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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

Contribution from the Moroccan Competition Council

-- Session III --

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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- Moroccan Competition Council [*] --

1. In 2012, the national turnover of the pharmaceuticals industry in Morocco was MAD 8.8 billion for the private sector (drugs sold in pharmacies). Compared with 2011, this represented an increase of 3.4% in terms of volume and 5.6% in terms of value. This turnover corresponds to annual expenditure on drug purchasing of the order of MAD 13.9 billion. Annual per capita spending on drugs in pharmacies is estimated to be MAD 408 (in other words less than USD 49.6, whereas the average per capita spend in North America is USD 770 per annum, in Japan USD 506 and in Europe USD 380). In terms of volume, per capita consumption is about 9 packets per person per year.

2. Total spending on health, which is around MAD 47.8 billion, accounts for 63% of GDP and has been rising very slowly for over a decade: 5.3% in 2003 and 5.9% in 2010. Compared with other countries such as South Africa (8.7%), Jordan (8.3%) and Turkey (6.7%), Morocco has performed creditably.

3. The pharmaceuticals industry in Morocco is liberalised and open to foreign investment with profits and capital gains being fully transferable abroad. Moreover, for the first five years of operation, export companies pay a reduced level of corporation tax – 17.5% instead of the normal rate of 30%. However, the State has not introduced any particular incentives for this sector as it has in other priority sectors of the national economy.

4. The private sector totally dominates the production, import and wholesale and retail distribution of pharmaceuticals. The sector has 40 industrial manufacturing units, with the distribution and dispensing of drugs and non-medicinal pharmaceuticals being carried out by 50 pharmaceutical wholesalers, on the one hand, and by around 11 000 pharmacies which cover the whole of the country, on the other hand.

5. The Moroccan pharmaceuticals industry is regarded as complying with international standards, and national pharmaceutical products are exported regularly to a large number of European countries, including France and Germany, but also to North America, not to mention Africa, Asia and the Arab world. This globally-oriented approach means that today the Moroccan pharmaceuticals sector ranks second in Africa after the Republic of South Africa.

6. All aspects of the pharmaceuticals sector are highly regulated, including the establishment, operation and monitoring of pharmaceuticals manufacturers and the placing on the market and pricing of drugs.

7. However, even though the pharmaceuticals industry manages to cover 65% of national demand, it does face a number of constraints such as the narrowness of the national market which hampers economies of scale and means that manufacturing resources are under-utilised. The restrictions placed on local manufacturers by the influx of imports and the difficulties of expanding export sales further constrain any expansion of this sector, especially in times of crisis or emergency.

[*] Contribution submitted by Mr. Khalid El Bouayachi (Rapporteur-General), Moroccan Competition Council.

1. Overview of the operation of the pharmaceuticals market in Morocco

8. In Morocco, the pharmaceutical sector is tightly controlled by the State and regulated at all levels: production, distribution and consumption. It is governed by Law No. 17-04 establishing the drugs and pharmacy code[1].

1.1 Establishment and monitoring of pharmaceuticals production units

9. The establishment of a pharmaceuticals manufacturing unit and its entry into business are subject to the grant of prior approval and to a final authorisation to enter into business, issued by the Secretariat General of the Government (SGG) following a favourable opinion from the Minister for Health and the National Council of the Order of Pharmacists. Authorisation is issued within 30 days and is notified to the relevant bodies.

10. It is worth noting that Law No. 17-104 liberalised the capital of the pharmaceutical industry which was previously reserved solely for persons with a pharmacy diploma. This opening up, which has facilitated the flow of capital towards the sector, thereby allowing the creation of several new production units, has been boosted by the fact that the Directorate for Drugs (Ministry of Health) has not set any limit on the number of marketing authorisations (MA) per molecule that a manufacturer may have.

11. Manufacturing units compete for a share of the drugs market by increasing their turnover and by using marketing strategies that are geared to quality and branding, since the price of a drug is the same everywhere in the Kingdom.

12. It should also be noted that the implementation of the regulations concerned is monitored by the competent authorities, professionals and pharmaceuticals manufacturers.

13. In this context, Ministry of Health pharmacy inspectors are supposed to monitor pharmaceuticals manufacturing units in order to ensure that they are complying with the technical standards in force and with good manufacturing practices (GMP) in terms of the storage and distribution of drugs.

1.2 Industrial property rights in respect of drugs in Morocco

14. Following the signature of the World Trade Organization (WTO) Agreements on Trade-Related Aspects of Intellectual Property Rights (TRIPs), Morocco has recast its legislative and regulatory instruments in order to bring them into line with its commitments under that Agreement, with particular regard to the grant of patents for drugs. As a result, any product which imitates a patented drug is now prohibited and liable to trade sanctions imposed by the dispute settlement body.

15. However, there are derogations from the rights conferred. A State may provide for such derogations where it considers, for example, that they are necessary in order to protect public health in cases or situations of *force majeure*.

1.3 Advertising

16. All advertising to the general public is subject to possession of a permit (Article 42 of the Drugs Code). However, the advertising of drugs to the public relates only to non-prescription drugs.

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[1] Royal Decree No. 1-06-151 of 30 Shawal 1427 (22 November 2006) promulgating Law No 17-04 establishing the drugs and pharmacy code (Official Bulletin No. 5480 of 15 Kaada 1427, 7 December 2006).

17. On the other hand, advertising campaigns for vaccines and family planning drugs or to combat smoking may be addressed to the public without any restriction.

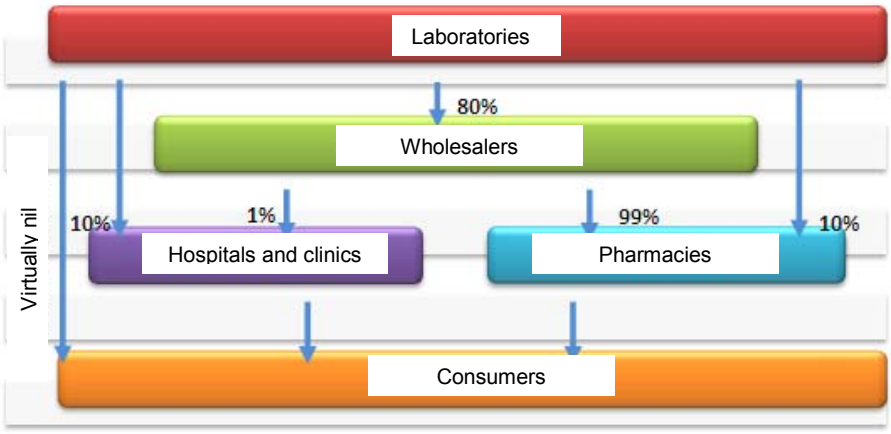
1.4 Distribution chains

18. In Morocco, drugs are distributed through two main chains: a direct chain and an indirect chain.

19. **The direct chain** involves contracts that are entered into directly between laboratories, on the one hand, and pharmacies, the Ministry of Health, military health authorities, institutions or clinics, on the other hand.

20. **The indirect chain** involves going via wholesalers who supply pharmacies and any other entity. This is the principal channel and accounts for 80% of the market.

Figure 1: Drugs distribution chains



Source: Moroccan Pharmaceutical Industry Association (AMIP) based on IMS health figures

21. The direct chain (laboratories-retail pharmacies) accounts for only 10%, the remainder being sales to hospitals (calls for tenders and direct sales to clinics sand hospitals).

22. Keeping the market supplied with drugs is a statutory obligation for holders of an MA (marketing authorisation), wholesalers and retail pharmacists. The Decree of 23 June 2003 requires pharmaceutical laboratories to hold at least 3 months' stock of finished products and wholesalers to hold 1 month's stock.

23. Alongside this indirect chain, there is a direct chain consisting, in essence, of direct sales to pharmacies or clinics which account for 6%-10% of sales. Direct sales to pharmacies basically cover drugs that are normally sold for self-medication or following consultation with a pharmacist. They may also cover certain widely prescribed prescription drugs such as antibiotics.

24. As a rule, direct sales involve fairly large quantities of drugs. In this case, the gross margin of the pharmacist will rise from the normal 30% to 50% as a result of free batches or quantity discounts.

25. Unlike the indirect chain, which is used by all laboratories, the direct chain is used only by entities with well-structured commercial and recovery systems. The fact that there are currently over 3 000 pharmacies on the verge of bankruptcy whose cheque book facilities have been withdrawn is a

potent threat to the pharmaceutical sector. The trading performance of the various industrial operators in terms of direct sales is highly variable. Their impact even on prescription drugs is considerable.

26. The practice of offering substitutes is prohibited but often used on various pretexts. In some cases, pharmacists may, in good faith, replace an expensive product by a cheaper alternative for patients on low income. However, the current system of fixed margins, in an economic climate which is difficult for retail pharmacies, limits this tendency to substitution on economic grounds. There is much less competition at the level of indirect marketing chains than at the level of direct chains. The main assets for a laboratory wanting to succeed in the direct sales market are:

- A large pharmaceuticals sales force;
- Good coverage of national territory by the sales force;
- Attractive trading terms for pharmacists (sliding scale of charges, free batches and delayed payment schedules);
- An efficient recovery department due to the large number of non-payment issues in the sector;
- An efficient logistics department to deal with the thousands of orders.

27. The right of pharmacists to substitute drugs has not yet been authorised. However, according to an announcement made by the Minister for Health at a national pharmacists' congress, they will soon be allowed to do so, but only according to certain specific procedures and using a different profit margin from the current fixed margin of 30% which hinders the proliferation of low-price drugs, particularly generics.

28. This right of substitution is already widely used in other Western countries. It gives pharmacists the right to give advice and to replace one drug with another which has the same composition but costs less. Unlike the system of fixed margins, which hinders the development of economic alternatives such as generic drugs, this system encourages greater and more widespread use of the latter because pharmacists have the incentive of variable margins, which will be greatest on the cheapest products.

29. Furthermore, direct sales to clinics relate basically to antiseptics or analgesics and anti-inflammatory drugs.

30. Direct sales by laboratories to patients concern only high-end drugs (cancer and hepatitis drugs, etc.). Although they are a flagrant breach of the law which confers a monopoly on pharmacists alone, they are tolerated in order to fill the vacuum created by the non-availability of these products at retail pharmacies.

31. Since the price of such drugs is prohibitive (several thousand dirhams), these laboratories can justify direct sales to patients by the non-availability of the drugs in the majority of pharmacies and by the fact that the pharmacist's margin would increase the price by more than 30%, which would be beyond the reach of patients. An alternative is under consideration because retail pharmacists have given an undertaking, through their representative bodies, to reduce their gross margin on such products to 5%.

32. Hospital procurement is a completely separate distribution chain. The lowest price is the trump card for being successful in this market. As a general rule, bid prices are usually much lower than prices to the general public.

33. However, the Drugs and Pharmacy Code clearly prohibits the sale and distribution of drugs through unauthorised channels and stipulates in Article 29 that the dispensing of drugs and other pharmaceutical products is reserved to retail pharmacists. There are several products which fall outside the

laboratory-wholesaler-pharmacy-consumer chain, given that they are sold directly to patients by associations. They are also sold to clinics and certain specialists.

34. Pharmacists receive strong competition from paediatricians in terms of vaccines, and veterinarians have cornered the market for the drugs that they use. In addition, most cosmetics, food supplements and other medical devices are usually sold these days through "parapharmacies" and thus fall outside the control of retail pharmacies.

35. Doctors do not constitute a link in the marketing chain. However, they play a decisive role in terms of the quality and quantity of drugs consumed. Apart from self-medication and purchase on the basis of consultation with a pharmacist, it is doctors who are going to choose which drugs to prescribe to their patients.

36. Since the choice made by doctors is decisive for the purchasing of drugs, it is therefore logical for laboratories to do everything in their power to attract the attention of doctors and act on the basis of what they prescribe.

1.5 Regulation of drug prices in Morocco

1.5.1 Marketing authorisation (MA)

37. All drugs manufactured on an industrial scale, imported or exported, even in the form of samples, must be covered by an authorisation issued by the administration known as a marketing authorisation (MA) prior to marketing or distribution, whether wholesale or retail and whether against payment or free of charge. The procedures and the time taken to grant these authorisations are regarded as lengthy, complicated and costly by manufacturers and can lead to unlawful practices.

38. It should be noted that these authorisations are always issued by the departments of the Ministry of Health because Morocco does not yet have an independent drugs agency.

1.5.2 Drug pricing system

39. The drug pricing system, which has been in force since the 1960s, is currently under review. At the beginning of 2010, a new system was put to the drug industry by the Ministry for Health, and this was accepted with a few slight amendments. However, this new system has not yet been implemented.

40. Under the old system, the price granted to a laboratory for a particular drug is calculated on the basis of the price in the country of origin according to two procedures, one for drugs manufactured in Morocco and the other for imported drugs. Only the departments of the Ministry of Health can set those prices or, to be more accurate, approve the prices suggested by the laboratories, following a negotiation process which has not always been steeped in transparency.

41. However, the price granted for the first generic drug is 30% lower than that granted for the originator drug. By contrast, the price granted for subsequent generics is 5% lower than that of the preceding generic.

42. Where an application relates to a generic pharmaceutical product within the meaning of Law No. 17-04, and the latter is the first generic drug to be placed on the national market, its price is 45% lower than the price of the reference proprietary drug marketed in Morocco where its PPM (public price in Morocco) is MAD 250 or less.

43. Nevertheless, where the PPM of the reference proprietary drug is more than MAD 250, the price of the first nine generics is 50% less than that of the originator drug. The price of the last five generics is set at 20% less than that of the first nine generics.

44. Added to that price is a margin of 10% for wholesalers and 30% for pharmacists. Thus the price setting method, which is based on dubious criteria, contributes in no small way to the current high price of drugs in Morocco.

1.5.3 Drug price levels in Morocco

45. In 2009, the Finance and Economic Development Committee of the Moroccan Parliament published a report on the situation regarding drug prices in Morocco. The principal findings of the report are as follows:

- Drug prices in Morocco are abnormally high, irrespective of the chosen comparator and the type of drug;
- The main responsibility lies with a section of the pharmaceutical industry and with the procedures introduced by the administration for setting drug prices and their reimbursement by health insurance companies;
- It is possible to bring about a rapid and significant decrease in the prices of drugs in Morocco as well as their cost to the taxpayer by applying a set of measures which are dependent essentially on the public authorities;
- The principal recommendation of the authors of this report was to abandon the current pricing structure.

1.6 Compulsory health insurance – AMO

46. Morocco has recently adopted a compulsory health insurance scheme which should enable certain categories of citizens to access healthcare services and make it possible gradually to extend medical cover to the whole population. This news should provide a boost for the healthcare economy as a whole by focusing demand more specifically on drugs. This scheme gives an entitlement, on terms and conditions set out by means of regulations, to reimbursement for and possible direct payment of curative and preventive treatment and rehabilitation costs that are medically necessary for the health of the beneficiary and relate to the services listed in the Law, which includes a list of drugs subject to reimbursement. However, due to its recent (2006) and gradual entry into force, it is still too early to assess its impact on the Moroccan pharmaceutical industry.

1.7 Output of the Moroccan pharmaceutical industry

47. The Moroccan pharmaceutical industry is mostly production-orientated, and its output covers over 65% of the country's needs, the remainder being imported mainly from EU countries, especially France. The national pharmaceutical industry is characterised by low levels of production and difficulties of making economies of scale, due to the narrowness of the local market. The latter stems partly from the weakness of Morocco's purchasing power and partly from the limitations of the social security system, particularly the inadequacy of health insurance cover.

1.7.1 Level of concentration

48. It is worth remembering that the fabric of the Moroccan pharmaceutical industry is made up of 40 units and dominated by the subsidiaries of multinational companies.

49. An analysis of the level of concentration in the pharmaceutical sector in 2010 using Cri concentration ratios (where i = 4, 8 and 12) and the Lorentz curve showed that, out of 40 operators in the pharmaceuticals manufacturing sector, the top four held 44% of the market share, the top eight 64% and the top twenty 95%.

50. The national pharmaceutical industry can therefore be regarded as an open oligopoly. It is a sector which contains a core of just a few operators who enjoy a very dominant position on the market and who co-exist with a large number of peripheral operators. It should be pointed out, however, that there is a very high level of concentration on the pharmaceuticals market in certain therapeutic sectors such as cancer, hepatitis-B, and diabetes drugs – sectors in which some manufacturers have know-how, skills and highly sought-after drug portfolios.

1.7.2 Barriers to entry

51. As emphasised above and due to the specific nature of drugs as a health product, the pharmaceuticals sector is highly regulated in Morocco at all levels. As a result, the main barriers to entry in this sector are those of a regulatory nature, which affect all operators in the drug distribution chain, and those of a structural nature which are linked to the size of the national market.

1.7.2.1 Regulatory barriers

- Ministry of Health

  The Ministry of Health's role is to ensure the protection of health in general and the safety of drugs in particular. On the one hand, it is responsible for ensuring the availability of these vital products by means of a regular supply, for all citizens, through traceable channels. On the other hand, it is required to guarantee the quality, efficacy and safety of drugs. For this reason, drugs and the operation of pharmacies are tightly regulated and structured by the Ministry of Health.

  Morocco's regulations are some of the most stringent, having been borrowed from countries with a highly developed and structured industry. These regulations, which define precisely the terms and conditions for operating in the sector for each of the various actors, from industrial manufacturers to retail pharmacies, set up a whole range of barriers aimed at protecting public health.

  However, due to their burdensome nature, these rules provide a real challenge for any new operator wishing to set up in the industrial drugs sector. The rules apply blindly to all operators without distinction, whether new or old, national or multinational.

  The protection of new drugs by means of patents also creates regulatory barriers because access to the market is dependent on those patents. However, it is worth remembering that patent rights are the result of a compromise between the interests of innovatory manufacturers, who are trying to write off the high pharmaceutical research costs needed to produce a new drug, and the interests of citizens, who need rapid access to the therapeutic advances represented by those drugs.

  It is worth noting that, because research is not very highly developed, either in universities or within the national pharmaceutical industry, the bulk of patents are owned by foreign laboratories.

- Welfare and health insurance institutions

  Welfare institutions aim to offer the best possible services to their members in terms of the quality of care provided. They also aim to balance their budgets in order to ensure their survival. In order to do so, they will try to optimise their resources by using the cheapest therapeutic alternatives.

In order to achieve that aim, reimbursement has to be based on the prices of generics. Because of this, the method of reimbursement risks creating a further barrier by favouring the cheapest drugs to the detriment of more expensive ones, except where the latter have no generic equivalent.

- The prescriber

The person prescribing a drug has the responsibility of choosing the drug that is best suited to his patient. He must try to secure the fullest and most rapid recovery possible for his patient, at the lowest possible cost. This highly complex choice will depend, first, on medical and pharmacological considerations and be made in the light of available or readily obtainable information regarding drugs.

However, it must be recognised that the abundance and complexity of the drug supply makes the prescriber's choice increasingly difficult, and, to varying degrees, he is subject to the influence, repeated entreaties and cleverly advertised blandishments of the pharmaceutical industry which today represents the main source of pharmacological knowledge and the instrument of its dissemination.

The power of drug promotion through visits to doctors and the power of communication remain the principal forces that are capable of influencing the flexibility of what a practitioner may prescribe. That prescription has a very important implication for the pharmaceutical industry, and large amounts of money are devoted to providing the conditions for being able to guide and influence it.

- Pharmacists and the sale of drugs

In retail pharmacies, drugs are sold according to a system whereby gross profit margins used to be set at 30% irrespective of the drug concerned. This constituted a barrier which tended to favour the most expensive drugs in the category to the detriment of the cheapest ones. However, the weak purchasing power of the customers of many retail pharmacies led numerous pharmacies to dispense the cheaper drugs for preference. Some of them substituted generics on economic grounds when this practice was still regarded as illegal. Others, if not the majority of local pharmacies, willingly accepted to give reductions of between 5% and 10% of the PPM in order to retain the loyalty of their customers, in addition to easy payment terms.

Today, that substitution is suggested to pharmacies as a way of easing the pressure of drug costs on health insurers, and it is coupled with a system of variable margins which tends to favour the use of generic drugs. However, retail pharmacists consider that, in its present form, the proposal from the Ministry of Health is a threat to the retail pharmacy sector, representing a danger to a sector which is already in bad shape. Without wanting to undermine the proposed system, they are asking for some of its provisions to be amended.

- Patients who use the drugs

Other than in the case of self-medication, patients do not always choose their own drugs. They are obliged to trust their doctor, or a pharmacist in the case of a pharmacy consultation. The only challenges for the patient are to find effective, safe treatment at the lowest possible cost. Where that patient has health insurance cover, access to the drug is no longer a problem provided that the drug can be reimbursed and that the portion of the cost to be borne by the patient is relatively modest and affordable.

1.7.2.2 Structural barriers

52. In the pharmaceutical industry, at global level, the structural barriers generally concern economies of scale. In the Moroccan pharmaceutical sector, economies of scale are a real challenge for industrial players. On the one hand, the market is characterised by its narrowness, and, on the other hand, the volume of drugs manufactured is low in global terms (an average of 8 packets per person per year). This quantity is manufactured by a large number of operators (40 pharmaceutical laboratories) and includes a considerable number of drugs (over 5 000 reference pharmaceuticals).

53. A strategic study of the pharmaceutical sector conducted by the Boston Consulting Group (BCG) has already pinpointed the dispersed nature of this market and its impact on economies of scale. Certain operators in the pharmaceutical industry have indicated that it is difficult for them to achieve economies of scale even where they hold a large share in their section of the market, especially where those markets have only low sales volumes. This is particularly true for operators with small industrial units, due to their size.

54. To overcome this problem, some have also decided to export and others have diversified their ranges in order to hold variable market shares over a range of sub-categories. This has also prompted certain multinationals to quit the manufacturing sector and to settle for importing drugs from their parent companies or to have their products made by other manufacturers, including national ones.

2. Competition problems that have been identified on the Moroccan drug market

55. In Morocco, the drug market is tightly regulated by the State, especially in terms of retail prices, which are administered and set by the public authorities such that it is not possible to talk of any price competition on that market. Nonetheless, some practices do have repercussions on the prices charged.

2.1 Influence of the pharmaceutical industry on the setting of drug prices

56. Any attempt to increase the price of a drug whose price has already been set is virtually ruled out. The Ministry of Health alone is empowered to set the prices of drugs and, where appropriate, to increase or reduce those prices. Pharmaceutical laboratories can always request an increase or decrease in the price of their drugs. The Ministry of Health will tend to respond positively and swiftly to any request for a decrease. In terms of an increase, a positive response is exceptional unless the price increases are justified by an increase in the price of one or more constituents of a drug or by altered parity between the national currency and the currencies used for purchasing raw materials or finished products.

57. The priority for industrial operators will therefore be to influence the initial price set for their drug. At the price setting stage, the administration may be subject to all kinds of pressure from manufacturers with a view to obtaining the “best prices”.

58. In the case of a new drug, the raw materials or finished products are imported by the local subsidiary of a foreign laboratory, in the majority of cases by a multinational from its parent company. The latter therefore sets the prices of the transfers and invoices for the raw materials or finished products. As happens the world over, this can give rise to over-invoicing thereby enabling certain subsidiaries to repatriate their profits to their parent companies. The local prices of drugs can be abnormally high compared with other countries as a result of this practice.

59. In terms of the pressure that may be exerted by certain industrial operators over the administration responsible for setting prices, diplomacy may come to the rescue of some multinational players, in order to obtain a high price. It is not uncommon for the ambassador of a Western country where the parent company of a multinational is situated to accompany the manager of the local subsidiary of that

multinational to a meeting with the Ministry of Health, with a view to obtaining "a good price" or to "settle" any other problems affecting the interests of that multinational.

60. In relations between the Ministry of Health and certain multinationals, blackmail has sometimes been used to obtain a favour or "a good price". Threatening to pull out of the country and dismiss large numbers of employees and to set up elsewhere, or to stop manufacturing the drug whose price is regarded as too low to ensure profitability, can be an effective tactic.

61. In the case of generic drugs, the prices set will be indexed in relation to that of the originator drug having the same qualitative and quantitative composition and identical pharmaceutical form. Thus, the price obtained for the originator drug will theoretically influence the price of all its generics.

62. In reality, this is not always the case. The proliferation of generics in a family of drugs can create a strong competitive momentum based on price.

2.2 Generic entry into the Moroccan pharmaceuticals market

63. The main characteristic of generic drugs is that they are much cheaper than the originator, often by at least 30%.

64. This price differential is favour of generics can be explained in part by the fact that a generic drug has no pharmaceutical research costs to offset and in part by the drug price setting system which automatically means that the price of generics is lower than that of the originator and often lower than that of the other generics that preceded it.

65. Generic drugs are therefore powerful and useful economic and therapeutic alternatives, especially in the case of treatments that are regarded as costly.

66. In 2010, the share of generic drugs in hospital procurement in Morocco was of the order of 90% by volume, whereas it was only 27.6% by volume and 28.3% by price on the private pharmaceuticals market (pharmacy sales). That share remained relatively low when compared with the comparable share in developed countries where the generics share was well in excess of 50% of all drugs consumed.

67. In this connection, it should be emphasised that Morocco has been profoundly affected by the clash on the world pharmaceutical market between originator and generic drugs. In these battles, whose violent nature is commensurate with the importance of the economic interests at stake, laboratories which produce originator drugs will do and attempt the impossible in order to retain their market share and protect their prices. To counter this, laboratories which produce generic drugs will try to penetrate and then conquer segments of the pharmaceuticals market with drugs whose prices are significantly lower than those of the originator.

68. The systematic confrontation between generic and originator drugs takes many forms and affects all facets of the drug market irrespective of scale, from scientific aspects to regulatory mechanisms, from commercial and marketing aspects to communication aspects and product and laboratory image…

69. The main thrust of the arguments traditionally used by manufacturers of originator drugs is the excessively high research cost to be offset, the allegedly higher quality of their products (reference products) and their years of experience. The arguments of generics manufacturers focus on improved access of the general public to generic drugs, on the one hand, and the contribution to safeguarding the budget of health insurance providers on the other.

70. The need to contain health spending in the face of increasing demand has prompted many of the most highly developed countries to encourage the use of generics. Generic copies were therefore authorised and marketed as soon as the patent giving a monopoly over the manufacture and marketing of the originator expired. As a result, the manufacturers of certain originators have lost their position on some markets. Certain multinational drug companies have instigated genuine "anti-generic" strategies for the purpose of hindering, by any means, the launch of generic drugs or restraining the development of their sales.

71. This battle between originator and generic drugs on the field of competition, which is being played out at international level, has obviously had repercussions in Morocco. Morocco appears to harbour certain anti-competitive practices that have been identified and combated in other countries.

72. Disparaging the quality of generics and justifying the prices of originator drugs by their incomparable "quality" are key anti-generic strategies used by laboratories possessing originator drugs.

73. Abuses have been frequent and denigration has often been taken to extreme lengths. A few years ago, a laboratory which manufactured an originator drug had no hesitation, in its publicity material directed at doctors, in saying "*If your patient is your enemy, prescribe him a generic drug.*" Another laboratory, when comparing its originator with generics, chose the image of a fresh egg alongside a "rotten" egg. The denigration has not ceased but is now taking more subtle forms.

74. Bioequivalence is the argument most widely used today, by laboratories which own originator drugs, as a means of combating generics. No distinction is made, in terms of pharmaceutical and pharmacological characteristics, between manufacturers of generics who are required to undertake bioequivalence studies and those who are exempt.

75. All generic drug manufacturers have nonetheless respected the requirement to undertake bioequivalence studies, ever since they were proposed by the Ministry of Health.

76. Public relations are another facet of this competitive clash. The amount of money devoted to this aspect is commensurate with the turnover to be achieved and the price level of the drugs concerned. What happens in the field of cancer and other chronic pathologies best exemplifies this type of conduct.

2.3 Virtual monopoly of costly drugs for serious pathologies

77. Costly drugs for serious pathologies are a real problem in Morocco. The prices of these drugs and the cost of treatment are a barrier to access by patients and a real danger for the budgets of health insurance companies.

78. There are many monopolistic situations on the market for serious pathology drugs (cancer, hepatitis, AIDS, etc.). These pathologies, which pose a serious challenge to medicine, are always calling out for cutting-edge innovative drugs. The life cycle of such products is therefore shortened. Generic drugs do not have the time to gain a foothold in those segments because, as soon as patents expire, other new drugs are launched onto the market.

79. An analysis of the arsenal of therapeutic anti-cancer drugs available in Morocco indicates its paucity. Just 67 International Non-proprietary Names (INNs), out of a total of 271 worldwide, are available in Morocco (in other words, 31% of all anti-cancer INNs). Of those 67 available in Morocco, only 22 are generic (33% of the INNs available in Morocco and 10% of those available worldwide).

80. In this situation, monopolies and dominant positions are legion.

81. However, taken together, all these elements are not in themselves enough to explain the very high prices of serious pathology drugs. The marketing tactics employed by some multinational companies which own these costly drugs complicate and aggravate the situation: exploitation of one's position or situation persists.

3. Conclusions

82. The Moroccan pharmaceuticals industry is a strategic sector for the national economy and for the regular, safe supply of drugs. The activities of this sector generate an annual turnover of around MAD 10 billion. The quality of the drugs produced in Morocco is internationally recognised, and Morocco exports nearly 60% of its drug production, much of which goes to Europe and Africa.

83. However, the industry is faced with a number of constraints that hamper its development. The narrowness of the national pharmaceuticals market and its dispersion over a large number of operators and over 5 000 drugs hinders economies of scale for manufacturers. Only 0.6% of the drugs marketed exceed 1 million packets per year by volume.

84. The pharmaceuticals manufacturing sector is highly concentrated. Out of all the operators in the sector, the top four performers hold a 44% market share. The top eight hold 64% and the top twenty 95%. The pharmaceuticals manufacturing sector in Morocco can be regarded as an open oligopoly. It has a core of a small number of operators who dominate the market. That core co-exists with large number of peripheral operators who have little market influence.

85. The pharmaceuticals manufacturing sector harbours a certain number of anti-competitive practices. Essentially, those practices seek to hinder the entry of generics into certain segments of the market where there are important financial and economic interests at stake. Serious and costly pathologies and, to a lesser extent, chronic pathologies are the main areas where such practices operate. The insulin case examined in 2012 by the Competition Council is a prominent example in this connection and raises the question of dumping and abuse of a collective dominant position by two laboratories which allegedly shared between them the procurement contracts issued by the Ministry of Health following requests for tenders over a period of several years[2].

86. The setting of drug prices is the responsibility of the Ministry of Health, but laboratories play a key role. They focus their efforts on market entry prices when obtaining a marketing authorisation, and, once their drugs have been registered, they try to obtain a "good price" in the knowledge that it is more difficult to put up the price once a drug has been marketed. Once the price has been set and the drug marketed, the cards are on the table and it is difficult to obtain an increase. However, pressure can be placed on the administration by industrial operators who resort to certain types of pressure with a view to obtaining high initial prices or increased prices of products already on the market.

87. A parliamentary committee is examining drug prices and has published a report on the matter. This report concluded that the price of drugs in Morocco was high compared with other countries such as France or Tunisia.

88. However, over the past few years, the relatively low price of generic drugs has helped to improve access to drugs for a large section of the population. Generic drugs have managed, despite a fraught competitive environment, to conquer many segments of the pharmaceuticals market. Generic drugs have become pre-eminent in the treatment of acute pathologies (antibiotics, etc.), and some generics have become market leaders in their therapeutic families (anti-hypertensive, anti-diabetic and lipid-lowering

[2] This case is still being examined by the Competition Council.

drugs, etc.), and, despite their late entry, generics have secured a strong position. Competition in these areas has improved considerably, especially since the beginning of the new millennium.

89. However, there are still problems associated with insulin for which there are only two suppliers, allowing little competition. The level of insulin prices is still very high compared to those of oral anti-diabetics where competition is strong.

90. It is clear that freedom of competition has arrived in the majority of the therapeutic segments of the market due to the entry of large numbers of generic drugs. This had led to drugs being offered at increasingly low prices. It is only the segments that relate to drugs for serious and costly pathologies (cancer, hepatitis, etc.), and also insulin, that still pose serious competition problems.