76-77-78].

Tunisia also applies a regulatory and legal framework that allowed the implementation of a national system of medicines quality control in compliance with international standards, the coordination of which is ensured by the Direction of Medicine and Pharmacy[79].

As for Algeria, the standards applied are not in compliance with the medicines international standards. The deficiencies lie at different levels, mostly in the administration, management and general organization, with insufficient computerization. The reference standards applied are mostly ISO standards and not pharmaceutical standards (BPF/GMP), which are the only valid standards for a recognition of medicines quality[80]. The regulatory and legal framework remains incomplete for some categories of products (biotechnology medicines, medical devices, OTC and paramedical products) and obsolete for the upgrading to standards and good practices (BFP, BPD and BPO) facing the important development of these standards worldwide[81].

■ The local production of medicines is booming (local and foreign investors)

The development of the pharmaceutical industry in the three countries grew with an increasing number of production units (4 units in 1985 to 56 in 2011 in Algeria, 8 units in 1965 to 40 in 2013 in Morocco, 3 units in 1987 to 31 in 2006 in Tunisia).

75 Daré I. « Harmonisation de l'enregistrement et du contrôle des médicaments vétérinaires en Afrique » [Harmonization of registration and control of veterinary medicines in Africa], OIE Conference, 2007.

76 Competition Council, 2011, op. cit.

77 Doctinews, 2012, op. cit.

78 Bouhdiba S., « Les systèmes de santé et le VIH au Maghreb » [Health systems and HIV in North Africa], 2008.

79 L'Industrie pharmaceutique en Tunisie 2010 [The pharmaceutical industry in Tunisia], www.cat2012.tn/media/Pharmaceutique.pdf

80 Euro-Développement PME Alger, « Analyse de la filière Industrie Pharmaceutique en Algérie » [Analysis of the Pharmaceutical Industry Sector in Algeria], October 2007.

81 www.nabni.org/nos-propositions/sante/bilan-et-situation-en-2012/04/08/2013

The national production in Algeria is clearly increasing (it doubled in five years) thanks to great investment efforts of about Dzd 100 billion realized over the last ten years. However, it stays behind compared to the fast growing market. It represents 35% (US$ 1 billion) of the current market even though the industry has acquired recent equipment up to international standards, it produces medicines that have fallen into the public domain for a long time, therefore with a low added value.

However, the Algerian pharmaceutical industry draws the most interest from multinational group, for its market is considered as the most important in the region.

Morocco is the most advanced country in medicines production, however, its industry is still reduced to manufacturing generic medicines from imported active substances. The 40 industrial pharmaceutical sites cover 65% of the population's needs, the rest being imported. Even so, they only work at 40% of their production capacity and their future remains uncertain in a globalized economy.

Morocco is trying to export part of its production; which could boost production in better conditions.

Over the period 1999-2008, investments evolved at a sustained pace, which explains the confidence of operators in this industry's future. Generally, investments registered a rapid growth from Dhs 25 million in 1985 to Dhs 100 million in 1990. Since 1995, the annual average lies between Dhs 200 and 300 million.

Tunisia lies somewhere between the other two countries. Over the last fifteen years, the local production of medicines registered a strong growth. From 1987 to 2008, the consumption covered by local production went from 8% to nearly 50%[82].

■ Centralization of medicines purchase for the public sector (PCH in Algeria, DA in Morocco and PCT in Tunisia)

The centralization of medicines purchase allows acquiring a real negotiation power face to an increasingly important concentration of the global pharmaceutical offer. This centralization presents advantages in terms of profitability, costs and order planning to avoid stockoutage or excess of stock[83].

The three North African countries have a centralized system for medicines purchase ensured by different institutions (Central Pharmacy, Ministry of Health, etc.).

The Hospitals Central Pharmacy in Algeria, legally in charge of supplying hospitals, supplies them on a regular basis at reasonable prices. As a public

82 Chaoui F. & Legros M., "Les systèmes de santé en Algérie, Maroc et Tunisie : défis nationaux et enjeux partagés" [Health systems in Algeria, Morocco and Tunisia: National challenges and joint issues], IPEMED Notes – Studies and analysis, April 2012.

83 BenMansour Sonia; Le Financement des systèmes de santé dans les pays du Maghreb [Financing healthcare systems in North African countries]; Thesis 2012.

organization, it ensures the functions of a purchasing body for public hospitals and takes part in prevention national programs[84].

The Supply Division (DA) of the Ministry of Health in Morocco also plays the role of a medicines purchasing body for hospitals and basic health centres. In terms of selection, purchasing and distribution of medicines, the DA implemented tools that should allow a better availability, lower costs and a better quality of medicines on the public market. The efforts of the Division mainly focus on the affordability of medicines in the public sector with the offensive use of bid that, indeed, are not international.

The PCT is the main regulator of the pharmaceutical supply system in Tunisia. This organization developed a good knowledge of the global pharmaceutical market and of contract negotiation, which is a valuable skill for the country's pharmaceutical system. Until now, this monopoly ensured cost control (acquisitions through bids), price uniformity and control, supply regularity of the country and support to healthcare programs through the mechanism of self-compensation, the principle of which is to increase the price of non-indispensable medicines and to use these benefits to balance the price of medicines used in healthcare programs[85].

■ A strategic position to reinforce the place of generic medicines

The public authorities of these three countries, aware of the current weakness of the generic medicines market and of their economic interest, fixed ambitious objectives in their pharmaceutical policies in order to reduce the colossal healthcare spending leading to deficits in the States' coffers. The consumption of generic medicines in Algeria registered a growth of 10 points in just one year (2008/2009), rising from 28% to 38%[86]. Algeria needs to optimize the use of its financial resources while stimulating the access of citizens to medicines and basic healthcare. To do so, the State encourages the production of generic medicines rather than their importation. It relies on promotion campaigns for generic medicines and the implication of doctors, on tax exemption in the promotion of generic medicines, the cancellation of the importer status and the creation of a pharmaceutical operating status as well as a better control of medical promotion.

In Morocco, generic medicines are booming and represented 30% of the national market in value in 2012. Wishing to reduce healthcare costs as well as to make access to medicines easier, the State committed itself in a reform process placing generic medicines at the centre of its priorities. The Ministry of Health aims at rising the share of generic medicines at 70% of the total consumption in the country by 2015, most of the current consumption being dedicated to the public sector. It is about to adopt important measures to promote the sales of generic medicines (implementation of substitution right with a revision of the margin system of pharmacists and the application of progressive margins with a more interesting price scale for generic medicines in favour of pharmacists[87].

84 Hospitals Central Pharmacy; www.santemaghreb.com/algerie/comptes_rendus/jnp.../jour2_1_delih.pdf

85 Pr. N. Achour ; Le système de santé Tunisien : état des lieux et défis [The Tunisian healthcare system: overview and challenges]; 2011.

86 Islamic Centre for Development of Trade; Pharmaceutical industry in the member States of OIC; 2012

87 Observatoire de l'entreprenariat – étude sectorielle pharmaceutique [Observatory of entrepreneuship – Pharmaceutical sectorial study], 2011.

For Tunisia, in 2009, generic medicines represented about 47% of the value of the pharmaceutical products sold over the country, or nearly Dt 141 million (€ 73 million).

Obstacles and assets linked to the integration through the market and through production

For years, everyone has agreed that a better integration of the economies of North African countries is necessary to boost the economic development of the area and reduce unemployment. In 2006, the IMF estimated the volume of economic and commercial North African exchanges at 3% of all their exchanges with foreign countries. The lost profit coming from the North African non-integration was estimated at two points of growth for the region's countries.

Since then, inter-North African trade increased. In 2008, the exchanges of Tunisia and Libya progressed of 40%, those with Algeria of 85%, with Morocco of 24% and with Mauritania of 52%. However, all of these exchanges only account for 7% of trade in the five UMA countries. During the symposium organized in February 2009, for the celebration of the 20th anniversary of the creation of the UMA, the participants highlighted the *"huge unexploited potential of the UMA, which must be exploited in the framework of a complementary economic union"*.

The aim of this partnership is to create a North African space to contribute to the creation of a real pharmaceutical market in the region. A better collaboration, through a unified pharmaceutical industry and registration procedures, could lead to a strong North African economic space in a betteposition to negotiate with suppliers[88].

Integration through the pharmaceutical market

■ Joint purchase of pharmaceuticals

The joint purchase of pharmaceuticals is an experience that dates back to the 1980's. It is the result of cooperation efforts in the healthcare sector between the UMA member States (Algeria, Libya, Mauritania, Morocco and Tunisia). At this time, the pharmaceutical regulation in the UMA member States was different, the range of products varied from one country to another, the local production was low and only satisfied a small part of their needs and purchase prices for the same products varied of more than 30% over the region. The governments, confronted to the challenge of maintaining and increasing the quality of life of a growing population, joined their efforts, at the end of the 1980's, in an initiative of regional cooperation aiming at medicines joint purchase.

88 « Faire du Maghreb une place forte de la pharmacie mondiale » [Making of North Africa a bastion of the wolrd's pharmacy], www.livretsante.com/pharm-info/articles.php?arti=170 01/09/2013

In 1981, Algeria and Tunisia created a "Dual committee for joint purchases". This experience, which lasted eight years, allowed buying regularly, and increasingly, medicines, raw materials as well as chemical products. Following this experience, and after two preliminary meetings in Casablanca (28-30 June 1988) and in Tripoli (28 November and 1st December 1988), the Ministers of Health of North African countries decided to broaden this Mixt committee to include the five North African countries, under the name of North African Committee for joint purchase. The first meeting of the Committee was held in Algiers from 3 to 5 April 1988. Two years later (Algiers, 5 May 1990), the North African Ministries of Health gave it a legal character by signing the Convention regarding its creation[89].

The process of joint purchase by the Committee was meticulously prepared and the tasks and responsibilities well defined and documented.

Indeed, the Committee created its own procedure of joint purchase management that starts, each year, by a declaration of bids in one of the North African countries. This country must establish the procedure regarding the realization of this bid over three sessions:

- first session: the Committee assesses the results of the previous year's bid and revises the conditions as well as the list of medicines that will be concerned by the new bid. It establishes a calendar for the bid process with the publication date, the deadline for the acceptation of offers and the date of the next meeting;
- second session: it is dedicated to the opening of envelopes, a first evaluation of offers and demand of counter-proposals to suppliers previously selected;
- third session: it consists in studying the counter-proposals and to make the ultimate decision regarding the bids' attributions.

TABLE 14 presents the realizations of the North African Committee for Joint Purchase over a period of ten years through the different bids launched and the evolution of the number of products demanded.

89 North African countries are represented at this committee by: ENAPHARMA, ENCOPHARM, ENOPHARM and PCH (Algeria), PCM (Morocco), DMEAICO and MSO (Libya), PCT and SIPHAT (Tunisia) and Direction of Medicine and Pharmacy of the Ministry of Health (Mauritania).

TABLE 14 Evolution of the number of pharmaceutical products bought in the framework of bids launched by the North African Committee for joint purchase

Year	Date	Place	Pharma. products	Raw materials	Packaging materials	Minor medical equipment
1989	02-05 April 01-03 July 17-21 September	Algeria	113	37	–	–
1990	29-31 January 07-11 May 16-18 July	Tunisia	128	38	–	–
1991	07-09 May 23-27 July 04-05 November	Morocco	144	42	–	
1992	20-22 January 01-04 May 28-30 July	Libya	144	42	07	–
1993	02-05 February 18-23 May 20-23 July	Mauritania	144	42	09	–
1994	–	–	–	–	–	–
1995	–	–	–	–	–	–
1996	24-26 February 30 May – 04 June 05-09 September	Algeria	128	39	13	–
1997	26-28 February 14-18 May 09-11 July	Tunisia	168	46	09	75
1998	23-25 February 16-20 May 14-16 July	Libya	171	46	09	75
1999	12-16 March 02-08 June 04-08 August	Mauritania	171	41	07	75
Total			**1,311**	**373**	**38**	**225**

For two years Morocco did not take part in the joint purchase system. It had left the Committee three years earlier. Besides, Algeria did not take part in the last purchase cycle. However, in spite of these withdrawals, the joint purchase system survived and maintained its operations. The Committee is still implied in the common purchase system for the three other UMA countries.

The North African Committee for the joint purchase of medicines was a flexible, productive and cheap mechanism, without administrative issues. It allowed the member States to gain new assets. They are mainly:

- better profits in terms of prices[90], delivery time and payment modalities;
- reinforcement of the cooperation between national laboratories in Algeria, Morocco and Tunisia, especially regarding the quality control of the samples concerned by bids;
- development and broadening of the list of medicines and pharmaceutical products that can benefit from joint purchase;
- knowledge of the North African pharmaceutical market, essential to the development of local production;
- encouragement of purchases with North African suppliers through the selection, among them, of the best candidates;
- encouragement of commercial complementarity and exchanges in the five North African countries in terms of medicines;
- evaluation of the possibility to standardize medicines registration methods;
- the Committee and its meetings represented some kind of observatory for information sharing regarding suppliers and pharmaceuticals, which allowed to choose the best suppliers and medicines and to include the best technical and scientific demands in the specifications;
- the Committee represents an adequate organization to fight against counterfeit medicines or non-compliant with international standards. International reports show that 25% of medicines in developing countries are either counterfeit medicines or non-compliant with international standards. This percentage reaches 60% in some poor countries;
- the Committee had started to create a file for each supplier and each medicine in order to provide some follow-up and observe their evolutions.

However, the North African Committee had difficulties regarding the realization of joint purchase. They are mostly:

- different custom procedures that had, in some cases, a negative impact on the medicines supply process in the imparted time;
- different legal texts relating to medicines registration, creating difficulties in the introduction of some medicines in the fixed list;
- lack of precision in the identification of purchased products that can, sometimes, prevent countries from fulfilling their obligations towards suppliers and undermine the committee's credibility;
- withdrawal of some members for certain offers. The amounts of medicines usually necessary were therefore revised downwards, thus impacting the prices;
- difference between the lists of essential medicines of the different member States, which prevented the creation of a unified medicines list.

Even though the joint purchase process presented potential positive effects of medicines accessibility for a wider public, the UMA suppliers were not always well prepared for this type of regional competition inherent to a joint purchase system. The production capacities did not suffice and suppliers had to make concessions in order to offer affordable price.

As for Moroccan producers of generic medicines, they consider that the joint purchase system is an opportunity rather than a threat. They discovered an exportation market way bigger than their local sales.

90 The assessment of prices before and after joint purchase, carried out by the Moroccan Ministry of Health, highlighted a price difference (and therefore savings) going from 1 to 5 thanks to the introduction of generic medicines and competition between suppliers.

In May 2008, the North African Ministers of Health gathered in Tunis for the 10th Ministerial Council. During this session, the council issued a certain number of recommendations aiming, among others, at reinforcing and developing cooperation relations as well as partnerships between North African countries, through:

- the activation of the medicines and vaccines common purchase medicines;
- the creation of a convention regarding medicines control, including raw materials;
- the creation of a data bank specific to medicines;
- the organization of a forum for the actors of the pharmaceutical sector;
- the preparation of fixed lists for essential medicines;
- the cooperation in the field of pharmaceutical inspection and protection of the right of intellectual property in the pharmaceutical sector.

Following these recommendations, a technical commission for medicines purchases was created. It aims at implementing a common mechanism of medicines, vaccines and serums purchase, creating a common list of basic medicines and a unified list of medicines joint purchases. It also wishes to facilitate the cooperation between national laboratories carrying out medicines quality control in order to fight efficiently against illicit trade of medicines.

Besides, the North African ministerial Committee adopted an exclusive program regarding, among other things, the joint purchase of medicines, vaccines, serums and medical items. This program was difficult to implement because of the absence of a permanent coordination and follow-up mechanism, in spite of the various meetings and encounters. Indeed, regarding the joint purchase of medicines and medical items, a meeting was held in December of the same year in order to boost the joint purchase Committee and broaden its mandate to include joint purchase of vaccines and serums. The first international bid must have been launched before the end of 2010.

The Technical Committee of medicines joint purchase also addressed, at the meeting held in Tunisia on 26 and 27 May 2009, the preparation of medicines, vaccines and serums lists concerned by this bid. It also organized the calendar of meetings regarding the bid announcement (24-25 February 2010), the opening of envelopes, the study of propositions (May 2010) and the final attribution of the bid (31 July 2010).

The meeting that was supposed to result in the bid announcement was cancelled because the representatives of some countries were absent and the medicines lists of the present countries were not available. Besides, and in spite of the reminders of the North African ministerial Council, it has not, to this day, received the lists of medicines, serums and vaccines.

Having noted the difficulties that prevented the announcement of the first bid in 2010, the North African Council of Ministers of Health, during the 11th session, held in Rabat from 14 to 16 January 2013[91], asked the medicines Committee to dedicate its next meeting to the question of the joint purchase

91 In the framework of the follow-up of the implementation of the recommendations of the Council of Ministers for Foreign Affairs of the Arab Maghreb Union (Rabat, 18 February 2012).

of medicines and vaccines. It concerned the evaluation of past experiences, the reflection and discussion of the necessary means to overcome the difficulties and obstacles that still prevent the realization of this bid and to make practical and precise propositions in this respect that would be submitted during the next Council.

■ Medicines registration

The basis of any system of flow control, and more particularly of the importation, of pharmaceutical products is their registration. It must allow to check the existence of a guarantee of fabrication quality, of the therapeutic relevance, of the security and harmlessness of the product, as well as the quality of joint information[92].

As already mentioned, the medicines registration process is well codified in the existing regulatory texts be it in Morocco, Algeria and Tunisia and the MA is the final process at the end of which the authority agrees on the marketing of the medicines object of the request. Indeed, all the countries in this study demand the registration (or homologation) of all the products marketed on their territories. These local MAs are delivered for a 5-year period. They can be refused, withdrawn, suspended, and renewed or not. The marketing authorization request is studied by a commission under the authority of a Pharmacy Directorate. The authorization is delivered by the Ministry of Health and registered by a service of the Pharmacy Directorate.

Besides, during the 10th session held in Tunisia in 2008 and the 11th session held in Rabat in 2013, the North African Council of Ministers of Health issued a certain number of recommendations aiming at the cooperation regarding medicines registration, their organizations and their regulation via the unification of the control systems of medicines quality of UMA countries and the standardization of scientific and technical files adopted in that field. In this respect, a workshop should be organized in Algeria for the redaction of a North African project of coordination of medicines registration systems. However, the current context in the region did not allow, until now and in spite of the many encounters on the question, to implement the legal and regulatory instruments as well as the institutional and organizational framework to improve the situation.

Therefore, Algeria, Morocco and Tunisia must make an effort to control the regulatory, economic and moral constraints in order to evolve towards a better organization of their healthcare authorities and towards a better control of the pharmaceutical market[93]. The necessary condition to obtain a controlled, available and accessible pharmaceutical specialty for consumers is the attribution of an MA by the concerned healthcare authorities.

A coordinated North African approach and a network of quality control laboratories is the best way to reach an efficient common system of MA for medicines within and between the countries. In this respect, the approach adopted by the European Union is considered as exemplary and can be a model in terms of standardization of the regulations leading to the marketing authorization of a medicine in North African countries.

92 C. BRUNETON ; J.P. NABOULET ; B. VAN DER HEIDE ; 1996 ; The drug trade between European countries and developing countries: efficiency of regulation systems, issues and perspectives.

93 Sabrina Boismenu; Politique de santé et enregistrement d'une spécialité pharmaceutique au Maghreb [Healthcare policy and registration of pharmaceuticals in North Africa]; 2006.

The European standardization of the regulations of medicines marketing was ensured by the creation, in 1993, of common registration procedures and also of the European Agency for the Evaluation of Medicinal Products. Indeed, while the medicines registration system had remained purely national for a long time, a European regulatory environment was implemented at the end of the 1980's for medicines derived from biotechnologies. This device, including a peculiar registration procedure for this type of medicines, was also open to other medicines of public interest. Therefore, most medicines used against the HIV infection were assessed via this procedure. A collaborative assessment had to take place as soon as the medicines were to be authorized in more than one State of the European Community. This collaborative procedure allowed the registration of over 80 pharmaceuticals, most of which are biotechnological products. It also allowed the national regulatory authorities to assess these new types of products simultaneously, with identical files and in the requested time.

Even though MA decisions remained under the authority of each State – and were granted without any standardization obligation and at a variable pace from one State to another – this procedure imposed a sharing of views at the scientific level, in the framework of a Committee for Proprietary Medicinal Products (CSP) and through the sharing of scientific reports. This committee and its working group on the pharmaceutical quality of medicines derived from biotechnologies represented a forum of scientific and regulatory discussions for this type of products. This space of mutual collaboration between the regulatory authorities of member States was undoubtedly one of the most productive and contributed to the creation of a European regulatory expertise over this period. It highly favoured the registration and marketing of medicines derived from biotechnologies during the first half of the 1990's. The success of this procedure was a determining element in the preparation of the following step, which was the implementation of the centralized procedure and the creation of the European Agency for the Evaluation of Medicinal Products[94].

Currently, to register a medicine in more than one Member State of the European Union, the enquirer can choose:

- the centralized procedure. The medicine cannot be already registered in one of the Union's countries. This procedure is compulsory for medicines derived from biotechnologies, innovating medicines for veterinary use, medicines for human use containing a new active substance dedicated to the treatment of HIV, viral diseases, cancers, neuro-degenerative diseases, diabetes, autoimmune diseases and other immune dysfunctions as well as orphan medicinal products;
- the DeCentralized procedure (DCP). The principle of this procedure is the recognition of the assessment of a Member State ("Reference Member State" or RMS) by other Member States where the medicine is to be marketed ("Concerned Member States" or CMS);
- the Mutual Recognition Procedure (MRP). The principle of the procedure is the same as that of the decentralized procedure but for the latter, no MA needs to have been granted previously in the EU and the file is submitted simultaneously in all the Member States (RMS + CMS), with the national

94 Patrick Le Courtois, European Agency for the Evaluation of Medicinal Products; Rendre possible un accès plus précoce au médicament [Making medicines more accessible]; February 2005.

assessment by the RMS and the preparation of the ER in 120 days. The European phase is the same as for an MRP (comments of the CMS on ER, etc.).

For the registration of a medicine in only one Member state of the EU, the enquirer can choose the national procedure[95].

Another example to mention in terms of standardization of medicines registration procedures at a regional scale is that of the Member States of the West African Economic and Monetary Union (WAEMU) that could serve as a model to implement a standardization system to regulate registrations and quality control. The Regional Economic Communities (RECs) offer the best institutional framework to promote these reforms. The reform started by WAEMU relies on three complementary devices led by regulatory texts:

- a centralized MA device organized around a Committee for Veterinary Medicinal Products (CVMP) in charge of MA requests;
- a unique device of quality control via a network of reliable laboratories from the WAEMU Member States;
- a regulatory device, presented by the WAEMU Veterinary Committee, a consultation body, in charge of coordinating regulatory actions.

In the light of these two examples, two approaches for the standardization of MA procedures can be contemplated in North African countries:

- a centralized procedure leading to the granting of a regional MA recognized by all stakeholder countries. This procedure could be managed by a Pharmaceutical Agency or by a Regional Committee (a lighter and cheaper structure, but with less missions than the agency).
- a decentralized procedure, based on the mutual recognition of national MAs delivered by the competent bodies of the concerned countries.

The procedure choice must come from a thorough analysis of the situation in order to assess the feasibility of each system, taking into account the specific characteristics (institutional and political framework, financial resources, etc.) of the groups of countries willing to commit themselves[96].

There is no need to insist on the importance of standardizing the registration systems to promote rapid access to essential and good quality medicines. This can result in a better efficiency and financial management of the pharmaceutical regulation national Agencies. One must also point out that the rapid authorization of the sale of good quality generic medicines reinforces competition and can thus lead to a reduction of prices. This reduction will benefit governments, international donors as well as populations. Pharmaceutical manufacturers will also benefit from the common documentation and from a more transparent and standardized authorization procedure.

Besides, the main objective of the standardization of pharmaceutical regulations in terms of medicines registration and control is to put in common the resources as well as management and assessment expertise of

95 Les entreprises du médicament (Leem); La réglementation du médicament [Medicines regulations]; 2012.

96 I. Daré ; Harmonisation de l'enregistrement et du contrôle des médicaments vétérinaires en Afrique, l'exemple de l'union économique et monétaire ouest-africaine (UEMOA) [Standardization of the registration and control of veterinary medicines in Africa, the exemple of the West African Economic and Monetary Union (WAEMU)]; OIE Conf. 2007, 133-147.

a group of countries in order to ensure a controlled flow of these products as well as their rational use, not presenting any risks for health or the environment.

The advantages of a common MA procedure would be significant:

- promoting better access to medicines for populations;
- supporting the emergence of a high-level scientific and technical community ("regulatory scientific community") via the sharing of knowledge and expertise in terms of medicines assessment and regulation between the concerned countries;
- giving more importance to the concerned countries in their international negotiations;
- developing the local pharmaceutical industry by making access to pharmaceutical markets easier at the North African scale (to benefit from economies of scale);
- reducing delivery times and the procedure costs.

A better convergence of marketing authorization procedures, the implementation of a scientific committee common to all concerned countries for the scientific assessment of MA requests, support policies towards complementary national productions etc. could be tangible actions converging towards a better integration of the pharmaceutical market in North Africa.

Integration through production

When talking about a North African common market of medicines and medical items, alliances in the industrial, commercial and legal sectors, as well as in the training and research sectors are included.

During the 10th session held in Tunisia in 2008 and the 11th session held in Rabat in 2013, the North African Council of Ministers of Health had issued a certain number of recommendations aiming at supporting the partnership between the countries of the Union in terms of integration of medicines production. In this regard, the Council invited investors and actors of the pharmaceutical industry of the countries of the Union to meet in order to examine the ways of creating a North African association for the pharmaceutical industry.

The cooperation between the three countries must be reinforced in order to face the consequences of the development of new non-communicable diseases that must increase the medicines bill. Besides, a better collaboration in the pharmaceutical industry will also improve the medicines supply in the region as well as its accessibility to the population.

By its internal specificities and its respect of international norms, the pharmaceutical sector can tackle many issues in terms of North African cooperation.

Morocco is the most advanced country in medicines production. The local production of pharmaceuticals covers the needs up to 65%. But its industry is still reduced to the fabrication of generic medicines from imported

active substances. As for Algeria, its pharmaceutical industry remains backwards since it only covers its needs up to 40%. Tunisia made a lot of progress in the regulation of the pharmaceutical sector, which presents specificities implying the intervention of public and private actors. It is currently able to cover 50% of the needs of the local market.

This sector represents both an investment challenge and opportunity. The challenge to meet the increasing needs of populations and the opportunity offered to investors by the North African and even African market. It is indeed positive that the North African cooperation leads to coordinate medicines purchase to multinational groups to obtain a better price and manage to get the North African preference for granting markets. However, it must also reach a structural coordination between North African medicines manufacturers in order to present themselves as a unified body for the international bids on African and global markets.

A good regional integration policy as well as well negotiated economic partnership agreements can support the development of a local pharmaceutical industry, capable of generating important resources, contributing to the improvement of the healthcare systems and quality of life in these countries.

Partnership opportunities must be imagined in the production of medicines, but also serums and vaccines, especially in promising fields such as medicines derived from biotechnologies.

Several reasons encourage the development of the pharmaceutical industry in North African countries:
- a very attractive pharmaceutical market, by its size, growth and added value;
- a rather developed pharmaceutical industry;
- a satisfactory production in compliance with international standards;
- competitive advantages in terms of workers' productivity and access to consumption markets;
- existence of a large North African market of the OIC's member States.

The efforts made by Tunisia allowed its pharmaceutical industry to progress and cover, by 2016, more than 60% of its pharmaceuticals needs. Tunisia has now started to produce vaccines, but also anti-cancer treatments. Besides, the implementation of the Sidi Thabet science and technology park will allow the production of specialties requiring a perfect mastering of biotechnology.

Moreover, the size of the North African market and its economic weight can encourage a technology transfer in favour of a network of medicines production and distribution companies along with the implementation of a rigorous surveillance system at the national level.

This industry must progressively replace medicines importations and be sufficiently pro-active to avoid stockoutage.

Yet, the level of performance of the pharmaceutical industry in North Africa is only capable, for now, to ensure the fabrication of generic medicines from imported raw materials. Most of the raw materials necessary to the

fabrication of medicines come from Europe, which prevents North African countries to cooperate in the fabrication and distribution of vaccines in the region.

These countries are currently confronted with several weaknesses in this sector[97]:

- low production of generic medicines, mainly due to a pharmaceutical lobby and lack of information and awareness of the population but also linked to some aspects related to the legislation and regulation of medicines prices;
- market fragmentation. The multiplicity of fabrication units, the size of which cannot face the competition and globalization, the price policy;
- the private pharmaceutical industry that remains mostly dependent upon foreign countries for raw material supplies that laboratories charge at prices often superior to the price of the international market;
- the issue also lies at the level of the protection of intellectual property and of the discriminating character of research and development in favour of rich countries;
- patents and licenses are the real cornerstones of the prosperity of pharmaceutical industry giants but they represent the main obstacle for the emergence of a production in developing countries in general and in North African countries in particular.

The North African pharmaceutical sector also remains mostly dominated by branches of multinational companies.

Besides, in terms of medicines production, a series of questions regarding industrial problems, linked to public health issues, can be asked to the three North African countries[98]:

- How are they going to get organized to produce their own raw materials in order to reduce the price of essential medicines?
- How are they going to negotiate their supply in medicines derived from biotechnologies that are quite costly and that they cannot produce, even when they fall into public domain?
- How are they going to negotiate with the international pharmaceutical industry to allow patients to benefit, at a lesser cost, from therapeutic progress?
- Is there a possibility of cooperation between the three North African countries and North African countries and Europe?

The other obstacle is that is it impossible to know the state of health of the population of the three countries and the medicines needs. It is also impossible to know the updated list of marketed, produced, imported and exported medicines. The data published on the website *www.santemaghreb.com* refer to the list of medicines available in the three countries (see detailed product list in appendix 1) without mentioning any reference date. The list still needs to be updated since some laboratories no longer exist today.

TABLE 15 summarizes the data to be updated. It shows that more than one thousand medicines were available in the three North African countries; a little more in Tunisia than in Morocco and Algeria.

97 Chaoui F. & Legros M "Les systèmes de santé en Algérie, Maroc et Tunisie : défis nationaux et enjeux partagés" [Health systems in Algeria, Morocco and Tunisia: National challenges and joint issues], IPEMED Notes – Studies and analysis, April 2012.

98 idem.

TABLE 15 Number of medicines available in Algeria, Morocco and Tunisia according to pharmaceutical laboratories

Laboratory	Algeria	Morocco	Tunisia
Aérocid			2
Aguettant			1
Alcon	1		
Alpharma France			1
AstraZeneca	24	35	29
Aventis	8	4	9
Bailly-Speab			3
Bayer Pharma		2	
Biocodex	1	7	7
Biorga			1
Bristol-Myers Squibb	3	6	4
Chefaro-Ardeval	1	1	1
Chiesi SA	2	2	4
Ciba Vision Ophtalmics	3		2
Clément	1	1	1
CS	1	2	1
Darci Pharma	2	7	2
Debat	6	5	8
Debat		1	1
Diepharmex	1	1	2
Dome – Hollister – Stier S.A.	1	1	1
Doms-Recordati	2	5	1
Dupont Pharma SA	1		1
EG Labo		2	1
Elaiapharm	1	1	1
Entéris		2	2
Etris			1
Europhta	1		1
Expanpharm International			1
Ferlux SA			1
Fournier SA	1	3	3
FUCA		1	2
Genopharm	1	2	2
Gerda	1	1	1
Glaxo SmithKline	4	3	4
Grimberg		4	
Guerbet	10	10	4
Inava	4	4	1
IREX	1		
Janssen-Cilag	14	21	20
Kérapharm		1	1
Lafon	1		4
Laphal		6	5
Leurquin-Médiolanum		1	1
Lipha Santé	11	13	12
Marion Merrel SA		1	
Martin Johnson & Johnson Msd	1	13	7
Mayoly-Splinder	1		
Medeva Pharma	1	2	2
Menarini France	3	1	1
Merck Génériques	1		1
Monot	2	5	3
Monsanto France S.A.	2	3	2
Novartis Pharma SA	22	22	28
Parke Davis	18	13	23
Pasteur Vaccins	3	2	
Pfizer	4	2	7
Pharmacia & UpJohn SA	1	2	2
Pharmafarm		1	
Pharmygiène-Scat		2	1
Pierre Fabre	7	11	9
Procter & Gamble Pharmaceuticals Fce	6	8	7
Renaudin	1	1	1
Richelet	1		1
Robapharm	1		
Roussel Diamant	1	2	
S.E.R.P	2	1	
Sanofi-Synthélabo France	27	20	27
Schering S.A.	26	34	26
Schwarz Pharma	1	2	2
SERB	1		1
Sinbio	1	1	
Solvay Pharma	14	9	16
Téofarma	3	3	4
Thérabel Lucien Pharma		1	1
Théraplix (Aventis)	2	1	3
Thératech		2	3
UCB Pharma SA	3	8	4
UPSA	11	11	18
Vedim Pharma	1	1	1
Warner-Lambert	10	9	8
Whitehall		1	1
Wyeth-Lederlé	3	6	4
Total	289	356	364

Source: www.santemaghreb.com

Recommendations and solutions allowing a better integration of the North African pharmaceutical market

Taking into account the complementarities between the Algerian, Moroccan and Tunisian pharmaceutical markets, as well as the obstacles and assets linked to the integration of these three markets, this report offers recommendations and solutions allowing this integration in order to boost the pharmaceutical sector in the region. Some of the recommendations here under have already been issued by official institutions in meetings, conferences and/or different experts in this field. They are still valid and are supported by the authors of this report.

■ General recommendations

- Boosting cooperation between all public healthcare actors so patients remain at the centre of their preoccupations, while keeping in mind that pharmaceutical issues cannot be separated from public health and sustainable economic development issues (National Council of the Pharmacists' Order of Tunisia – CNOPT);
- Working for the implementation of a North African strategy in the pharmaceutical sector in the production, mutual recognition of marketing authorizations and resumption of medicines joint purchase (CNOPT);
- Creating, at a regional level, supranational professional organizations to ensure the regulation standardization of the joint purchase procedure of medicines, vaccines and serums, to ensure the good quality of local productions, to create a development plan for basic infrastructures for medicines industrialization;
- Ensuring a regional cooperation for medicines purchase and a better development of the pharmaceutical industry via the implementation of a permanent secretariat with personnel hired in this view (North African college of pharmacists – CIP);
- Creating a North African committee to reflect upon the future of the pharmaceutical sector, given the demographic evolution of populations and health-care human resources and given the information and communication technologies revolution going on in this sector (CNOPT);
- Reinforcing the link between the different Pharmacy universities in North African countries, orders of pharmacists, learned societies and all the professionals of the pharmaceutical sector – (CNOPT);
- Guaranteeing initial and ongoing training meeting the current and future needs of the sector – (CNOPT);
- Taking on the market through performance and managing to balance the debate between liberalization and protectionism (Coulibaly A[99]);
- Boosting the North African bureau of pharmaceutical information that would act as a link between the concerned North African institutions. Its objective would be to carry out market studies and exchange information on companies manufacturing medicines in order to standardize the systems of medicines quality control in compliance with the international standards and achieve the mutual recognition of medicines conformity certificates between North African countries (UMA);
- Developing the volume of commercial and scientific exchanges by bringing North African pharmacists together and establishing privileged partner-

99 « L'industrie pharmaceutique et la production pharmaceutique en Afrique de l'Ouest » [Pharmaceutical industry and production in West Africa].

ship reports between the professionals of the sector (Inter-Order of North African Pharmacists – IOPM);
- Reinforcing the regional capacities for the control of locally produced or imported medicines (Coulibaly A.).

■ Recommendations regarding the integration via medicines joint purchase

- Reactivating the North African Committee for medicines joint purchase and giving it the responsibility to buy a list of products defined by joint agreement (UMA);
- Drawing up a list of the common needs regarding pharmaceutical products in North African countries while awaiting for the creation of a common list of basic medicines and the updating of the North African joint purchase convention (UMA);
- Implementing a permanent commission of bid preparation for medicines joint purchases;
- Applying to pharmaceuticals and medical items manufactured in North Africa the principle of national treatment regarding the taxes demanded in the importer country.

■ Recommendations regarding integration via MA

- Organizing workshops, meetings and symposiums on the standardization procedures of medicines registration and control;
- Making easier the cooperation between national laboratories of pharmaceuticals quality control and carrying on with the fight against counterfeit medicines or non-compliant with the standards (UMA);
- Implementing a North African project for the coordination of medicines registration systems (UMA);
- Drawing up the final version of the North African project for the coordination of medicines registration systems (UMA);
- Accelerating the implementation of the recommendations of the North African Council of Ministers during the 10th and 11th sessions regarding the integration of the medicines registration process in North African countries (UMA).

■ Recommendations regarding integration via medicines production

- Implementing a structure gathering North African pharmaceutical industrials (IOPM);
- Ensuring a diversification of the production throughout the integration of the different technologies: injectable forms, aerosols, etc. (Coulibaly A.);
- Ensuring the follow-up of WHO's indicators aiming at assessing the capacities of the pharmaceutical industry and the measure of the sector's performances (see **APPENDIX N°2**);
- Developing infrastructures, promoting human resources, integrating new information and communication technologies and carrying out technology transfer;
- Starting the integration by the production of vaccines, oncology products, serums and medicines derived from biotechnologies;
- Reinforcing the local production capacity via the implementation of an incentive framework favouring investment in this sector (Coulibaly A.);

- Developing the North African cooperation in terms of medicines production (and especially of generic ones);
- Implementing an independent association of medicines manufacturers so that the pharmaceutical industry can benefit from scientific, commercial and industrial exchanges (CIP).

TABLE 16 Summary of recommendations by source or institution

Type of recommendation	Recommendation	Source
General recommendations	Creating, at a regional level, supranational professional organizations to ensure the regulation standardization of the joint purchase procedure of medicines, vaccines and serums, to ensure the good quality of local productions, to create a development plan for basic infrastructures for medicines industrialization	Authors of this report
Integration via common purchase	Implementing a permanent commission of bid preparation for medicines joint purchases	Authors of this report
Integration via common purchase	Applying to pharmaceuticals and medical items manufactured in North Africa the principle of national treatment regarding the taxes demanded in the importer country	Authors of this report
Integration via MA	Organizing meetings on the standardization procedures of medicines registration and control	Authors of this report
Integration via production	Ensuring the follow-up of indicators developed by the WHO aiming at assessing the capacities of the pharmaceutical industry and the measure of the sector's performances	Authors of this report
Integration via production	Developing infrastructures, promoting human resources, integrating new ICTs and carrying out technology transfer	Authors of this report
Integration via production	Starting the integration by the production of vaccines, oncology products, serums and medicines derived from biotechnologies	Authors of this report
Integration via production	Developing the North African cooperation in terms of medicines production (and especially of generic ones)	Authors of this report
General recommendations	Ensuring a regional coordination for medicines purchases and a better development of the pharmaceutical industry via the implementation of a permanent secretariat	CIP
Integration via production	Setting up an independent association of medicines manufacturers	CIP
General recommendations	Boosting cooperation between all public healthcare actors so that patients remain at the centre of their preoccupations, while keeping in mind that pharmaceutical issues cannot be separated from public health and sustainable economic development issues	CNOPT
General recommendations	Working for the implementation of a North African strategy in the pharmaceutical sector in the production, mutual recognition of marketing authorizations and resumption of medicines joint purchase	CNOPT
General recommendations	Creating a North African committee to reflect upon the future of the pharmaceutical sector	CNOPT
General recommendations	Reinforcing the link between the different Pharmacy universities in North African countries, orders of pharmacists, learned societies and all the professionals of the pharmaceutical sector	CNOPT
General recommendations	Guaranteeing initial and ongoing training meeting the current and future needs of the sector	CNOPT
General recommendations	Taking on the market through performance and managing to balance the debate between liberalization and protectionism	Dr Assane COULIBALY

Type of recommendation	Recommendation	Source
General recommendations	Reinforcing the regional capacities for the control of locally produced or imported medicines	Dr Assane COULIBALY
Integration via production	Ensuring a diversification of the production range for an integration of the different technologies	Dr Assane COULIBALY
Integration via production	Reinforcing the local production capacity via the implementation of an incentive framework favouring investment in this sector	Dr Assane COULIBALY
General recommendations	Developing the volume of commercial and scientific exchanges by bringing North African pharmacists together and establishing privileged partnership reports between the professionals of the sector	IOPM
Integration via production	Implementing a structure gathering North African pharmaceutical industrials	IOPM
General recommendations	Boosting the North African bureau of pharmaceutical information	UMA
Integration via common purchase	Reactivating the North African committee for medicines joint purchase and give it the responsibility to buy a list of products defined by joint agreement	UMA
Integration via common purchase	Drawing up a list of the common needs regarding pharmaceutical products in North African countries while awaiting for the creation of a common list of basic medicines and the updating of the North African joint purchase convention	UMA
Integration via MA	Making easier the cooperation between national laboratories of pharmaceuticals quality control and carrying on with the fight against counterfeit medicines or non-compliant with the standards	UMA
Integration via MA	Implementing a North African project for the coordination of medicines registration systems	UMA
Integration via MA	Drawing up the final version of the North African project for the coordination of medicines registration systems	UMA
Integration via MA	Accelerating the implementation of the recommendations of the North African Council of Ministers during the 10th and 11th sessions regarding the integration of the medicines registration process in North African countries	UMA

Conclusion

At the national scale, medicines are key for various players in the pharmaceutical chain in each of the three North African countries:

- The Ministry of Health must ensure the availability of this vital product for all citizens, via regular supply and traceable circuits. Besides, it must ensure the quality, efficiency and safety of medicines. Therefore, medicines and pharmacy are highly regulated and controlled by the Ministry of Health.
- Insurance organizations aim at offering the best services possible for their members in terms of healthcare quality. They also aim at maintaining their financial balance, which guarantee their durability. To do so, they try to maximize their resources via the use of the most economical therapeutic alternatives.
- The prescriber has responsibility for choosing the medicines best adapted to his patient. His objective is a fast and complete recovery for his patient, its safety and if possible at the lowest cost. The richness and complexity of the pharmaceutical offer make the prescriber's choice increasingly difficult and he is influenced, at different levels, by the pharmaceutical industry, which is today the main source of pharmaceutical knowledge.
- At the pharmacy, medicines are delivered according to a system where gross profit margins are fixed, whatever the price of medicines. This represents a barrier that tend to favour the most expensive medicines in their categories at the expense of cheaper ones. Today, pharmacists have the choice to substitute the medicines in order to control the pressure of medicines costs over health insurance and it works with a system of variable margins that tend to favour generic medicines.
- Apart from self-medication, the patient cannot always choose his medicines. The only issues for the patient are therapeutic efficiency, medicine safety and as much as possible, a low price. When the patient is covered by a health insurance, the access to medicines is no longer a problem – as long as this medicine is reimbursable and if the costs that remained to be paid are quite low.
- The pharmaceutical sector, although it is highly regulated and controlled, still follows the market forces and the law of free competition. Indeed, even though medicines are vital and strategic health products, they remain an industrial and commercial product that follows the market forces and needs to make profitable the invested capital and win market shares. It is also a therapeutic product with an obligation of efficiency and safety and must be accessible both geographically and economically.
- The pharmaceutical industry faces a certain number of constraints. The limited size of the national market is an obstacle to economies of scale and leads to an under-use of industrial facilities. Local production is penalized by importations and the development of exportation remain difficult, which also represent obstacles to the development of this sector.
- The pharmaceutical industrial sector can be considered as an industry evolving in a cutting-edge technology sector. This requires that industrials adapt to the constraints linked to the evolution of international standards in terms of medicines production and quality. These adaptations require from pharmaceutical industrials to make heavy and regular investments.

At the regional scale and for a better integration of the North African pharmaceutical market, one must also take into account the necessary conditions for its success as well as the challenges to be taken up. They are, in particular:

- giving more significance to political agreements and commitments taken by the various Ministries;
- implementing a regional coordination via a permanent secretariat constituting a data bank and ensuring the communication and diffusion of information to the concerned countries;
- signing a framework agreement (internal rules) regulating the different processes and procedures regarding the North African cooperation contemplated (joint purchase, MA, production, etc.);
- reinforcing the use of generic medicines in the pharmaceutical markets of the three countries;
- paying particular attention to the consequences of political instabilities in the countries on the integration of the pharmaceutical market.

However, even though all these issues do not always converge and obstacles can exist for each different player and at different, national and regional, levels, the solving of the equation “medicines accessibility” / “conservation of the pharmaceutical sector” is not impossible. The patients’ interests must be placed above any other consideration.

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APPENDIX 1

List of medicines available in Algeria, Morocco, Tunisia

Name of the Product	Algeria	Morocco	Tunisia	Laboratory
Acidrine – Pills	x	x	x	Téofarma
Acti 5		x		Pierre Fabre
Activarol C 500	x	x	x	Monot
Activarol C 100	x	x	x	Monot
Acuilix	x	x	x	Parke Davis
Acuitel	x	x	x	Parke Davis
Adépal	x	x		Wyeth-Lederlé
AGram		x		Inava
Agyrax pills	x	x	x	Vedim Pharma
Aldactazine	x	x	x	Monsanto France S.A.
Aldactone 50 mg		x		Monsanto France S.A.
Aldactone 75 mg	x	x	x	Monsanto France S.A.
Algésal – Balm		x		Solvay Pharma
Algésal suractivé – Ointment	x	x	x	Solvay Pharma
Algipan	x	x		Darci Pharma
Allergefon			x	Lafon
Allergènes	x	x	x	Dome – Hollister – Stier S.A.
Alodont – Solution	x	x		Parke Davis
Alphachymotrypsine	x	x	x	Sanofi-Synthélabo France
Alphacutanée – Vials			x	Leurquin-Médiolanum
Alphintern – Pills		x		Leurquin-Médiolanum
Alpress LP			x	Pfizer
Alvityl Sugar-coated pills		x	x	Solvay Pharma
Alvityl Syrup			x	Solvay Pharma
Ametycine	x			Sanofi-Synthélabo France
Amiklin		x		Bristol-Myers Squibb
Anaxéryl			x	Bailly-Speab
Androcur	x	x	x	Schering S.A.
Androtardyl	x	x	x	Schering S.A.
Angispray		x	x	Monot
Antibio-Aberel gel	x	x	x	Janssen-Cilag

Name of the Product	Algeria	Morocco	Tunisia	Laboratory
Antibio-Aberel tampons	x	x	x	Janssen-Cilag
Anusol – ointment	x			Warner-Lambert
Anusol – suppositories	x			Warner-Lambert
Apacef (Céfotetan)	x	x	x	AstraZeneca
Apaisyl gel		x		Monot
Aphilan R pills	x	x	x	Darci Pharma
Aphtiria – Powder	x		x	Debat
Arimidex		x	x	AstraZeneca
Artane	x	x	x	Aventis
Arthrol (Liniment)		x	x	Biocodex
Ascofer		x		Gerda
Aspirine 100mg sachets	x			UPSA
Aspirine UPSA 500 mg	x			UPSA
Aspirine UPSA high in vitamin C			x	UPSA
Atarax pills	x	x	x	UCB Pharma SA
Atarax injectable		x		UCB Pharma SA
Atarax syrup	x	x	x	UCB Pharma SA
Atropine – eye drops	x			Alcon
Augmentin		x		Glaxo SmithKline
Avibon	x	x	x	Aventis
Avolcardyl (Propanolol) pills	x	x	x	AstraZeneca
Avlocardyl Retard (Propanolol)	x	x	x	AstraZeneca
Balsamorhinol – drops			x	Etris
Balsofumine	x		x	Sanofi-Synthélabo France
Basdène		x	x	Doms-Recordati
BCG intradermique	x	x		Pasteur Vaccins
Benylin – syrup	x		x	Parke Davis
Biclinocilline	x	x	x	Sanofi-Synthélabo France
Biocidan (collutory)	x			Menarini France
Biodermine (cream)		x	x	Biocodex
Bleu Patenté	x	x		Guerbet
Bricanyl (pills, injectables, aerosol)	x	x	x	AstraZeneca
Bricanyl (syrup)	x			AstraZeneca
Bricanyl turbuhaler	x	x	x	AstraZeneca
Bristopen	x	x	x	Bristol-Myers Squibb

Name of the Product	Algeria	Morocco	Tunisia	Laboratory
Broncoclar syrup	x			UPSA
CAC 1000 Sandoz – effervescent tablets	x		x	Novartis Pharma SA
Calcibronat – vials	x	x	x	Novartis Pharma SA
Calcibronat – effeverscent tablets	x	x	x	Novartis Pharma SA
Calcibronat – syrup	x	x	x	Novartis Pharma SA
Calciforte		x		Grimberg
Calciparine	x	x	x	Sanofi-Synthélabo France
Calcium Sandoz forte – effervescent tablets	x	x	x	Novartis Pharma SA
Captolane	x			Aventis
Carbophos	x			UPSA
Carbosylane		x		Grimberg
Casodex		x	x	AstraZeneca
Catalgine (Catalgix in Tunisia)	x	x	x	Lipha Santé
Cefacidal	x	x		Bristol-Myers Squibb
Cefaloject			x	Bristol-Myers Squibb
Celestamine			x	Schering S.A.
Celestène chronodose	x	x	x	Schering S.A.
Celestène drops	x	x	x	Schering S.A.
Celestène 2 mg	x	x	x	Schering S.A.
Celestène 8 mg / 4 mg inj.		x	x	Schering S.A.
Cepevit K pills		x		Darci Pharma
Cequinyl fort	x			Glaxo SmithKline
Cetavlon		x		CS
Cicatryl – Ointment		x	x	Darci Pharma
Clamoxyl			x	Glaxo SmithKline
Clarityne	x	x	x	Schering S.A.
Clérégil adulte – drinkable vials		x		Monot
Climène	x	x	x	Schering S.A.
Clomid		x		Marion Merrel SA
Cogitum		x		Glaxo SmithKline
Collu-Hextril – collutory	x	x	x	Warner-Lambert
Combantrin 125 mg – pills	x	x	x	Téofarma
Combantrin 15 ml – suspension			x	Téofarma
Corbionax – pills	x			IREX
Cordarone	x	x	x	Sanofi-Synthélabo France

Name of the Product	Algeria	Morocco	Tunisia	Laboratory
Corticotulle Lumière – 5 compresses 10 x 10	x			Solvay Pharma
Corticotulle Lumière – 30 compresses 20 x 20	x			Solvay Pharma
Covatine			x	Bailly-Speab
Cyclo 3	x	x	x	Pierre Fabre
Cytéal	x	x		Sinbio
Dacryne		x	x	Martin Johnson & Johnson Msd
Dacryosérum		x	x	Martin Johnson & Johnson Msd
Dacryoboraline		x	x	Martin Johnson & Johnson Msd
Dafalgan 80 mg – suppositories			x	UPSA
Dafalgan 150 mg – suppositories	x		x	UPSA
Dafalgan 150 mg – sachets	x			UPSA
Dafalgan 500 mg – pills	x			UPSA
Daktarin – pills	x	x		Janssen-Cilag
Daktarin – skin cream	x	x		Janssen-Cilag
Dantrium 25 mg – capsules	x			Lipha Santé
Dantrium 100 mg – capsules	x			Lipha Santé
Débridat – comp./susp. drink./ suppo./inj.	x		x	Parke Davis
Dénoral – pills	x		x	Théraplix (Aventis)
Dénoral – syrup			x	Théraplix (Aventis)
Dépakine	x	x	x	Sanofi-Synthélabo France
Depamide			x	Sanofi-Synthélabo France
Dermacide	x	x	x	CS
Desernil – pills	x			Novartis Pharma SA
Desuric	x		x	Novartis Pharma SA
Détensiel 10 mg – pills		x	x	Lipha Santé
Diafusor		x	x	Pierre Fabre
Diane 35	x	x	x	Schering S.A.
Diamox	x	x	x	Théraplix (Aventis)
Diarsed		x	x	Sanofi-Synthélabo France
Dicetel – pills		x	x	Solvay Pharma
Didronel	x	x	x	Procter & Gamble Pharmaceuticals Fce
Digitaline – vials	x	x	x	Procter & Gamble Pharmaceuticals Fce

Name of the Product	Algeria	Morocco	Tunisia	Laboratory
Digitaline – pills	x	x	x	Procter & Gamble Pharmaceuticals Fce
Digitaline – solution		x	x	Procter & Gamble Pharmaceuticals Fce
Digoxine Nativelle – pills	x	x	x	Procter & Gamble Pharmaceuticals Fce
Digoxine – solution	x	x	x	Procter & Gamble Pharmaceuticals Fce
Di-Hydan	x	x	x	Genopharm
Dioparine	x		x	Ciba Vision Ophtalmics
Dipipéron – pills			x	Janssen-Cilag
Diprivan (Propofol)	x	x		AstraZeneca
Diprolène	x	x		Schering S.A.
Diprosalic	x	x	x	Schering S.A.
Diprosone all forms	x	x	x	Schering S.A.
Diprostène injectable	x	x	x	Schering S.A.
Dolgit 5% cream		x	x	Lipha Santé
Dopamine Nativelle – inj. vial	x	x	x	Procter & Gamble Pharmaceuticals Fce
Doxium	x		x	Europhta
Dramamine		x	x	Pharmacia & UpJohn SA
Driptane 5 mg		x	x	Debat
Droleptan – inj. am. solution	x	x	x	Janssen-Cilag
Duphalac – drinkable solution	x		x	Solvay Pharma
Duphaston – pills	x	x	x	Solvay Pharma
Duspatalin – pills	x	x	x	Solvay Pharma
Efferalgan solution		x	x	UPSA
Efferalgan high in vitamin C		x	x	UPSA
Efferalgan 500 mg		x	x	UPSA
Elase – ointment			x	Parke Davis
Eludril	x	x		Inava
Endotelon		x		Sanofi-Synthélabo France
Epuram – pills		x		Pharmafarm
Equanil (inj., suppo., caps.)	x	x	x	Sanofi-Synthélabo France
Eryfluid		x		Pierre Fabre
Esperal	x			Sanofi-Synthélabo France
Estulic – pills	x	x	x	Novartis Pharma SA
Eucalyptine – syrup		x		Martin Johnson & Johnson Msd

Name of the Product	Algeria	Morocco	Tunisia	Laboratory
Eucalyptine suppository adults		x		Martin Johnson & Johnson Msd
Eucalyptine suppository children		x		Martin Johnson & Johnson Msd
Eucalyptine suppository infants		x		Martin Johnson & Johnson Msd
Eulexine	x	x	x	Schering S.A.
Fasigyne 500 mg – pills	x	x	x	Téofarma
Fazol – cream	x		x	Aventis
Fazol – ovules			x	Aventis
Feldène 20 mg – IM vials	x	x	x	Pfizer
Feldène 10 mg – capsules	x	x	x	Pfizer
Feldène 20 mg – capsules			x	Pfizer
Feldène 20 mg – dispersion			x	Pfizer
Feldène 20 mg – suppositories	x		x	Pfizer
Fentanyl sol. inj. vials	x		x	Merck Génériques
Ferrostrane – syrup	x		x	Parke Davis
Flodil L.P. 5 mg		x		AstraZeneca
Fludara	x			Schering S.A.
Fluothane (Halothane)	x	x	x	AstraZeneca
Fongeryl			x	SERB
Fonlipol			x	Lafon
Formocarbine – granules	x		x	Glaxo SmithKline
Fumafer	x	x	x	Sanofi-Synthélabo France
Furadantine – capsules			x	Lipha Santé
Furadoïne – pills	x	x	x	Lipha Santé
Gastralgine	x			UPSA
Gastrografine	x	x	x	Schering S.A.
Gaviscon	x	x	x	Glaxo SmithKline
Gel de Polysilane		x	x	UPSA
Geldène			x	Pfizer
Gélucystine – capsules	x		x	Parke Davis
Gélusil – pills	x	x	x	Warner-Lambert
Gentalline 10 – 40 – 80 – 160	x	x		Schering S.A.
Glucophage 500 mg – pills		x		Lipha Santé
Glucophage 850 mg – pills	x	x	x	Lipha Santé
Glycerotone	x		x	Ciba Vision Ophtalmics
Granudoxy – capsules	x			Pierre Fabre

Name of the Product	Algeria	Morocco	Tunisia	Laboratory
Grisefuline – pills			x	Sanofi-Synthélabo France
Grisefuline – ointment		x		Sanofi-Synthélabo France
Gynergene caféiné – sugar-coated pills	x	x	x	Novartis Pharma SA
Gynergene caféiné – suppositories	x			Novartis Pharma SA
Gynergene – vials			x	Novartis Pharma SA
Gyno-Daktarin – vaginal gel			x	Janssen-Cilag
Gyno-Daktarin 100 mg – ovules	x			Janssen-Cilag
Gyno-Daktarin 400 mg – ovules		x	x	Janssen-Cilag
Gyno-Pévaryl 150 – ovules		x	x	Janssen-Cilag
Haldol – vials	x	x	x	Janssen-Cilag
Haldol 1 mg – pills	x		x	Janssen-Cilag
Haldol – Drops 2/	x	x	x	Janssen-Cilag
Haldol 5 mg – pills			x	Janssen-Cilag
Haldol faible 0,5% – drops	x	x	x	Janssen-Cilag
Haldol Decanoas – injectable vials		x	x	Janssen-Cilag
Halopéridol	x	x	x	Renaudin
Hémoclar			x	Sanofi-Synthélabo France
Hépadial – pills		x		Biocodex
Héparine	x			Sanofi-Synthélabo France
Héparine – Alphachymostrypsine			x	Sanofi-Synthélabo France
Héparine Calcique Fournier	x		x	Sanofi-Synthélabo France
Hepax			x	UPSA
Hept-a-Myl	x	x	x	Sanofi-Synthélabo France
Héxabrix 160	x	x		Guerbet
Héxabrix 200	x	x	x	Guerbet
Héxabrix 320	x	x	x	Guerbet
Hexalyse – sublingual pills		x		Doms-Recordati
Hexapneumine composé – pills		x		Doms-Recordati
Hexapneumine (syrup, suppositories)		x		Doms-Recordati
Hexaspray pressurized collutory	x			Doms-Recordati
Hexomédine	x	x	x	Aventis
Hextril – solution	x	x	x	Warner-Lambert
Hiconcil		x	x	UPSA
Hyaluronidase	x			Sanofi-Synthélabo France

Name of the Product	Algeria	Morocco	Tunisia	Laboratory
Hydergine – vials		x	x	Novartis Pharma SA
Hydergine – pills			x	Novartis Pharma SA
Hydergine – solution	x		x	Novartis Pharma SA
Hydrosol Polyvitamine		x		Doms-Recordati
Ikaran	x	x	x	Pierre Fabre
Imodium – capsules	x	x	x	Janssen-Cilag
Imodium solution – flask	x	x	x	Janssen-Cilag
Imudon – pills	x	x	x	Solvay Pharma
Introna	x	x	x	Schering S.A.
Iopamiron 200			x	Schering S.A.
Iopamiron 300			x	Schering S.A.
Iopamiron 370			x	Schering S.A.
Iskedyl		x	x	Pierre Fabre
Isobar – pills			x	Chiesi SA
Isoprinosine		x		Sanofi-Synthélabo France
Jamylène			x	Expanpharm International
Josacine – pills		x		Bayer Pharma
Josacine – suspension		x		Bayer Pharma
Kaologeais – granules	x		x	Chiesi SA
Karayal – granules			x	Chiesi SA
Keal		x		EG Labo
Kératosane			x	Biorga
Kétalar injectable	x	x	x	Parke Davis
Kétoderm – cream		x	x	Janssen-Cilag
Kinurea H			x	FUCA
Lamaline – suppositories			x	Solvay Pharma
Lansoyl 225 g	x	x	x	Warner-Lambert
Lansoyl 225 g sugar free	x	x		Warner-Lambert
Lespenephryl – solution		x		Darci Pharma
Lévothyrox 50 µg	x	x	x	Lipha Santé
Lévothyrox 100 µg	x	x	x	Lipha Santé
Lipanthil 200M	x	x	x	Fournier SA
Lipiodol U.F.	x	x	x	Guerbet
Lipur – pills			x	Parke Davis
Locacid	x	x	x	Pierre Fabre

Name of the Product	Algeria	Morocco	Tunisia	Laboratory
Logecine		x	x	Genopharm
Longacor – gel	x	x	x	Elaiapharm
Lucidril	x	x	x	Lipha Santé
Lysanxia	x		x	Parke Davis
Lysanxia – pills	x	x	x	Parke Davis
Lyso 6 – pills		x		Darci Pharma
Magne B6		x		Sanofi-Synthélabo France
Magnevist	x	x	x	Schering S.A.
Mantadix	x		x	Dupont Pharma SA
Marcaïne 0,25% – flask		x	x	AstraZeneca
Marcaïne 0,25% – adr.		x		AstraZeneca
Marcaïne 0,50% – flask	x	x	x	AstraZeneca
Marcaïne 0,50% – adr.		x		AstraZeneca
Marcaïne Rachia. – vials		x	x	AstraZeneca
Maxilase 3000 and syrup	x	x	x	Sanofi-Synthélabo France
Maxilase Bacitracine	x		x	Sanofi-Synthélabo France
Mégabyl granules – sachets			x	Martin Johnson & Johnson Msd
Mégabyl solution – flask		x		Martin Johnson & Johnson Msd
Meliane	x			Schering S.A.
Melleril 10 – pills	x	x	x	Novartis Pharma SA
Melleril 50 – sugar-coated pills		x	x	Novartis Pharma SA
Melleril solution 4%	x		x	Novartis Pharma SA
Melleril suspension 2%	x		x	Novartis Pharma SA
Mepronizine	x	x	x	Sanofi-Synthélabo France
Mercryl Lauryle	x	x	x	Menarini France
Merfène colored or colorless tincture		x		Novartis Pharma SA
Methergin – vials	x	x	x	Novartis Pharma SA
Methergin – solution		x	x	Novartis Pharma SA
Miacalci 80 UI – vials	x			Novartis Pharma SA
Microlax	x	x	x	Pharmacia & UpJohn SA
Mictasol – pills			x	Martin Johnson & Johnson Msd
Mictasol bleu	x	x	x	Martin Johnson & Johnson Msd
Migralgine – capsules		x		Martin Johnson & Johnson Msd
Milligynon		x		Schering S.A.
Minipress	x			Pfizer

Name of the Product	Algeria	Morocco	Tunisia	Laboratory
Moneva		x		Schering S.A.
Monicor		x	x	Pierre Fabre
Mopral 10 mg – capsules	x	x	x	AstraZeneca
Mopral 20 mg – capsules	x	x	x	AstraZeneca
Mopral IV 40 mg – vial	x	x	x	AstraZeneca
Motilium – pills		x		Janssen-Cilag
Motilium drinkable suspension – flask		x		Janssen-Cilag
Muciclar – syrup children		x	x	Parke Davis
Muciclar – syrup adults		x	x	Parke Davis
Mucofluid – vials		x		UCB Pharma SA
Mucothiol – pills		x	x	Thératech
Mucothiol – sachets		x	x	Thératech
Mutagrip	x	x		Pasteur Vaccins
Mycodécyl	x	x	x	Diepharmex
Mycoster		x	x	Pierre Fabre
Mynocine capsules		x		Wyeth-Lederlé
Mynocine IM		x		Wyeth-Lederlé
Myoviton		x	x	Thérabel Lucien Pharma
Mysoline (Primidone)	x		x	AstraZeneca
Nalorphine Serb	x			SERB
Natispray		x		Procter & Gamble Pharmaceuticals Fce
Néomycine Diamant – eye drops	x			Roussel Diamant
Netromicine 25 – 50 – 100 – 150		x	x	Schering S.A.
Nibiol – pills	x	x	x	Debat
Nibiol Forte – pills	x	x	x	Debat
Nibiol – suspension	x	x	x	Debat
Niflugel			x	UPSA
Nifluril – gingival gel		x	x	UPSA
Nifluril – capsules		x	x	UPSA
Nifluril adult/children suppo.		x	x	UPSA
Nifluril ointment	x	x	x	UPSA
Nizoral – pills		x		Janssen-Cilag
Nizoral – suspension	x			Janssen-Cilag
Nocertone			x	Sanofi-Synthélabo France

Name of the Product	Algeria	Morocco	Tunisia	Laboratory
Noctran	x			Menarini France
Nolvadex	x	x		AstraZeneca
Nootropyl – capsules		x	x	UCB Pharma SA
Nootropyl injectable		x	x	UCB Pharma SA
Nootropyl drinkable solution		x		UCB Pharma SA
Norbiline – vials	x		x	Aventis
Noristerat		x		Schering S.A.
Normogastryl		x		UPSA
Nova T		x		Schering S.A.
Octofène 100 mg			x	Debat
Octofène 200 mg			x	Debat
Optalidon – sugar-coated pills		x		Novartis Pharma SA
Optalidon – suppositories		x		Novartis Pharma SA
Oracéfal		x	x	UPSA
Oracilline	x	x	x	Schwarz Pharma
Orap – pills			x	Janssen-Cilag
Oromédine	x		x	Sanofi-Synthélabo France
Oropivalone	x	x	x	Parke Davis
Ospen – pills		x	x	Novartis Pharma SA
Otaralgyl – solution		x		Martin Johnson & Johnson Msd
Otipax – oto. drops	x	x	x	Biocodex
Oxadilène – capsules		x		Medeva Pharma
Oxyplastine – ointment	x		x	Parke Davis
Ozothine – injection 5 ml		x		Laphal
Ozothine – syrup		x	x	Laphal
Ozothine – adults, children, infants suppo.		x	x	Laphal
Ozothine with Diprophylline Suppo A		x	x	Laphal
Ozothine with Diprophylline – pills		x	x	Laphal
Padéryl	x		x	Gerda
Para Spécial poux – aerosol 90 g.		x		Pharmygiène-Scat
Parfénac		x	x	Whitehall
Parlodel – pills	x	x	x	Novartis Pharma SA
Passiflorine – solution			x	Thératech
Pereflat – pills			x	Solvay Pharma

Name of the Product	Algeria	Morocco	Tunisia	Laboratory
Peridys	x			Robapharm
Permixon	x	x	x	Pierre Fabre
Pévaryl (powder-spray, solution-spray, lotion)	x	x	x	Janssen-Cilag
Pévaryl cream		x	x	Janssen-Cilag
Phaeva		x		Schering S.A.
Physiomycine		x	x	Laphal
Pilocarpine – eye drops	x			Ciba Vision Ophtalmics
Pivalone nasal spray		x	x	Parke Davis
Pivalone néomycine	x	x	x	Parke Davis
Pivalone endosinus	x		x	Parke Davis
Plastenan		x	x	Kérapharm
Plényl	x			UPSA
Polaramine 2-6 syrup	x	x	x	Schering S.A.
Poly-Karaya		x		Sanofi-Synthélabo France
Ponstyl – suppositories		x	x	Parke Davis
Ponstyl fort – pills		x	x	Parke Davis
Poudre Dops		x	x	Fuca
Povanyl – pills			x	Warner-Lambert
Povanyl – suspension		x	x	Warner-Lambert
Praxilène 100 mg – capsules	x	x	x	Lipha Santé
Praxilène 200 mg – pills	x	x	x	Lipha Santé
Prazinil			x	Pierre Fabre
Préfagyl			x	UPSA
Pre-Par – injectable vials	x		x	Solvay Pharma
Pre-Par – pills	x		x	Solvay Pharma
Primalan	x			Inava
Primolut – Nor – pills		x	x	Schering S.A.
Princi B fort	x	x		S.E.R.P
Princi B simple	x			S.E.R.P
Proctolog – ointment, syrup	x	x	x	Parke Davis
Pro-Dafalgan	x		x	UPSA
Progestérone retard Pharlon	x	x	x	Schering S.A.
Progynova	x	x		Schering S.A.
Prorhinel – vials		x	x	Novartis Pharma SA
Protamine choay	x			Sanofi-Synthélabo France

Name of the Product	Algeria	Morocco	Tunisia	Laboratory
Pulmicort 200 ug – aerosol	x	x	x	AstraZeneca
Pulmicort turbuhaler		x		AstraZeneca
Pulmofluide simple – flask	x	x		Warner-Lambert
Pulmofluide éphédriné – flask	x	x		Warner-Lambert
Pulmofluide – flask (children, infants)	x	x		Warner-Lambert
Pulmosérum			x	Bailly-Speab
Pulvo 47		x	x	Fournier SA
Pulvo 47 néomycine		x	x	Fournier SA
Pursennide – sugar-coated pills		x	x	Novartis Pharma SA
Pyréflor antipoux (lotion, shampoo)	x	x	x	Clément
Pyridoxine			x	Aguettant
Questran	x	x	x	Bristol-Myers Squibb
Quinimax	x		x	Sanofi-Synthélabo France
Quotivit	x			Mayoly-Splinder
Revitalose C 1000		x		Darci Pharma
Rhinofébral – capsules		x		Martin Johnson & Johnson Msd
Ribatran			x	Ferlux SA
Ribomunyl	x	x	x	Inava
Ricridène		x		Lipha Santé
Rifadine		x		Roussel Diamant
Rifinah		x		Roussel Diamant
Rinutan – pills			x	Warner-Lambert
Rinutan – syrup			x	Warner-Lambert
Risordan	x	x	x	Aventis
Rocgel	x	x	x	Chiesi SA
Rocmaline – drinkable vials		x		Chiesi SA
Rufol – pills	x	x	x	Debat
Rumicine		x		Schering S.A.
Sacolène		x	x	EG Labo
Salgydal	x			Doms-Recordati
Sandimmun solution	x			Novartis Pharma SA
Sanmigran – pills	x	x		Novartis Pharma SA
Savarine		x	x	AstraZeneca
Seglor		x	x	Schwarz Pharma
Sémap – pills			x	Janssen-Cilag

Name of the Product	Algeria	Morocco	Tunisia	Laboratory
Septivon	x	x	x	Chefaro-Ardeval
Serc – pills	x	x	x	Solvay Pharma
Seresta 10 mg – pills			x	Wyeth-Lederlé
Seresta 50 mg – pills			x	Wyeth-Lederlé
Sérum anti-rabique Pasteur	x			Pasteur Vaccins
Sibélium – pills		x		Janssen-Cilag
Sorbitol Delalande	x			Sanofi-Synthélabo France
Sotalex		x		Bristol-Myers Squibb
Soufrane	x	x	x	Sanofi-Synthélabo France
Spasfon (vials, pills, suppositories)	x		x	Lafon
Spasmag – vials		x		Grimberg
Spasmag – capsules		x		Grimberg
Sprégal / A-Par aerosol		x	x	Pharmygiène-Scat
Stagid – pills	x	x		Lipha Santé
Stédiril		x		Wyeth-Lederlé
Stimol – vials		x	x	Biocodex
Stresam – capsules		x	x	Biocodex
Sulfarlem – granules	x		x	Solvay Pharma
Sulfarlem S25	x	x		Solvay Pharma
Sulfuryl inhalant – pills			x	Aérocid
Sulfuryl Bain – powder			x	Aérocid
Sureptil	x	x	x	Sanofi-Synthélabo France
Surfortan			x	Diepharmex
Synergon			x	Lipha Santé
Synthol solution	x		x	Glaxo SmithKline
Syntocinon 2 UI – vials		x	x	Novartis Pharma SA
Syntocinon 5 UI – vials		x	x	Novartis Pharma SA
Tadénan	x	x	x	Debat
Tagamet – pills		x	x	Entéris
Tagamet injectable		x	x	Entéris
Tanganil	x			Pierre Fabre
Télébrix 12 sodium	x	x		Guerbet
Télébrix 38	x	x	x	Guerbet
Télébrix 30 M	x	x		Guerbet
Télébrix Gastro	x	x		Guerbet

Name of the Product	Algeria	Morocco	Tunisia	Laboratory
Télébrix Hystiro	x	x		Guerbet
Témesta 1 mg – pills	x	x	x	Wyeth-Lederlé
Témesta 2,5 mg – pills	x	x	x	Wyeth-Lederlé
Temgésic – sublingual pill	x	x	x	Schering S.A.
Temgésic injectable	x	x	x	Schering S.A.
Ténordate		x	x	AstraZeneca
Téralithe	x		x	Aventis
Tercian			x	Aventis
Tenormine		x		AstraZeneca
Théostat	x	x		Inava
Théralène	x	x	x	Medeva Pharma
Thiophénicol	x		x	Sanofi-Synthélabo France
Thiovalone	x		x	Parke Davis
Tocomine			x	Parke Davis
Topaal	x	x		Pierre Fabre
Totapen		x	x	Bristol-Myers Squibb
Tranxène	x	x	x	Sanofi-Synthélabo France
Trentadil suppositories			x	Medeva Pharma
Triaminic – pills			x	Novartis Pharma SA
Triella oral contraceptive		x		Janssen-Cilag
Trophigil			x	Sanofi-Synthélabo France
Trophirès – syrup, suppositories	x	x	x	Sanofi-Synthélabo France
Tulle gras Lumière – 10 compresses 10 x 10	x		x	Solvay Pharma
Tulle gras Lumière – 30 compresses 20 x 20	x		x	Solvay Pharma
Ulfon / 20			x	Lafon
Ultraderme	x		x	Richelet
Ultralan		x		Schering S.A.
Ultra-Levure 50 mg – capsules			x	Biocodex
Ultra-Levure 250 mg – sachets		x	x	Biocodex
Ultravist 300	x	x		Schering S.A.
Ultravist 370	x	x		Schering S.A.
UPSA C			x	UPSA
Uraseptine Rogier			x	Alpharma France
Urokinase choay	x			Sanofi-Synthélabo France

Name of the Product	Algeria	Morocco	Tunisia	Laboratory
Uvéline		x	x	Martin Johnson & Johnson Msd
Xylocaïne gel 15 gr – tube		x	x	AstraZeneca
Xylocaïne 1% – flask	x	x	x	AstraZeneca
Xylocaïne 1% – adr.	x	x	x	AstraZeneca
Xylocaïne 2% – flask	x	x	x	AstraZeneca
Xylocaïne 2% – adr.	x	x	x	AstraZeneca
Xylocaïne 5% contact – flask	x	x	x	AstraZeneca
Xylocaïne 5% vaporiser	x	x	x	AstraZeneca
Xylocaïne 5% naphaz. – flask	x	x	x	AstraZeneca
Xylocaïne visqueuse – tube	x	x	x	AstraZeneca
Zaditen – capsules	x	x	x	Novartis Pharma SA
Zaditen – solution	x		x	Novartis Pharma SA
Zamig		x	x	AstraZeneca
Zarontin – capsules	x			Parke Davis
Zarontin – syrup	x			Parke Davis
Zoladex (Goséréline)	x	x	x	AstraZeneca
Zymafluor 1/4 mg – pills	x		x	Novartis Pharma SA
Zyrtec	x	x		UCB Pharma SA

APPENDIX 2

WHO's indicators suggested for the follow-up of the national pharmaceutical production (WHO Geneva 1996)

General indicators:

- Total value of the national pharmaceutical production sold in the country (ex-works price);
- Total number of medicines manufacturing units in the country.

Structural indicators:

- Is there a standard checklist form for the inspection of the different pharmaceutical establishments? (this indicator does not concern only production);
- Is there, in the country or abroad, organisms able to perform medicines quality control? (this indicator does not concern only production);

Performance indicators:

- Number of medicines on the national list of essential medicines manufactured and sold in the country out of the number of medicines on the national list of essential medicines;
- Value of medicines bought to national manufacturers via bids, over the total value of medicines purchased via bids in the public sector;
- Number of tested medicines or medicines batches over the number of medicines received (this indicator does not concern only local production);
- Number of medicines or medicines batches that did not pass the quality control over the total of tested medicines or medicines batches (this indicator does not concern only local production).

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