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ASSESSMENT OF THE CURRENT PRICING POLICY ON THE PHARMACEUTICAL SECTOR

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EXECUTIVE SUMMARY

Pharmaceuticals production is one of Jordan's largest and most significant industries, generating almost 20% of the country's GDP from manufacturing.

The pharmaceuticals industry's importance also stems from the fact that it is Jordan's only significant "next-generation" industry, as well as the fact that it is driven by exports. It is also "home-grown," with no substantial foreign investment to date (unlike garments, the country's top export), and is not based on natural resources, like potash, phosphates, and vegetables (the country's third, fourth, and fifth largest exports).

It's growth performance also has indirect impact on a number of major economic activities ranging from transportation, packaging, CROs, banking, training and consultancy, to the retail and wholesale selling of drugs.

More importantly however, the existence of this industry has allowed the government of Jordan to save substantially on its general medical and health expenditure. As such, it is imperative to strike a fair balance between keeping medical costs at reasonable levels while at the same time preserving the competitiveness and growth potential of this critical and vital industry.

One of the main concerns of this industry has been to institute a clearer mechanism for adjusting the prices of locally manufactured generics in a manner that would serve the dual purpose of providing reasonable prices for patients and preserving the competitiveness of this industry. Reference is particularly made to setting the price of newly manufactured and registered generics to the *lowest* price previously assigned to other similar generics.

While many commodities, including basic ones are adjusted periodically, pharmaceutical manufacturers claim that they are unjustly treated by not tying their prices to the prevailing market price. Moreover, since this sector is one of Jordan's major exporting industries, and since the export price is set by the country of origin, locally manufactured generics remain at a competitive disadvantage in export markets as long as their prices are not linked to *current* market prices.

The main objectives of this report is to shed light on the pricing policy in Jordan, examine its shortfalls, and compare it with policies in a number of regional countries including Saudi Arabia, Algeria, UAE and Egypt.

PHARMACEUTICAL INDUSTRY

The Jordanian pharmaceuticals industry has a high level of product competition, with 16 private manufacturers, six of which are listed on the Amman Stock Exchange (ASE). All are eager to gain entry to new export markets and are striving to capture a greater share of the small domestic market.

Prior to 1990, there were only six pharmaceutical manufacturers in Jordan. The increase in the number of manufacturers between 1991 and 1999 was primarily driven by the hope of new entrants to tap into the seemingly lucrative export markets for generic drugs that their predecessors had penetrated. These opportunists did not anticipate Jordan's accession to the World Trade Organization (WTO), which took place in April 2000, and the consequent requirements of adhering to stringent IPR and patent laws.

The Government of Jordan established the Jordan Food and Drug Administration (JFDA) in April 2003, following the introduction of the Food and Drug Administration Law for Year 2003. JFDA is a financially and administratively independence body that is governed by a Board of Directors and chaired by the Minister of Health. JFDA is divided into two main functions; food and drugs. The Drug Directorate within JFDA is responsible for ensuring that:

- Drugs are safe, efficacious and of good quality.
- Safety of products including infants milk formula and their special formula, supplementary food, medicinal plants, natural products, disinfectants and detergents, medical equipment and supplies, pharmaceutical preparations containing vitamins and minerals, cosmetic preparations and any other substances related to treatment or cure of human beings from diseases.

PRICING POLICIES

JORDAN

Pricing of pharmaceutical products in the Jordanian market is entrusted to JFDA as specified in Article 5 of the Drug and Pharmacy Law (Temporary Law No. 80 for Year 2001).

JFDA is the competent authority in Jordan to approve a pharmaceutical product prior to its sale. JFDA approves and registers generic versions of originator pharmaceutical products that comply with the relevant requirements.

For pricing of new chemical entities (originator pharmaceutical products), the drug price is the lowest of four benchmarks:

- (1) The export price. If the good is on a CIF basis, customs duties, bank charges, insurance, clearing and inland transportation costs are added to the cost price on the basis of the ex-factory price in the issued invoice. If the good is on a FOB basis, shipping costs are added.
- (2) The public price in the country of origin, following deduction of Value Added Tax, the wholesaler and pharmacist profits. Shipping, bank charges, insurance, clearing and inland transportation costs are also added.
- (3) The median price resulting from comparing the public price after deduction of the VAT, the wholesaler and pharmacist profits of the following European countries: France, Spain, Italy, Germany, Greece, the Netherlands and the United Kingdom. The median price is computed provided the drug is priced in at least three of these countries.

- (4) The public price in Saudi Arabia. For drugs not registered in Saudi Arabia, the Jordanian price will be reviewed once they are registered in Saudi Arabia. The agent is obliged to provide the Jordanian authorities with the CIF export price to Saudi Arabia within a period not exceeding four months from the date of pricing in Saudi Arabia.

Furthermore, if the product is only registered and priced in its country of origin, then they will determine the drugs which have close chemical composition and/or therapeutic effect, and pricing will be based upon those comparable drugs.

Where a drug has a registered equivalent (generic), the price is determined as the lowest price resulting from the application of the following methods (whichever is less):

1. The price computed from applying the benchmark outlined in (1) above.
2. The price computed from applying the benchmark outlined in (2) above.
3. The export price to the Saudi Market, and if it is not registered there, its pricing shall be reviewed upon its registration and the agent is committed to provide JFDA with the price within a period not exceeding four months.
4. Provided that the requested price does not exceed 80% of the price of the originator drug when first registered and priced or upon re-pricing it or 80% of its current price whichever is less.

SAUDI ARABIA

Saudi Arabia is the world's largest per capita single market for medical products and equipment. In 2005, the kingdom represented 65% of the Gulf market's annual expenditure on pharmaceuticals and is the 24th largest market in annual medical drug consumption. In 2007, Saudi Market represented 0.25-0.3% of global pharmaceutical market; close to \$2bn.

Like many GCC markets, the Saudi market is highly dependent on imported drugs, whereby local manufacturers possess around 15% of the local market. However, the local industry is highly perceived by the local medical profession. Moreover, the Saudi government is supporting the private sector in establishing local medicine production facilities. This support can be summarized as follows:

1) *Support for local generics*

Saudi Arabia supports its local generic industry by:

- a. Providing various financial and other incentives such as free land, interest-free loans and a 10% subsidy to the production cost of medicines and pharmaceutical products.
- b. Reviewing prices of local products every five years, compared to four years for foreign importers.
- c. Generic products manufactured by the local companies receive a price less than at least 15% of the originator product, while foreign generics receive the following:
 - i. If there is no locally manufactured generic:
 - 1st generic product would receive price of innovative product minus 30%,
 - 2nd generic product would receive price of 1st generic product minus 10% from price of 1st generic product
 - For generic products manufactured and marketed in the US or registered by EMEA, the following applies:

1. The first generic applicant is given 30% less than originator irrespective of number of previously registered generics at time of registration.
 2. Second generic would receive price of product registered as per (i) above minus 10%.
 - ii. In case of existing local manufactured and marketed generic product:
 - The first generic applicant from any country would receive 10% less than the price of the locally manufactured.
 - Subsequent generics would receive 10% less than the latest preceding generic as per (i) above.
- 2) *Support for foreign investment and transfer of technology:*
 Saudi Arabia encourages foreign investment and technology transfer by providing the following preferential price treatment:
- a. Products manufactured under license and still under patent and registered and priced for the company which is the licensor, are given the same price accredited to the licensor.
 - b. Products manufactured under license and still under patent and introduced for the first time through a local manufacturer, shall be priced in accordance with the 'common pricing criteria' assuming the price is given to the licensor company and then be given to the local manufacturer at the same price.
 - c. Products manufactured under license and still under patent and is produced locally under the name given by a local manufacturer (2nd brand) is given a price 10% less than the accredited price for the licensor company.
- 3) *Re-pricing guidelines for registered products*
- a. The public price is amended in light of the exchange rates issued by the Saudi Financial Corporation in January of every year if the change upward or downward in exchange price of currency was 10%.
 - b. The following points are considered when revising products' prices:
 - i. The price of the product in 30 countries
 - ii. Therapeutic significance and availability of alternatives
 - iii. Lowering the originator product that has no substitute generic by 15% after passing of 5 years from date of registration
 - iv. For products that have one or more substitute generic, the originator product shall be lowered by percentage of 15% to 25% in accordance with therapeutic significance of product, and generic is then lowered by 15% of the new price of originator.

UNITED ARAB EMIRATES

The UAE provides support to local generics through:

1. If the generic is locally or GCC manufactured it receives 20% less than originator price.
2. If generic is foreign manufactured it receives 30% less than the originator price.

EGYPT

In Egypt, the pricing system appears to be bureaucratic and arbitrary, maintaining the following features:

1. Does not allow for price increases to compensate for inflation
2. The most crucial step in the pricing process in Egypt is the price negotiations phase between the pricing committee and the company, which although employ certain criterion have wide discretionary powers. Their decisions are ultimately subject to the approval of the Minister of Health.
3. Pricing of generics are restrictive, basing the criteria on cost of raw materials, cost of packaging, cost of production, profit margins, taxes and tariffs.

Egypt supports local generics by:

1. First four products would all receive 60-75% of the price of the originator. Subsequent products would receive consecutive 10% reductions in the set price.
2. For imported generics, the price is based on the following considerations:
 - a. Availability of similar generics in the Egyptian markets.
 - b. The date of pricing of the local generic product.

ALGERIA

In Algeria, the pricing policy can be summed as follows:

1. Locally manufactured drugs have their ex-factory price fixed, taking into account the costs incurred. The price conversion of imported raw materials is determined by the exchange rate on the day of customs clearance.
2. In the case of imported drugs, it is the responsibility of the company to price the product according to the legislation on custom duties, taxes and margins, though the authorities can overrule. The law recommends the use of reference pricing. It has the case that some generics are priced as high as their original products.
3. Originator products will not be registered if there exists already a similar generic product in the market or if its price is higher than the reference price published in the official documentation of the General Secretariat of Government by 25%. Imports will only be allowed for those drugs whose local production does not suffice the Algerian market.

The mechanisms analyzed in bench-marked countries have the same common objective; to provide products at the lowest possible prices. Saudi Arabia and UAE offer a more transparent system, while the mechanism employed by Algeria and Egypt seems largely arbitrary and lacks transparency. It is also noticeable that re-pricing mechanisms employed by bench-marked countries are more flexible than those used in Jordan.

An important common feature in all bench-marked countries is that the pricing structure of generic drugs differentiates between local and foreign manufactured generics. For example, Saudi Arabia, UAE, and Egypt give preferential prices to local generics that are higher than imported generics. This logic behind this is twofold:

1. Higher prices for local generics provides them with higher profit margins
2. Higher prices ensures that entry into export markets would be based on a high price index in the country of origin.

In addition to the above, Saudi Arabia provides other advantages to its local industry by subjecting its prices for a review every five years instead of four years to foreign drugs. Furthermore, Saudi Arabia has a clear policy Saudi Arabia encourages foreign investment and technology transfer by providing preferential price treatment outlined above. It is evident that Saudi Arabia pricing mechanism vigorously supports local industry and encourages investment in this area.

MAIN SHORTFALL OF JORDAN'S PRICING POLICY

The following shortfalls were deduced from interviews conducted with the top management of three companies (referred to hereafter as companies A, B, and C) that were believed to be representative of large, medium and small pharmaceutical industries in Jordan.

Shortfalls of the pricing policy can be summed as follows:

- 1) *Newly registered generics take 80% of the price of the originator drug when first registered and priced, or upon re-pricing it, or of its current price, whichever is less.*

According to manufacturers, being bound by the lowest price has caused a number of their products to be unfairly priced at rates that are well below the 80% ceiling of the originator's current price.

Moreover, lack of readily available information and data on the prices of registered drugs puts manufacturers in disarray when choosing to price competitively.

- 2) *There is no clear mechanism for raising prices of locally manufactured generics.*

Manufacturers believe that the pricing policy favors prices to be lowered, and does not allow for increases in the prices of locally manufactured generics. Once the price is fixed though, it is difficult to raise it unless the manufacturer gives a compelling case that the generic is the only alternative to the originator, or if it is a life saving drug.¹ Although it is widely believed that prices of generics normally exhibit a downward trend year on year, nonetheless, manufacturers might need to raise their prices for four reasons deduced from the interviews:

- a. Manufacturers might be faced with market externalities (ex. fluctuations in oil prices) that may require prices to be adjusted upwards.
- b. Manufacturers at the time of registration may opt for a low price, as mentioned earlier, in order to compete in the local market and gain a better market share.
- c. Additional spending on R&D to enhance release, taste, color, or packaging of the drug among many others.
- d. Complying with Good Manufacturing Practices (GMP). This is a procedure that adds substantively to operational expenses.

¹ Recently the prices of 10 molecules per local manufacturer were revised and some were increase due to a significant lobbying effort led by JAPM. Nonetheless, no price increase mechanism has been instituted.

3) Comparing prices of originators to their prices in the Saudi market

Comparing the prices of originators to their prices in the Saudi market is considered to be unfair by local manufacturers. Being an oil rich state translates into cheaper energy, and hence lower production costs for manufacturers in Saudi Arabia.

More importantly, a number of policy measures provide support to locally manufactured generics in Saudi Arabia, and subsequently put other generics at a competitive disadvantage.

4) Prices of foreign generics are adjusted for changes in the exchange rate

Manufacturers claim that it is possible for imported generics to end up being priced higher than locally manufactured generics.

Prices of foreign generics can be adjusted upwards based on changes in the exchange rate; a privilege not enjoyed equally by local generics given that raw materials are imported and comprise a substantive 40% of total production costs. Prices of raw materials might increase as a result of foreign currency appreciation, and this is not reflected in the selling price of locally manufactured drugs.

5) Under licensed products manufactured in Jordan are treated as local products

Under licensed products do not enjoy additional privileges when being priced; they are priced as locally manufactured generics although under licensed products incur additional costs in order to comply with the requirements of the under licensee. These include sourcing raw materials, complying with GMP, on-going payment for royalties, technology transfer and special training. Moreover, they do not enjoy the privilege of adjusting for changes in exchange rates as do foreign generics. The latter adjust their prices in the local market based on the prevailing exchange rate.

6) Flat rate profit margin for pharmacists favor originators' products

In Jordan, pharmacists enjoy high flat markup of 26%. This mark up is applied across the board on all price-regulated drugs. Manufacturers claim that pharmacists tend to recommend to walk-in patients originator drugs since they are priced higher than the local generics and hence generate more profit in absolute terms.

This is a drawback to the local industry as their products are always priced lower. Pharmacists denied that citing that they benefit more from bonus schemes provided by the local manufacturers.

MOVING FORWARD

In light of the analysis of the Jordanian pharmaceutical pricing system and benchmarked countries, it is recommended that the Government of Jordan considers the following measures which would enhance the current system and assist local manufacturers in their exporting efforts:

1) Remove “lowest” and affix price to the prevailing market price

The Government of Jordan should consider amending Article 5(4) of the Pricing Criteria by removing the condition that the lesser price should be taken into consideration when pricing a generic and affix the originator price to the **actual** market price.

2) Consider providing preferential price structure to local generics

The analysis of the pricing policies of the benchmarked countries clearly indicated that they provide preferential price treatment for their local generics. Preferential treatment, as adopted in Saudi Arabia, UAE and Egypt, essentially means that local generics get a higher price than foreign generics entering the market. The Jordanian Government should consider providing such preferential treatment while ensuring that such policy does not conflict with Jordan’s commitments under bilateral and multilateral trade agreements.

3) Adopt Saudi Arabia’s and Algeria’s tier system

The tier system in Saudi Arabia provides wholesalers and pharmacists with a regressing markup scheme that seems to benefit the lower priced local products. JFDA has indicated during one interview that this system was under study for possible implementation in Jordan.

In Algeria there is a similar tier system where the profit at the level of the importer and the pharmacy is controlled according to price as well. It stipulates that if the medicine landed cost is less than 70 Algerian Dinars the importer margin is 20% and the pharmacy margin is 50% alternatively if the landed cost of the medicine is between 70 AD and 110 AD the importer margin is 15% and the pharmacy is 33%. Moreover, if the price is between 110 AD and 150 AD profits are 12% and 25% to the importer and pharmacy respectively. Lastly if price is > 150 AD then profits are 10% and 20 % to the importer and pharmacy respectively.

4) Change the pricing policy regarding locally produced under licensed products

It is recommended to amend Article 10 of Pricing Criteria to provide price incentives, similar to those adopted in Saudi Arabia, for transfer of technology transactions conducted between foreign and Jordanian companies for production of innovative drugs .

INTRODUCTION

Pharmaceuticals production is one of Jordan's largest and most significant industries, generating almost 20% of the country's GDP from manufacturing.

The pharmaceuticals industry's importance also stems from the fact that it is Jordan's only significant "next-generation" industry, as well as the fact that it is driven by exports. It is also "home-grown," with no substantial foreign investment to date (unlike garments, the country's top export), and is not based on natural resources, like potash, phosphates, and vegetables (the country's third, fourth, and fifth largest exports).

It's growth performance also has indirect impact on a number of major economic activities ranging from transportation, packaging, CROs, banking, training and consultancy, to the retail and wholesale selling of drugs.

More importantly however, the existence of this industry has allowed the government of Jordan to save substantially on its general medical and health expenditure. As such, it is imperative to strike a fair balance between keeping medical costs at reasonable levels while at the same time preserving the competitiveness and growth potential of this critical and vital industry.

One of the main concerns of this industry has been to institute a clearer mechanism for adjusting the prices of locally manufactured generics in a manner that would serve the dual purpose of providing reasonable prices for patients and sustaining the competitiveness of this industry. Reference is particularly made to setting the price of newly manufactured and registered generics to the *lowest* price previously assigned to other similar generics.

At time of registration, manufacturers might have different reasons for setting the price well below the 80% cap of the originator's price. One main reason would be the desirability of the manufacturer to compete with similar generics, and even the originator drug, and capture a sizeable share of the market with the lower price. Once registered, the price of generics can only be lowered. Adjustments for fluctuations in the exchange rates are only granted to foreign generics and originator drugs.

In 2007, manufacturers were hit hard with the rising inflationary pressures instigated primarily by the soaring energy costs. The general rise in prices caused operational expenses, including cost of imported raw material, which comprises 40% of manufacturing costs, to increase at a high rate.

While many commodities, including basic ones are adjusted periodically, pharmaceutical manufacturers claim that they are unjustly treated by not tying their prices to the prevailing market price. Moreover, since this sector is one of Jordan's major exporting industries, and since the export price is set by the country of origin, locally manufactured generics remain at

a competitive disadvantage in export markets as long as their prices are not linked to *current* market prices.

Three manufacturers were interviewed representing large, medium and small manufacturers respectively. The team of consultants had limited access to data to substantiate the arguments put forth by the interviewed manufacturers. This was primarily due to the fact that the JFDA was looking into raising the prices of a number of generics. Prices of those generics were eventually raised by 1-20%.

The main objectives of this report is to shed light on the pricing policy in Jordan, examine its shortfalls, and compare it with policies in a number of regional countries including Saudi Arabia, Algeria, UAE and Egypt.

SECTOR OVERVIEW

DOMESTIC PHARMACEUTICAL PRODUCERS

The Jordanian pharmaceuticals industry has a high level of product competition, with 16 private manufacturers (listed below), six of which are listed on the Amman Stock Exchange (ASE). All are eager to gain entry to new export markets and are striving to capture a greater share of the small domestic market.

Prior to 1990, there were only six pharmaceutical manufacturers in Jordan. The increase in the number of manufacturers between 1991 and 1999 was primarily driven by the hope of new entrants to tap into the seemingly lucrative export markets for generic drugs that their predecessors had penetrated. These opportunists did not anticipate Jordan's accession to the World Trade Organization (WTO), which took place in April 2000, and the consequent requirements of adhering to stringent IPR laws.

EXPORT PERFORMANCE

Jordan currently exports approximately 70 to 80% of its total pharmaceuticals production. As can be seen in Table 2, pharmaceutical exports were the country's second largest in 2007 accounting for around 10% of total exports and outstripping traditional resource-based commodities, such as potash and phosphate.

Table 2: Jordan's Top Five Exports (2007)

Commodity	% of Total Exports
Textiles and clothes	24.2
Pharmaceuticals	9.2
Potash	8.8
Phosphate	6.2
Vegetables	6.1

Source: Department of Statistics

Furthermore, Jordan's pharmaceutical exports have been growing over time. These exports have more than tripled over the past 10 years. In particular, they have grown by

Table 5: List of Domestic Producers in Jordan

#	Name
1	Hikma
2	Dar Al Dawa
3	Arab Pharmaceutical Manufacturing (APM)
4	Ram Pharmaceutical
5	Pharma International
6	Jordan Pharmaceutical Manufacturing
7	Jordan Sweden Medical and Sterilization Company (JOSWE)
8	Middle East Pharmaceuticals
9	United Pharmaceutical Manufacturing
10	Hayat
11	Arab Center for Pharmaceuticals and Chemicals (A.C.P)
12	Amman Pharmaceutical Industry
13	Jordan River Pharmaceutical Industries (JORIVER)
14	Al Kindi Pharmaceutical
15	Jerash Pharmaceuticals
16	Philadelphia Pharmaceuticals

approximately 60% percent over the period 2003-2006, as can be seen in the following table.

Table 3: Growth of Jordan's Pharmaceuticals Exports (2002-2006)
Domestic Exports: Value F.O.B. in US\$

	HS 3002	HS 3003	HS 3004	Total
2002	4,886,269	73,070,800	92,420,166	170,377,236
2003	1,086,871	84,775,285	70,744,579	156,606,734
% change 2002 - 2003	-78%	16%	-23%	-8%
2004	1,819,956	78,777,636	108,828,498	189,426,090
% change 2003 - 2004	67%	-7%	54%	21%
2005	5,017,612	87,198,988	144,671,294	236,887,894
% change 2004 - 2005	176%	11%	33%	25%
2006	5,169,465	65,109,129	181,336,922	251,615,516
% change 2005 - 2006	3%	-25%	25%	6%
% change 2003 - 2006	376%	-23%	156%	61%

Source: Department of Statistics

Notes:

3002 Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; anti sera and other blood fractions; vaccines, toxins, cultures of micro-organisms (excluding yeasts) and similar products.

3003 Medicaments (excluding goods of heading no.30.02,30.05 or 30.06) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packing for retail sale .

3004 Medicaments (excluding goods of heading no.30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses or in forms or packing for retail sale.

- 15% from each category has been estimated for Vet exports and was deducted from the total values.

Arab countries are the main export destination for Jordanian pharmaceuticals, with 98% of total exports going to these markets. Of these, main markets include Algeria, Iraq, and Saudi Arabia.

From the above tables outlining the exports and imports value for 2002 - 2006, the below table represents the balance of trade in the pharmaceutical sector.

Table 4: Balance of Trade in Pharmaceuticals, 2002 - 2006 in US\$

Year	Exports	Imports	Balance of Trade
2002	170,377.2	65,963	104,414.2
2003	156,606.7	78,056.9	78,549.8
2002 - 2003 % change	-8%	18%	-25%
2004	189,426.1	86,534.4	102,891.7
2003 - 2004 % change	21%	11%	31%
2005	236,887.9	100,314.5	136,573.4
2004 - 2005 % change	25%	16%	33%
2006	251,615.5	105,412.7	146,202.8
2005 - 2006 % change	6%	5%	7%
Total (2002 - 2006)	1,004,913.5	436,281.5	568,631.8

Note: All values are in thousands

15% was deducted from the total value of exports for Vet exports

Source: Exports - Department of Statistics
Imports – IMS

INDUSTRY SWOT ANALYSIS

Table1: SWOT

Strengths	Weaknesses
<ul style="list-style-type: none"> • Extensive regional export base, coupled with excellent regional reputation • Low risk on investment • High standards of local producers • Zero tax on profits generated by exports until 2015 and possibly beyond • Highly-skilled, low-wage workforce • Sufficient infrastructure • Extensive knowledge of local and regional market 	<ul style="list-style-type: none"> • Low investment in R&D • Product concentration • Low local market share • Small domestic market size • Underdeveloped cluster of weak supporting institutions and supplier networks • Restrictive drug pricing policy • All raw materials and packaging materials are being sourced from abroad which results in high cost of finished product.
Opportunities	Threats
<ul style="list-style-type: none"> • Relocation from Europe due to wage and cost pressures • IPR protection • Existence of Bolar provision in Jordan 	<ul style="list-style-type: none"> • High reliance on traditional export markets • High international industry standards and strict regulations • Instating Bolar provision into E.U. law • IPR protection • Continuous increase in production costs mainly energy • Emerging generic industries in export markets

REGULATORY ENVIRONMENT

JORDAN FOOD & DRUG ADMINISTRATION (JFDA)

The Government of Jordan established the Jordan Food and Drug Administration (JFDA) in April 2003, following the introduction of the Food and Drug Administration Law for Year 2003. JFDA is a financially and administratively independent body that is governed by a Board of Directors and chaired by the Minister of Health. JFDA is divided into two main functions; food and drugs. The Drug Directorate within JFDA is responsible for ensuring that:

- Drugs are safe, efficacious and of good quality.
- Safety of products including infants milk formula and their special formula, supplementary food, medicinal plants, natural products, disinfectants and detergents, medical equipment and supplies, pharmaceutical preparations containing vitamins and minerals, cosmetic preparations and any other substances related to treatment or cure of human beings from diseases.

Therefore, JFDA is the competent authority in Jordan to approve a pharmaceutical product prior to its sale. JFDA approves and registers generic versions of originator pharmaceutical products that comply with the relevant requirements. For registering a generic pharmaceutical product for approval in Jordan, the manufacturer files a technical dossier in compliance with ICH (International Conference on Harmonization) guidelines along with bio-equivalence data. As per regulations, the originator pharmaceutical product on which the generic pharmaceutical product is based must already be registered for at least one year in the country of origin. In addition, the originator pharmaceutical product must also be registered in the applicant's country of origin. As per regulations in Jordan, products marketed in Jordan should be manufactured in production facilities in compliance with Arabian and WHO GMP guidelines. The cost of registration of a drug in Jordan is US\$2,000 for originator pharmaceutical products and US\$1000 for generic pharmaceutical products. The registration process takes close to one year in Jordan.

In addition, JFDA performs the audit and inspection standards of its peers in Europe and the United States.

INTELLECTUAL PROPERTY

As a prerequisite to joining the WTO, Jordan had to amend and adopt several IP related legislation to bring it in line with the TRIPS Agreement. These encompassed a new Patent Law (No. 32/1999). Some of said legislative changes in the field of patent include the following: the duration of the patent protection was modified to 20 years from the date of filing an application (instead of 16 years from the date of granting under the old law); introduction of penalties against violators of patents; compulsory licensing was made possible only under very strict conditions and circumstances; more importantly the new law subjected all medical drugs, pharmaceutical compositions and food items to patent protection covering not only processes but also end products as well.

Furthermore, the newly introduced Unfair Competition and Trade Secrets Law introduced a five year data protection for undisclosed data the origination of which requires considerable effort relating to new chemical entities of pharmaceutical and agricultural products. Moreover, unlike other developing countries members of WTO, Jordan did not benefit from

any transitional periods to restructure its industry, within available resources, and had to implement the said laws prior to, or upon WTO accession

Following entry into WTO, the Jordanian Government began negotiating a free trade agreement with the United States. The negotiations led to the successful adoption of the Jordan United States Free Trade Agreement (JUSTFA), coming into force on December 17, 2001. JUSTFA included numerous IP commitments increasing the level of protection beyond the TRIPS Agreement (termed as “TRIPS Plus Commitments”). More significantly, the JUSTFA included several obligations concerning patents laws, pharmaceutical products and data protection.

PRICING POLICIES

JORDAN

Pricing of pharmaceutical products in the Jordanian market is entrusted to JFDA as specified in Article 5 of the Drug and Pharmacy Law (Temporary Law No. 80 for Year 2001). In this regard, the Director General of JFDA issued the Criteria and Standards related to Drugs Pricing, Re-pricing and Objections to Pricing Decisions on January 29, 2004 and were further amended on May 31, 2008 (hereinafter referred to as “Pricing Criteria”). Moreover, the Pricing Criteria established a Pricing Committee to oversee the implementation of the pricing standards and criterion. The section below highlights the main aspects of the pricing of pharmaceutical products, with particular emphasis on generic drugs:

PRICING MECHANISM

Pricing of New Chemical Entities

For pricing of new chemical entities (originator pharmaceutical products), the drug price is the lowest of four benchmarks:²

- (1) The export price. If the good is on a CIF basis, customs duties, bank charges, insurance, clearing and inland transportation costs are added to the cost price on the basis of the ex-factory price in the issued invoice. If the good is on a FOB basis, shipping costs are added.
- (2) The public price in the country of origin, following deduction of Value Added Tax, the wholesaler and pharmacist profits. Shipping, bank charges, insurance, clearing and inland transportation costs are also added.
- (3) The median price resulting from comparing the public price after deduction of the VAT, the wholesaler and pharmacist profits of the following European countries: France, Spain, Italy, Germany, Greece, the Netherlands and the United Kingdom. The median price is computed provided the drug is priced in at least three of these countries.

² Article (4) Pricing Criteria

- (4) The public price in Saudi Arabia. For drugs not registered in Saudi Arabia, the Jordanian price will be reviewed once they are registered in Saudi Arabia. The agent is obliged to provide the Jordanian authorities with the CIF export price to Saudi Arabia within a period not exceeding four months from the date of pricing in Saudi Arabia.

Furthermore, If the product is only registered and priced in its country of origin, then they will determine the drugs which have close chemical composition and/or therapeutic effect, and pricing will be based upon those comparable drugs.³

Pricing of Generics

Where a drug has a registered equivalent (generic), the price is determined as the lowest price resulting from the application of the following methods (whichever is less):⁴

1. The price computed from applying the benchmark outlined in (1) above.
2. The price computed from applying the benchmark outlined in (2) above.
3. The export price to the Saudi Market, and if it is not registered there, its pricing shall be reviewed upon its registration and the agent is committed to provide JFDA with the price within a period not exceeding four months.
4. Provided that the requested price does not exceed 80% of the price of the originator drug when first registered and priced or upon re-pricing it or 80% of its current price whichever is less.

Furthermore, the Pricing Criteria stipules that where there is a price reduction in the originator drug, all generics must reduce their price, except where the price is due to an exchange rate movement or at the request of the originator.

The applicant has 30 days in which to appeal a pricing decision of the Director General of the JFDA. Such an appeal will be referred to the Drug Pricing Committee which in turn has 30 days to make its recommendation. A price is considered inoperative if the applicant has not accepted it within 6 months of notification.⁵

The Director General of the JFDA issues a schedule of exchange rates in July each year and these are determined from the average rate for June using exchange rates published by the Central Bank of Jordan. Prices of products can be revised if the variation in the exchange rates exceeds 5% for three consecutive months.⁶

The Director General of JFDA, by a recommendation from the Pricing Committee, is entitled to cancel the registration of a drug or prohibit its re-registration except after one year from its cancellation and/or fining the agent with the financial compensation in the event of committing the following breaches:⁷

1. If it becomes apparent that it's pricing was done on the basis of false information submitted by the manufacturing company or the agent.
2. If the price to the Public in the Country of Origin is reduced and such reduction was not reflected on the selling price to the Jordanian Public, and the manufacturing company or its agent did not notify the Committee within a period not exceeding four months from the date of the reduction.

³ Article (4)(e) Pricing Criteria

⁴ Article (5) Pricing Criteria

⁵ Article (11) Pricing Criteria

⁶ Article (13) pricing Criteria

⁷ Article (14) Pricing Criteria

3. If the manufacturing company or its agents did not submit the export price to Saudi Arabia within four months from its pricing there, unless a document from the manufacturing company or its agent is submitted proving that the drug is not being marketed there.

The Pricing Criteria also stipulates that:⁸

1. The Pricing Committee must revise the prices of the new drugs (of new chemical composition) after two years of its registration and in accordance with the approved pricing Criteria.
2. The Pricing Committee must revise the prices of all registered drugs upon the renewal of its registration and in accordance with the approved pricing Criteria.

However, in such cases, due observance should be given not to exceed the previously determined price.

Upon the reduction of the Jordanian Public prices of the originator drug, the prices of all registered generic drugs shall be reduced in accordance with article 4(d) of Pricing Criteria (which states: "price does not exceed 80% of the price of the originator drug when first registered and priced or upon re-pricing it or 80% of its current price whichever is less.") except for reductions resulting from

- the variation in currency exchange rates
- Or on the basis of a request from the manufacturing company of the originator drug.

Implementation of new generic drug prices occurs only after the first importation of the reduced priced originator or upon generic drug renewal whichever comes first.

SAUDI ARABIA

BACKGROUND

Saudi Arabia is the world's largest per capita single market for medical products and equipment. In 2005, the kingdom represented 65% of the Gulf market's annual expenditure on pharmaceuticals and is the 24th largest market in annual medical drug consumption.⁹ In 2007, Saudi Market represent 0.25-0.3% of global pharmaceutical market; close to \$2bn.

Like many GCC markets, the Saudi market is highly dependent on imported drugs, whereby local manufacturers possess around 15% of the local market. However, the local industry is highly perceived by locally medical profession. Moreover, the Saudi government is supporting the private sector in establishing local medicine production facilities. Incentives such as free land, interest-free loans and a 10% subsidy to the production cost of medicines and pharmaceutical products have been implemented.¹⁰

The government uses a reference price mechanism to control the price of pharmaceutical products. The supplier must provide the authorities with information on the prices of the

⁸ Article (15) Pricing Criteria

⁹ Pharmaceutical Pricing and Reimbursement System in Saudi Arabia, published by URCH, June 2005

¹⁰ Ibid

product in around 40 countries, including many developing and least-developed countries, such as Bangladesh and Libya, or non-economically comparable countries like Lebanon or Jordan. The lowest of those prices is typically chosen by the Pricing Commission within the General Directorate of Medicinal and Pharmaceutical Licenses as the official Saudi price. The pricing procedure is launched in parallel to the registration procedure.¹¹

The largest single buyer of pharmaceuticals is the Ministry of Health. The Executive board of the Health Ministers Council for the Gulf Cooperation Council comes next. Around %73 of pharmaceuticals are purchased by the government and are therefore not affected by pricing policy as it depends mainly on tender business; only 23% is affected by pricing policy.¹²

Products can be sold in the country only after the Ministry of Health (MoH) has approved their prices. The Pharmaceutical Research Manufacturers of America (PhRMA) says that these controls act as a considerable barrier to investment. PhRMA says that price controls in Saudi Arabia act as a considerable barrier to market access for its members. The body alleges that government policies over the lowering of drug prices are not suitably transparent and have not been discussed with the drug industry.¹³ PhRMA also criticizes the Saudi government's alleged policy of 'dollarization', whereby euro import prices are converted into dollars, based on an arbitrary exchange rate. This has led to losses of up to 20% for PhRMA member companies due to the difference in value between the euro and the dollar.¹⁴ PhRMA also notes that Saudi Arabia has increased the number of reference countries used for pricing pharmaceutical products, and that Saudi Arabia's re-pricing criteria favor local producers over foreign importers.¹⁵ This is because domestic drug makers have their prices reviewed every five years, compared to four years for foreign importers. Prices for imported drugs are calculated by the country's pricing committee, which considers manufacturers', wholesale and retail prices in the 'country of origin', export (CIF) prices to Saudi Arabia, and CIF prices to 30 other countries. However, usually the lowest price is accepted. PhRMA argues that these markets are not comparable to Saudi Arabia in terms of living standards, drug consumption patterns, income levels, exchange rates or regulatory requirements.

Meanwhile, the health authorities in the country are also accused of discriminating in favor of local or regional (GCC-based) companies by providing them with faster registration times and preferential pricing. The prices of imported drugs are reviewed every four years, with new prices always set lower than previous levels. In comparison, local manufacturers have their prices reviewed every five years. In government tenders, a 10% preference is granted to local or GCC-based companies compared to multinationals. Observers expect this bias to continue, as integration within the GCC gathers pace, despite clear WTO provisions against it.¹⁶

The body also alleges that the MoH discriminates in favor of local drug firms, which have their prices reviewed every five years, compared to four years for foreign companies since price revisions end with price deductions, local drugs therefore benefit from an additional year where their prices are higher than their foreign counterparts.¹⁷ Imports dominate the market, accounting for around 90% of drug consumption, because of the traditional wealth of the country. However, the government is looking to curb health spending – recently introducing mandatory insurance for expatriates – and is encouraging generic substitution.¹⁸

¹¹ Ibid

¹² Presentation by Saudi Pharmaceutical Committee in Pricing Workshop May 2008 (see <http://www.sfda.gov.sa/Ar/Drug>)

¹³ The Saudi Arabia Pharmaceuticals and Healthcare Report 2008, Business Monitoring Group

¹⁴ Ibid

¹⁵ Ibid

¹⁶ Ibid

¹⁷ Ibid

¹⁸ Ibid

This should provide a boost to domestic manufacturers, with Saudi Pharmaceutical Industries and Medical Appliances Corporation (SPIMACO) the most likely beneficiary. SPIMACO is the leading domestic drug maker and has recently recorded strong results.¹⁹

Pricing Mechanism

Saudi Arabia has the following common pricing requirements and criteria (“common pricing criteria”) for patented innovative products with no equivalent products marketed in Saudi Arabia:

- Ex factory price in country of origin
- Wholesaler price in country of origin.
- Public (retail) prices in country of origin.
- Suggested Cost, Insurance and Freight (CIF) price by the applicant company in currency of country of origin.
- The price in official reference countries (an extensive list of 30 countries)
- Product price in official published references.
- Therapeutic significance of products.

However, pricing of originator products with similar product in the market (i.e. of the same molecule not indication) is based on:

- (1) Common pricing criteria (as outlined above).
- (2) Prices of the similar products already registered in Saudi Arabia.
- (3) Benefits/Risks ratio.
- (4) Cost of therapeutic regimen.
- (5) Cost of daily therapeutic dose.

Generic Products

The Pricing Regulation provides that **imported** generic products would be priced in accordance with the following: (computation resulting in the lowest price would be selected)

- (a) Common pricing criteria (as outlined above)
- (b) Product therapeutic significance including the following:
 - a. Price will not exceed lowest price of similar registered product
 - b. If there is no locally manufactured generic:
 - i. 1st generic product would receive price of innovative product minus 30%
 - ii. 2nd generic product would receive price of 1st generic product minus 10% from price of 1st generic product
 - iii. For generic products manufactured and marketed in the US or registered by EMEA, the following applies:

¹⁹ Ibid

1. The First generic applicant is given 30% less than originator irrespective of number of previously registered generics at time of registration.
 2. Second generic would receive price of product registered as per (a) above minus 10%
- c. In case of existing local manufactured and marketed generic product:
- i. First generic applicant from any country would receive 10% less than the price of the locally manufactured.
 - ii. Subsequent generics would receive 10% less than latest preceding generic as be (i) above.

For locally manufactured generic pharmaceuticals, they are priced according to the following criteria:

1. Products manufactured under license and still under patent and registered and priced for the company which is the licensor, are given the same price accredited to the licensor.
2. Products manufactured under license and still under patent and introduced for the first time through a local manufacturer, shall be priced in accordance with the 'Common pricing criteria' assuming the price is given to the licensor company and then be given to the local manufacturer at the same price.
3. Products manufactured under license and still under patent and is produced locally under the name given by a local manufacturer (2nd brand) is given a price 10% less than the accredited price for the licensor company.
4. Generic products manufactured by the local companies receive a price less than at least 15% of the originator product.
- 5.

Re-Pricing guidelines for registered products

The Pricing Regulations provides for the review the exportation (CIF) prices for the registered products every 5 years (unless otherwise necessitated).

The public price is amended in light of the exchange rates issued by the Saudi Financial Corporation in January of every year if the change upward or downward in exchange price of currency was 10%.

Furthermore, the following points are considered when revising products' prices:

- A. The price of the product in 30 countries.
- B. Therapeutic significance and availability of alternatives
- C. lowering the originator product that has no substitute generic by 15% after passing of 5 years from date of registration
- D. For products that have one or more substitute generic, the originator product shall be lowered by percentage of 15% to 25% in accordance with therapeutic significance of product, and generic is then lowered by 15% of the new price of originator.

In addition, when re-pricing for certain products that are essential for a specific category of patients for which the lowering of the price is determined to be the reason for its non-availability in the market, the Pricing Committee has the right to increase its price for the public good.

Lastly, it is worth noting that the Ministry of Health is working on new pricing guidelines that are expected to change the system described above. The issuance of said guidelines is expected before end of 2008.

UNITED ARAB EMIRATES

BACKGROUND

The United Arab Emirates may not be the largest pharmaceutical market in the Middle East and Africa (MEA), but it possesses several advantages that make it an attractive prospect. The drug market is estimated to be worth US\$0.9bn in 2007 and expected to reach a value of US\$1.45bn by 2012.²⁰

The government is keen to attract foreign investment and diversify the country's economy, which is highly reliant on oil. To this end, the government has identified the pharmaceutical and healthcare industries as important industries to develop. Authorities have created two notable free zones to attract foreign investment. DuBiotech is aimed at developing the UAE's biotech industry, while Dubai Healthcare City (DHCC) should enhance the country's healthcare system and should enhance the UAE's reputation as a centre for premium healthcare, encouraging growth as a medical tourism destination.²¹

Meanwhile, the pharmaceutical manufacturing business is in danger of getting left behind the fast developing biotech and healthcare sectors. The largest domestic player, Julphar, only generates 7% of sales in the UAE. A wealthy population with a preference for novel therapies ensures there is a high demand for imports of patented drugs. Consequently, the pharmaceutical trade balance is in the red and expected to become more negative over the five year forecast period, although a relaxation of the rules governing foreign ownership of companies should serve to boost investment in the local manufacturing industry.²²

The pricing of drugs in the United Arab Emirates is the responsibility of the Registration and Pricing Unit. The Unit is part of the Medicine Regulatory Affairs Section of the Drug Control Department within the Ministry of Health. The Drug Control Department is sometimes referred to as the Medicine and Pharmacy Control (MPC) Department, and the Medicine Regulatory Affairs Section is sometimes also named Technical Affairs Section. The Drug Control Department reports to the Undersecretary for Pharmacy and Supplies and advises the Minister of Health in achieving the strategic aims of the Ministry.

²⁰ The UAE Pharmaceuticals and Healthcare Report 2008, Business Monitoring Group

²¹ Ibid

²² Ibid

Drug prices are currently fixed against different currencies depending on their origin.²³ Prices are set taking into consideration the prices of similar pharmaceuticals, the prices in GCC countries and the prices in neighboring countries to the country of origin. Price setting takes as well the real cost of manufacturing the product into consideration.²⁴

A revised price list came into force on 15 September 2005. Prices were decreased by up to 7%, following a reduction in the profit margins of around 3,000 drugs from 55% to 44%.²⁵ Local pharmaceutical companies are not exempt from the price changes. 2,903 drugs with CIF price quoted in dollars and 159 medicines from Saudi Arabia will see their prices decreased by 7.1%, 540 drugs with CIF price quoted in pounds sterling will face reductions of 4.5%, while 47 pharmaceuticals from Jordan had their prices reduced by 6 to 7%.²⁶ Pharmaceuticals with CIF prices quoted in yen decreased by 2.07%. Prices denominated in euros will remain stable, despite the decrease in profit margins, as the exchange rate used for conversion by the Ministry of Health will be raised to 4.3 from 4 previously.²⁷

Pricing Mechanism

The UAE Ministry of Health requires that any foreign company applying for registration of its products in UAE to provide a legalized price certificate that contains the following information:

- 1- Name of the manufacturer with country of origin.
- 2- Name of the product with dosage form, as to be registered.
- 3- Pack size with descriptions (like blister/strip/bottle, ampoule/vial/syringe pack, dry powder/ready to use liquid, unit size and number in a pack).
- 4- Proposed CIF price in the currency of the country of origin or in US dollars.
- 5- Ex-factory, wholesale and Retail Prices in the country of origin (preferably in the same currency of the CIF price).
- 6- GCC price certificate: The company shall submit CIF price certificate of GCC countries (authenticated).

The price certificate with all the above information should be submitted along with other registration documents. Only registered products are allowed to be imported to the UAE either for private market or for the Government Sector. Registration of any product is complete only after its pricing. No registration certificate is granted to non-priced products. Registration of the products shall be cancelled, if the company disagrees to its price.

The pricing procedure entail that the CIF and/or the calculated retail prices will be compared to the following reference prices:

- Ex-factory price.
- Wholesale and Retail prices in the country of origin.
- Retail prices of the similar products available in UAE.

²³ Pharmaceutical Pricing and Reimbursement System in UAE, published by URCH, June 2005

²⁴ Ibid

²⁵ Ibid

²⁶ Ibid

²⁷ Ibid

- Net price given in BNF
- Trade price given in Chemists & Druggists price list of UK.
- CIF prices given in the official price-list of Saudi Arabia and other GCC countries and other Arab Countries.
- Red Book, Vidal, or any other reference (depending on the country of origin of the product).

The pricing committee will always favor the least price from among the above.

In addition, the following conditions apply:

- a) The retail prices should be proportionate to the prices of similar products available in UAE.
- b) The approved CIF should not exceed the ex-factory price by the more than 15%.
- c) Prices of the products of the multinational companies will be compared with similar products from other multinational research companies, especially with those from the same origin (if available).
- d) Prices of products of Arab companies will be compared with similar products from other Arab countries.

The price of generic products will be determined in accordance with the following:

1. If generic is local or GCC manufactured, it shall receive a price of similar innovative (originator) products minus 20%
2. If generic is foreign manufactured, it shall receive a price of similar innovative (originator) products minus 30%

In addition to the above, if the quoted CIF price is found to be unreasonable, the company will be asked to reduce the same by giving two weeks' notice. If the company fails to respond in time, the Ministry of Health shall have the right to price the product based on the available information. If the company does not accept this price the ministry shall have the right to revoke registration of such products after serving the company a show-cause notice of two weeks.

The company can appeal against any approved price, with necessary documents, within one month from the date of issue of the price decree. The pricing committee in its next meeting will discuss such appeals and the decision will be communicated to the company in due course.

The following conditions apply when revising or reducing registered products:

- 1- If the prevailing price of any product is found to be considerably higher when compared with its prices in the GCC/other Arab counties, or the country of origin, or the reference prices or similar product, the company will be served a two week's notice to reduce the price. If the company fails to respond in time the Ministry will have the right to reduce the price accordingly without serving any further notice to the company.
- 2- If the exchange rate of currency of CIF varies by 10% or more than the prevailing rate, the ministry shall have the right to revise the retail prices accordingly after serving a one-week notice to the agent.

- 3- If the prevailing prices of any product are reduced in the country of origin or in the GCC/other Arab Countries the company should inform the ministry in time. If otherwise the ministry will have the right to reduce such price(s) without serving notice to the company.
- 4- If the import price of any product for selling in the public market in the UAE is found to be considerably lower than its approved CIF price, the ministry can reduce its CIF price accordingly, after giving the company a chance to explain by serving two weeks' notice.
- 5- The ministry shall have right to revise the prevailing price of any product when discussed for minor change or renewal of registration.
- 6- A notice of two weeks will be served to the company prior to reduction of any existing price, in cases other than the general revision of exchange rates.

EGYPT

BACKGROUND

Egypt's pharmaceutical market is fairly small in global terms, but should experience strong growth over the next five years. Valued at an estimated 1.05bn in 2007, the market should expand to US\$1.69bn by 2012 – representing a CAGR of almost 10%. The small market size is a result of low per capita drug expenditure of around US\$14 per annum and strict government price controls.²⁸

Local manufacturing is a high volume, low value business. Domestic drug makers supply around 93% of the market in volume terms, but just 52% in value terms. Due to strict price controls that result in some of the lowest drug prices in the region, imports of high margin patented drugs are most attractive, which accounts for the high size of the patented drug.²⁹

Without the substantial oil reserves of the Gulf states, Egypt has attempted to create an affordable healthcare system through drug price controls. This has served to further deter foreign investment from the drug market, leaving domestic industry focused on basic medicines.³⁰

Drug price control was set by ministerial decree No.341 in September 1991. The government sets the price of drugs to ensure an affordable supply to poorer Egyptians but does not allow for price increases to compensate for inflation.³¹ A pricing committee within the Ministry of Health and Population reviews and approves for sale all drugs marketed in the country. It determines what prices are appropriate for imported and locally produced drugs. If the price is deemed too high for the Egyptian market, permission is not granted.³² The price setting mechanism lacks transparency and it has already happened that different prices were set for similar drugs produced by public companies and private companies.³³

²⁸ Egypt Pharmaceuticals and Healthcare Report 2008, Business Monitoring Group

²⁹ Ibid

³⁰ Ibid

³¹ Ibid

³² Pharmaceutical Pricing and Reimbursement System in Egypt, published by URCH, June 2005

³³ Ibid

Many regulations regarding manufacture and registration are opaque and vague. The lack of clear accountability, timelines and procedures lead to long delays in new product registration, in some cases as long as 2–3 years. Delays in new product registration constitute a serious trade barrier for foreign manufacturers. By comparison, local companies appear to enjoy a preferential status in the registration process, gaining faster approvals.³⁴

PRICING MECHANISM

Pricing of Innovative Products

The criterion is based on the following:

1. Cost plus method which entails calculating the retail price of the product according to a cost sheet which consists of:
 - a. CIF or FOB price of the product.
 - b. Profit margin: company/ distributor/ pharmacist
 - c. Customs and tariffs.
2. Price comparative study of the products in:
 - a. Country of origin.
 - b. In neighboring and EU countries (KSA, Bahrain, Jordan, UAE, Greece, etc).
 - c. The available official published references (BNF, VIDAL, etc).
3. Comparison of the product with the alternative brands in the same therapeutic group.
 - a. Examining risk/ benefit ratio with alternative brands.
 - b. Taking into consideration the difference of doses and the overall average cost of therapeutic regimen.
 - c. The pricing committee sets the price to be the lowest among any neighboring countries.
4. In addition of the above, the most crucial step in the pricing process in Egypt is the price negotiations phase between the pricing committee and the company, which although employ the above criteria have wide discretionary powers. Their decisions are ultimately subject to the approval of the Minister of Health.

³⁴ Ibid

Pricing of Generics

The criterion is based on the following:

1. The retail price is based on the cost, which is calculated by adding the following:
 - a. Cost of Raw materials.
 - b. Cost of Packaging.
 - c. Cost of Production.
 - d. Profit margins.
 - e. Taxes & Tariffs.
2. For locally manufactured generic products, the first four products would all receive 60-75% of the price of the originator. Subsequent products would receive consecutive 10% reductions in the set price.
3. For imported generic products, the price is based on the following considerations:
 - a. Availability of similar generics in the Egyptian markets.
 - b. The date of pricing of the above products.

The above price is reviewed occasionally upon currency exchange rate variations which affect the raw materials and packaging materials.

ALGERIA

BACKGROUND

The State monopoly on imports of drugs was abolished in 1989. Official statistics indicate 66 importers of pharmaceutical products are registered. 89% of the drug bill is imported by the 42 largest importers. The Ministry of Health, Population and Hospital Reform requires distributors to obtain authorizations to sell imported drugs, and expects those to have been marketed in their country of origin, as well as in another country. ³⁵

Saidal is the largest local manufacturer, and accounts for around 95% of the total domestic production. It hopes to increase its turnover to \$150m by 2010, primarily by expanding its sales into the African market. Saidal covers approximately 42% of the Algerian drug needs. Simedal and the Algerian Central Pharmacy are the two other public-sector companies involved in importing pharmaceuticals.³⁶

³⁵ Pharmaceutical Pricing and Reimbursement System in Algeria, published by URCH, June 2005

³⁶ Ibid

The Algerian Central Procurement Office imports and distributes all pharmaceutical products for rare diseases. Some of Sidal's products which are more expensive than their respective imported drugs have been favored by the Ministry of Health, Population and Hospital Reform so far, despite the law stating a product should be imported if the local price exceeds the import price by 10%.³⁷

At the beginning of 2001, 44 production units across the country were registered. National production satisfies 30% of the national demand for pharmaceuticals, but barely 10% of the Essential Drug List. A domestic private sector has emerged (five companies in 2000), but until recently, it does not account for more than 5% of the total domestic production.³⁸

The Directorate of Pharmacy and Medicine, part of the Ministry of Health, Population and Hospital Reform legislates and controls the evaluation, registration, pricing, marketing, import and export of pharmaceuticals.³⁹

The registration dossier takes between six months and a year to be approved. It should include pharmaceutical, pharmacological, toxicological, therapeutic and clinical evidence, as well as information on the manufacturing process.⁴⁰

Amid growing consumer complaints about the high price of prescription drugs and government concerns about its rising bill for imported medications, the Algerian government recently passed legislation to promote the use of generic pharmaceuticals.⁴¹

On March 4th, 2008, the cabinet approved measures encouraging the production and distribution of generic drugs. The legislation provides for the creation of a national pharmaceutical agency tasked with monitoring drug availability, safety, quality, inspections and regulatory compliance. The list of state-reimbursed drugs was also expanded from 116 to 295 internationally-recognized medications.⁴²

The move comes in response to President Bouteflika's demand in late February that the government promote the national pharmaceutical industry and secure the co-operation of foreign competitors in order to reduce the country's drug costs.⁴³

According to Minister of Labor and Social Protection Tayeb Louh, this new policy should contribute to reducing price of drugs and a slowdown in social security spending, which climbed from 7.6% in 2006 to 18.8% in 2007.⁴⁴

³⁷ Ibid

³⁸ Ibid

³⁹ Ibid

⁴⁰ Ibid

⁴¹ See http://www.magharebia.com/cocoon/awi/xhtml1/en_GB/features/awi/features/2008/03/14/feature-01

⁴² Ibid

⁴³ Ibid

⁴⁴ Ibid

PRICING MECHANISM

The Directorate of Pharmacy and Medicine, part of the Ministry of Health, Population and Hospital Reform legislates and controls the evaluation, registration, pricing, marketing, import and export of pharmaceuticals.

The Decree dated March 1998 defines the pricing mechanism, and fixes the margins of wholesalers and pharmacists for all pharmaceuticals.⁴⁵

Locally manufactured drugs have their ex-factory price fixed, taking into account the costs incurred. The price conversion of imported raw materials is determined by the exchange rate on the day of customs clearance.⁴⁶

In the case of imported drugs, it is the responsibility of the company to price the product according to the legislation on custom duties, taxes and margins, though the authorities can overrule. The law recommends the use of reference pricing. It has been the case that some generics are priced as high as their original products. The Decree dated 21 July 2004 on reference pricing has been applied properly. Estimates of annual achievable savings are of the order of \$100 million.⁴⁷ (and now it is expected to reach \$300 million in 2009).

In 2005, generics have very limited presence in the Algerian market, but they now constitute about 30% in term of value and more than 50% in terms of units. Sidal, the dominant local manufacturer, has a Centre for Research and Development which develops five to six generics per year. 60% of the drugs on the 2003 Essential Drug List were original products.⁴⁸

On 7 September 2003, the Ministry of Health, Population and Hospital Reform issued new regulations coming in force on 1 January 2004 to promote generics. Following these guidelines, branded medicines will not be registered if there exists already a similar generic product in the market, or if its price is higher than the reference price published in the official documentation of the General Secretariat of Government (*Journal Officiel de la République Algérienne Démocratique et Populaire*) by 25%. Imports will only be allowed for those drugs whose local production does not suffice the Algerian market.⁴⁹

⁴⁵ Pharmaceutical Pricing and Reimbursement System in Algeria, published by URCH, June 2005

⁴⁶ Ibid

⁴⁷ Ibid

⁴⁸ Ibid

⁴⁹ Ibid

BRIEF SUMMARY OF MAIN FEATURES OF BENCH-MARKED COUNTRIES

The mechanisms analyzed in bench-marked countries have the same common objective; to provide products at the lowest possible prices. Saudi Arabia and UAE offer a more transparent system, while the mechanism employed by Algeria and Egypt seems largely arbitrary and lacks transparency. It is also noticeable that re-pricing mechanisms employed by bench-marked countries are more flexible than those used in Jordan.

An important common feature in all bench-marked countries is that the pricing structure of generic drugs differentiates between local and foreign manufactured generics. For example, Saudi Arabia, UAE, and Egypt give preferential prices to local generics that are higher than imported generics. This logic behind this is twofold:

1. Higher prices for local generics provides them with higher profit margins
2. Higher prices ensure that entry into export markets would be based on a high price index in the country of origin.

In addition to the above, Saudi Arabia provides other advantages to its local industry by subjecting its prices for a review every five years instead of four years to foreign drugs. Furthermore, Saudi Arabia has a clear policy Saudi Arabia encourages foreign investment and technology transfer by providing preferential price treatment outlined above. It is evident that Saudi Arabia pricing mechanism vigorously supports local industry and encourages investment in this area.

MATRIX OF BENCH-MARKED COUNTRIES

Issue	Jordan	Saudi Arabia	UAE	Egypt	Algeria
Compares Prices to other countries	Yes	Yes	Yes	Yes	Yes
Generic receive assigned percentage less than their originator counterparts	Yes (no more than 80%)	Yes First foreign generic receives 30% less than Originator. Second foreign generic 10% of previous price If local generic exists then foreign generic receives 10% less than local generic	Yes If local or GCC 20% less than originator If foreign 30% less than originator	Yes Local generic receives 65% to 75% of originator	No
Prices are revised regularly	Yes Every five years unless change occurs earlier in Saudi Market	Yes Every five years for local and every four years for foreign	Yes	Yes	Yes
Local generics are given preferential price treatment	No	Yes	Yes	Yes	No
Under licensed product receive same price as local	Yes	No If certain conditions met it received same price as foreign	Yes	Yes	Yes

SHORTFALLS OF THE PRICING POLICY

The following shortfalls were deduced from interviews conducted with the top management of three companies were believed to be representative of large, medium and small pharmaceutical industries in Jordan.

Shortfalls of the pricing policy can be summed as follows:

1) NEWLY REGISTERED GENERICS TAKE 80% OF THE PRICE OF THE ORIGINATOR DRUG WHEN FIRST REGISTERED AND PRICED, OR UPON RE-PRICING IT, OR OF ITS CURRENT PRICE, WHICHEVER IS LESS.

Article 5 of the Pricing Policy stipulates that the price of newly registered generic drugs is set at the *lowest* of four different computations as stated in Box 1.

Box 1: Pricing Policy Article 5

The price of a generic drug to the Jordanian Public is determined as a result of applying any of the following mechanisms, whichever is less:

1. The price computed from applying Article (2)
If the goods are on CIF basis, the drug price to the Jordanian Public is computed from the cost price on the basis of the factory-listed price in the invoice issued from the party designated to issue invoices by adding to it customs duties, bank's charges, insurance, clearing and inland transportation (plus the profits of the wholesaler, pharmacy and their administrative costs), but if the basis of shipment is FOB, the shipping costs shall be added to the above.
2. The price computed from applying Article (3)
The drug price to the Jordanian Public is computed from the cost of the imported drug on the basis of the public price in the Country of Origin after deducting the Value Added Tax there, if applicable, and after deducting the profits of wholesalers and retailers there, adding the shipping costs, bank's expenses and charges, insurance clearing and inland transportation (plus the profits of the drug store and pharmacy and their administrative costs).
3. The export price to the Saudi Market, and if it is not registered there, its pricing shall be reviewed upon its registration and the agent is committed to provide the Administration with the price within a period not exceeding four months.
4. Provided that the requested price does not exceed 80% of the price of the originator drug when first registered and priced or upon re-pricing it by virtue of Article (16) or of its current price, whichever is less.

The main issue manufacturers have with the above computation formula is particularly linked to the fourth option where it states that the requested price of a newly registered generic must be the **lowest** of the following three scenarios:

- (1) Price set at 80% of the price of the originator drug when *first registered and priced*, or

- (2) Price set at 80% of the price of the originator drug when *re-priced*, or
- (3) Price set at 80% of the price of the originator drug at its *current price*.

According to manufacturers, being bound by the lowest price has caused a number of their products to be unfairly priced at rates that are well below the 80% ceiling of the originator’s current price. Examples of this can be viewed in the table below where a number of Hikma and JOSWE generics are priced at a range between 49-61% of the originator’s current price.

Table 6: Examples of Generics Priced below 80% of Originator Hikma Products

Originator Product	Current Price (JD)	Local Generic	Price (JD)	% of Originator
Plavix 75 mg tabs	73.83	Hikma / Cloplav tabs	45.43	61
Lipitor 40 mg tabs	65.27	Hikma / Vastor 40 mg tabs	31.86	49
Lipitor 20 mg tabs	57.15	Hikma / Vastor 20 mg tabs	27.23	47
Lipitor 10 mg tabs	36.91	Hikma / Vastor 10 mg tabs	19.31	52
Fasomax	24	JOSWE / Alandomax	13	54
Diovan	39	JOSWE / Arbiten	21	54

Source: Market Survey

At the time of registration, manufacturers might opt to price their product below the 80% cap, and sometimes well below, in order to give their product a price advantage in the local market and effectively capture a larger share of the market. Market dynamics however, in addition to unforeseen forces such as increases in costs of production might make the originally set price either unfeasible or unfair, especially to other manufacturers (*see Box 2*). Nonetheless, because manufacturers are bound to the “lowest” criteria, they are never able to raise their price to the 80% cap that is granted to them by law.

Box 2: Price

Originator drug Plavex was registered to sell at JD72. JOSWE registered a generic at JD45 (Klovex) to capture a sizeable market share. When Hikma applied to register Cloplav, it was granted the low price of JOSWE generic that was previously registered in the market. This was disadvantageous to Hikma because they were aiming at the 80% ceiling.

As a side note, the lack of readily available data and information on the prices of drugs makes pricing of new generics very difficult for manufacturers particularly when they decide to price competitively, i.e., lower than what they are entitled to.

The local drug is negotiated at JFDA to take the same price as the preceding registered generic product even if the price was less than 80% of the originator’s price given by law. This can be particularly disadvantageous to local manufacturers especially if the lowest price

is that of an imported generic that is manufactured in a country where costs of production are much cheaper than those in Jordan.

Every five years a re-registration file should be submitted to JFDA with all requirements including its price in the country of origin and accordingly prices are amended. However, if any change in the price occurs before the 5-year period lapses, the JFDA must be notified within a period of 4 months after the price change, otherwise penalties are incurred on the company. Prices in the country of origin decrease due to the fact that within two years of release the medicament enters the health insurance system which reduces the price and this should be taken into account and thereby the price to the public in Jordan is decreased.

Upon re-registration of an originator the whole study of prices mentioned above is redone and the lowest price is approved for retail in Jordan. The retail price of a locally manufactured drug is affixed at 80% of the originator price in Jordan at time of registration or re-registration or re-pricing whichever is lowest (JFDA)

Manufacturers believe that setting their current prices at 80% of the current originator's price is fair. As such, it was recommended by the interviewed manufacturers that the forth price computation in article 5 be re-worded as follows:

“Provided that the requested price does not exceed 80% of the originator drug's **current** price.”

As a side note, it is worth mentioning that there were no scientific grounds for setting the 80% cap on the pricing of generics. It is considered to be somewhat high compared to the worldwide trend which sets the cap at 50-60%. Even in Saudi Arabia the cap is set at a lower rate of 70%. According to Dr. Ibrahim Beiruti, General Manager of Amin Shockair Est., and one of the pricing policy legislators, this cap was set high in order to protect and encourage the local pharmaceutical industry.

2) THERE IS NO CLEAR MECHANISM FOR RAISING PRICES OF LOCALLY MANUFACTURED GENERICS

Manufacturers believe that the pricing policy favors prices to be lowered, and does not allow for increases in the prices of locally manufactured generics. Once the price is fixed though, it is almost impossible to raise it unless the manufacturer gives a compelling case that the generic is the only alternative to the originator, or if it is a life saving drug.⁵⁰ Although it is widely believed that prices of generics normally exhibit a downward trend year on year, nonetheless, manufacturers might need to raise their prices for four reasons deduced from the interviews:

- a. Manufacturers might be faced with market externalities that may require prices to be adjusted upwards. The year 2007 was a clear example of that; costs of production increased as a result of rising prices and soaring energy costs. Manufacturers often question why all products, ranging from basic to luxury, are frequently adjusted to price changes – i.e. tied to inflation, while drugs are the exception.
- b. Manufacturers at the time of registration may opt for a low price, as mentioned earlier, in order to compete in the local market and gain a better market share. This

⁵⁰ Interview with JFDA

price can be as low as 40% of the originator price. Once the product fares well in the market, the price cannot be adjusted to the level the manufacturer is lawfully entitled to.

- c. Additional spending on R&D to enhance release, taste, color, or packaging of the drug among many others. This ceiling cap on prices can in fact deter manufacturers from incurring additional costs that might increase operational expenses and reduce profit margins. These include spending on R&D. Any enhancements on the product do not grant the manufacturer an increase in the selling price. Two such examples are JOSWE's Peptacid Effervescent tablets and Floxar 1000 mg sustained release tablets. (see Box 3)⁵¹
- d. Complying with Good Manufacturing Practices (GMP). This is a procedure that adds substantively to operational expenses. Manufacturers cannot reflect this additional cost on the retail price of the drug.

Box 3: Pricing policy does not account for added costs in product enhancement

Peptacid Effervescent tablets have no equivalent form in the Jordanian market. Ranitidine 100mg has the same active ingredient, but it is in the form of regular and not effervescent tablets. When developed, JOSWE invested in developing the effervescent tablets, and packaged it in a container that seals and dispenses the tablets better. When pricing Peptacid, it was compared to Ranitidine and the additional costs incurred by JOSWE to enhance the product were discarded.

Floxar (Ciproflaxacillin) 1000 mg was also developed by JOSWE. Additional costs were incurred to develop the product into sustained release, and higher 1000mg dosage tablets. Upon registration, it was priced based on the originator's 750 mg dosage price plus a 25% markup for the additional 250mg dosage. Price obtained was JD6 and did not take into account that JOSWE's product had the additional feature of 'sustained release'. When Sandoz introduced a form of Ciproflaxzcillin it was priced at a higher JD8.5 and for a dosage of 500mg.

There is no set criterion at JFDA to study price increase requests/appeals, especially for old generation products which manufacturers claim are no longer profitable to make based on the prevailing hiked costs.

The price increase application process begins with drafting a letter requesting the price increase and providing a compelling reason for doing so. The Pricing Committee studies the application and depending on how convincing the reason(s) is (are) a decision is taken to accept or deny. There are no regulations or set standards/criteria that govern the price-increase decision-making process. Moreover, the committee that reviews the price-increase requests is different from the committee that formulated the pricing policy in the first place.

The Pricing Committee reviews price increase requests every Sunday. The committee is comprised of the Director General of the Drug Department at JFDA, the Head of the Pricing

⁵¹ Based on interview with Dr. M. A. Shaheen Managing Director of JOSWE

Department at JFDA, the Head of the Supply Department at JFDA, an MD internist selected by the Minister of Health, a clinical pharmacist selected by the Minister of Health, and two 'experts' selected by the Director General one of which on cost analysis.

The recent hike in prices, coupled with an intensive advocacy campaign led by JAPM, resulted in JFDA looking into price increase requests by all local manufacturers based on the directives of the Prime Minister. Local manufacturers were allowed to apply for price increases for 10 molecules each. While the 80% cap might not be achieved for most, price increases are expected to be granted in varying degrees based on the case presented by the manufacturer.⁵² JFDA stated that some applicants decided to 'ride the wave' and submitted their requests without stating the reason for applying, instead citing the reason as "upon the request of JAPM, we hereby list our choice of 10 molecules for price increase."

During the years 2007-2008, around 60% of price increase applications were reviewed and approved – based on JFDA's records, and by varying degrees. The remaining 40% were denied due to lack of 'convincing' justification. In 2007, 49 applied for price increases. This number shot up to 200 in 2008. JFDA records also show that in 2003, only 31 applications were received requesting price increases.

The government is inclined to raise the prices of some locally manufactured drugs but sensibly and in the best interest of the Jordanian patients. The JFDA pointed out that their main objective is to provide the medicine to patients at a suitable price. Under no condition is JFDA concerned with increasing the profit margins of importers, manufacturers, and pharmacies.

The fee for a price-increase application is JD100 per strength (not per molecule).

3) COMPARING PRICES OF ORIGINATORS TO THEIR PRICES IN THE SAUDI MARKET

Comparing the prices of originators to their prices in the Saudi market is considered to be unfair by local manufacturers for a variety of reasons. Foremost, Saudi Arabia's economy is 24 times larger than Jordan's; secondly, Saudi Arabia has 4 times more people. Subsequently, per capita income is roughly 6 times higher in Saudi Arabia. Being an oil rich state also translates into cheaper energy, and hence lower production costs for manufacturers. Table 7 illustrates the difference between the two markets taking Hikma's Factive as an example of their absorptive capacity.

Table 7: Factive Sales in Jordan and Saudi Arabia

Market	Number of Units MAT/4/08	Sales (USD) MAT/4/08
Saudi Arabia	91,000	1,520,000
Jordan	11,000	244,000

Source: IMS 2008 1st quarter

⁵² Price increases were not released at time of writing the report

More importantly, a number of policy measures provide support to locally manufactured generics in Saudi Arabia, and **subsequently put other generics at a competitive disadvantage**. These policy measures can be summed as follows:

- 1) *Support for local generics*
 - a. Providing various financial and other incentives such as free land, interest-free loans and a 10% subsidy to the production cost of medicines and pharmaceutical products.
 - b. Reviewing prices of local products every five years, compared to four years for foreign importers
 - c. Generic products manufactured by the local companies receive a price less than at least 15% of the originator product, while foreign generics receive 30% less (if first generic product and no locally manufactured one), and 10% less of first generic for second generic (if no locally manufactured one is available).⁵³
 - d. In case of existing local manufactured and marketed generic products, the first generic applicant from any country would receive 10% less than the price of the locally manufactured. Subsequent generics would receive 10% less than the latest preceding generic.

- 2) *Support for foreign investment and transfer of technology:*
 - a. Products manufactured under license and still under patent and registered and priced for the company which is the licensor, are given the same price accredited to the licensor.
 - b. Products manufactured under license and still under patent and introduced for the first time through a local manufacturer, shall be priced in accordance with the 'common pricing criteria' assuming the price is given to the licensor company and then be given to the local manufacturer at the same price.
 - c. Products manufactured under license and still under patent and is produced locally under the name given by a local manufacturer (2nd brand) is given a price 10% less than the accredited price for the licensor company.

4) PRICES OF FOREIGN GENERICS ARE ADJUSTED FOR CHANGES IN THE EXCHANGE RATE

Manufacturers claim that it is possible for imported generics to end up being priced higher than locally manufactured generics.

Box 4: Imported generics priced higher than local generics

Amoclan 1gm, a Hikma antibiotic, is sold for JD0.86/tablet. Klavox 1g, manufactured by Spimaco and originating from Saudi Arabia, is sold for JD1/tablet. Saudi Arabian drugs are priced high in their country of origin in order to obtain high prices in export markets, including Jordan.

⁵³ First generic products manufactured and marketed in the United States or registered by EMEA receive 30% less of originator price irrespective of number of previously registered generics, and the second generic would receive 10% less of first.

Table 8: Example of Local Generic Priced below Imported Generic

Origin	Drug	No. of Tablets	Pack Price (JD)	Unit Price (JD)
Saudi	Omol Extra	20	0.77	0.0385
Jordanian /JOSWE	Panda Extra	36	0.90	0.0250
Originator	Panadol Extra GSK	24	1.94	0.0808

Prices of foreign generics can be adjusted upwards based on changes in the exchange rate; a privilege not enjoyed equally by local generics given that raw materials are imported and comprise a substantive 40% of total production costs. Prices of raw materials might increase as a result of foreign currency appreciation, and this is not reflected in the selling price of locally manufactured drugs.

The Director General of the JFDA issues a schedule of exchange rates in July each year and these are determined from the average rate for June using exchange rates published by the Central Bank of Jordan. Prices of products can be revised if the variation in the exchange rates exceeds 5% for three consecutive months.

5) UNDER LICENSED PRODUCTS MANUFACTURED IN JORDAN ARE TREATED AS LOCAL PRODUCTS

Under licensed products do not enjoy additional privileges when being priced; they are priced as locally manufactured generics although under licensed products incur additional costs in order to comply with the requirements of the under licensee. These include sourcing raw materials, complying with GMP, on-going payment for royalties, technology transfer and special training. Moreover, they do not enjoy the privilege of adjusting for changes in exchange rates as do foreign generics. The latter adjust their prices in the local market based on the prevailing exchange rate.

Box 5: Under licensed product priced as a local generic

Riabal is an under-licensed product by Hikma. It is treated as a local product and is priced at JD0.90. Buscopan is the originator and currently sells for JD3.50 in the local market.

Producing an under licensed product grants the manufacturer a patency for five years. It facilitates technology and know-how transfer, builds the product portfolio of the manufacturer, and provides a substantive boost in export markets.

Moreover, and as pointed out during the interviews, licensees prefer to grant the license to manufacturers in large markets such as Saudi Arabia or Algeria due to the larger volume of sales in those markets. Therefore, when local manufacturers overcome the 'small market' disadvantage, this under licensed product should not be treated as a local generic and priced accordingly.

Box 6: Prices for products in Saudi Arabia drive prices down in Jordan

Example Factiv (Algea) a Hikma under license product obtained JD23 in Jordan. When the licensee Algea gave license to Tabouk Pharma in Saudi the price in Saudi Arabia was JD17 this reflected on the product price in Jordan and the price was decreased to JD17.

6) FLAT RATE PROFIT MARGIN FOR PHARMACISTS FAVOR ORIGINATORS' PRODUCTS

In Jordan, pharmacists enjoy high flat markup of 26%. This mark up is applied across the board on all price-regulated drugs. Manufacturers claim that pharmacists tend to recommend to walk-in patients originator drugs since they are priced higher than the local generics and hence generate more profit in absolute terms.

This is a drawback to the local industry as their products are always priced lower. Pharmacists⁵⁴ denied that citing that they benefit more from bonus schemes provided by the local manufacturers.

⁵⁴ Interview with Dr. Samira Shammas, Manager of the Arab Drug Store and owner of Farabi Pharmacy.

MOVING FORWARD

Apart from being a major exporter, earner of foreign currency, and propeller of economic growth, the local pharmaceutical industry has enabled the government to save on medical expenditure and provide citizens with a wide range of cheaper alternatives. The regulatory scene for the pharmaceutical industry however is changing, and the cost of maintaining facilities and products GMP compliant is increasing whether locally or internationally.

It is evident that the policy framework in Jordan is less 'protective' of its pharmaceutical industry, thereby giving it a competitive disadvantage in export markets both within and outside the region.

In light of the analysis of the Jordanian pharmaceutical pricing system and benchmarked countries, it is recommended that the Government of Jordan considers the following measures which would enhance the current system and assist local manufacturers in their exporting efforts:

REMOVE “LOWEST” AND AFFIX PRICE TO THE PREVAILING MARKET PRICE

According to manufacturers, being bound by the lowest price has caused a number of their products to be unfairly priced at rates that are well below the 80% ceiling of the originator's current price.

At the time of registration, manufacturers might opt to price their product below the 80% cap, and sometimes well below, in order to give their product a price advantage in the local market and effectively capture a larger share of the market. Market dynamics however, in addition to unforeseen forces such as increases in costs of production might make the originally set price either unfeasible or unfair. Nonetheless, because manufacturers are bound to the “*lowest*” criteria, they are never able to raise their price to the 80% cap that is granted to them by law.

Based on the above, the Government of Jordan should consider amending Article 5(4) of the Pricing Criteria by removing the condition that the lesser price should be taken into consideration when pricing a generic and affix the originator price to the actual market price.

CONSIDER PROVIDING PREFERENTIAL PRICE STRUCTURE TO LOCAL GENERICS

The above analysis of benchmarked countries clearly indicated that they provide preferential price treatment for their local generics. Preferential treatment, as adopted in Saudi Arabia, UAE and Egypt, essentially means that local generics get a higher price than foreign generics entering the market. The Jordanian Government should consider providing such preferential treatment while ensuring that such policy does not conflict with Jordan's commitments under bilateral and multilateral trade agreements.

ADOPT SAUDI ARABIA’S & ALGERIA’S TIER SYSTEM

The tier system in Saudi Arabia provides wholesalers and pharmacists with a regressing markup scheme that seems to benefit the lower priced local products. JFDA has indicated during one interview that this system was under study for possible implementation in Jordan.

Table 9: Tier System in Saudi Arabia

Price of Drug	Wholesaler Profit	Pharmacy Profit
SR50 or less	15%	20%
Greater than SR50 – SR200	10%	15%
More than SR200	10%	10%

Source: Saudi Pricing Policy

In Algeria there is a similar tier system where the profit at the level of the importer and the pharmacy is controlled according to price as well. It stipulates that if the medicine landed cost is less than 70 Algerian Dinars the importer margin is 20% and the pharmacy margin is 50% alternatively if the landed cost of the medicine is between 70 AD and 110 AD the importer margin is 15% and the pharmacy is 33%. Moreover, if the price is between 110 AD and 150 AD profits are 12% and 25% to the importer and pharmacy respectively. Lastly if price is > 150 AD then profits are 10% and 20 % to the importer and pharmacy respectively.

CHANGE PRICING POLICY REGARDING LOCALLY PRODUCED UNDER LICENSED PRODUCTS

As mentioned above producing an under licensed product facilitates technology and know-how transfer, builds the product portfolio of the manufacturer, and provides a substantive boost in export markets. Unfortunately, licensees prefer to grant the license to manufacturers in large markets such as Saudi Arabia or Algeria due to the larger volume of sales. Therefore, for local manufacturers to overcome the ‘small market’ disadvantage, the system in Jordan must encourage foreign investment and transactions that entail “real” technology transfer and know-how. It is therefore, recommended to amend Article 10 of Pricing Criteria to provide price incentives, similar to those adopted in Saudi Arabia, for transfer of technology transactions conducted between foreign and Jordanian companies for production of innovative drugs .

APPENDIX I – INTERVIEW NOTES

MEETING WITH JAPM TO REVIEW QUESTIONS

Date 1/9/2008

Time: 10.30 AM

The following questions were compiled by the team of consultants to be answered by policy and decision makers:

- 1- Explain the current pricing policy of drugs (generic and originator) – initial and later based on changes in originator prices either up or down. Why not CPI adjusted?
- 2- Formula of pricing for imported drugs
- 3- Formula for pricing local drugs
- 4- Why the 80%?
- 5- What is the breakdown of the selling price (local and imported) – profit margins to all
- 6- Duration of patency
- 7- Impact of foreign exchange on costs of inputs
- 8- Existence of any subsidies if any
- 9- Customs duties regulations on the industry
- 10- Drugs/drug categories that are currently registered at JFDA at or lower than 80% of originators (provide specific examples for pricing and %)
- 11- Differences in prices of local and imported generics (from list provided by JAPM)
- 12- Price change requests – what is the process?
- 13- Number of applications received by JFDA (2007-2008); accepted/turned down; % of increase?
- 14- What are the categories of drugs that are requesting price increase?
- 15- Does the change of formula (not active ingredient) qualify for price increase?
- 16- Liberating prices of OTC?

The following questions were compiled by the team of consultants to be answered by a sample of manufacturers in the industry:

- 1- What is a suitable pricing formula and why?
- 2- How is the current pricing policy affecting your company and the sector as a whole? What is the impact on competitiveness locally and in export markets? Specify export markets.
- 3- What is the anticipated result of sustaining the status quo?
- 4- RPM expenses. Price structure.
- 5- Liberating price of OTC?

MINUTES OF MEETING WITH JFDA

Date: 1/9/2008

Time: 10.00 AM

- 1) The regulations for pricing medicaments adopted by JFDA and published in the official newspaper that was published and amended in May 2008 were handed to the team of consultants. Document is in Arabic and it is recommended that it is translated into English to be annexed with final report.
- 2) The document discusses the process and policies of drug pricing whether originator, imported generic or local generic by which the Pricing Committee that is comprised of Drug Department president, head of pricing department at JFDA, Supply Department head, MD internist selected by the Minister of Health, Clinical pharmacist selected by the Minister of Health and two experts selected by president one of them should be an expert on cost analysis.
 - b) Originator pricing
 - The price for a new molecule is fixed on the lowest price in JD that comes out from the calculation of the export price, public price in country of origin, median price in countries namely Britain, France, Spain, Italy, Belgium, Greece and Holland or export price to Saudi Arabia.
 - Every five years a re-registration file should be submitted to JFDA with all requirements including its price in COO and thereby prices are amended however if any change on the prices occur prior to the 5 years the JFDA should be notified within 4 months after the price change, otherwise penalties are incurred on the company. Prices in the country of origin decrease due to the fact that within two years of release the medicament enters the health insurance system which reduces the price and this should be taken into account and thereby the price to the public in Jordan is decreased.
 - Upon re-registration of an originator the whole study of prices mentioned above is redone and the lowest price is approved for retail in Jordan.
 - The pricing of a new drug takes less than one month at the JFDA otherwise the applicant can sell the drug at the price requested in the application
 - c) Imported Generics
 - The price of a generic is fixed after calculating the lowest price originating from export price to Jordan, price in the Saudi market provided that these prices do not exceed the 80% calculated from the originator price at registration time or re-registration time or re-pricing whichever is lowest
 - d) Locally Manufactured Drugs
 - The retail price of a locally manufactured drug is affixed at 80% of the originator price in Jordan at time of registration or re-registration or re-pricing whichever is lowest.

General Notes

- 1) In the Saudi market the prices are affixed at 70% of originator prices
- 2) The JFDA cannot come up with a product list/ category of locally manufactured drugs that are registered currently at lower than the 80% of the originator as it is time consuming and not doable
- 3) There are no custom duties on imported medicaments

- 4) Saudi Arabia considers the export prices to 33 countries prior to fixing the retail price in Saudi market and they will make it 40 countries now
- 5) Currency exchange rates are fixed by JFDA and we were handed a list, now these prices remain the same for 3 months if the exchange rate goes up or down by 5% for 3 months every day then the exchange rate is modified.
- 6) Due to competition and perfect substitution in generics the tendency of prices is to decrease worldwide
- 7) The formula for calculation of price of an imported drug is as follows

CIF X CIF COEFFICIENT X EXCHANGE RATE= PUBLIC PRICE IN THE JORDANIAN DINARS

FOB X FOB COEFFICIENT X EXCHANGE RATE= PUBLIC PRICE IN THE JORDANIAN DINARS

The coefficient varies if the drug is antibiotic or no antibiotic in this coefficient is embedded the transport, clearing, G&A expenses and the importer margin

The margin of the importer is 19% including profit and expenses

The margin of the pharmacist is 26% including expenses and profit.

Calculations regarding public price in the country of origin

Public price in the Jordanian market = Your Ex-factory price (should be indicated in price cert) x FOB COEFFICIENT X exchange rate

Now the price any drug will take is the lowest obtained in any of the calculations above taking into consideration the interest of the Jordanian public, if your price to Saudi Arabia is less, then this price will be assigned.

- 8) Concerning the liberation of OTC prices, it has been done for paracetamol for a short period of time. Vitamins prices have been liberated e.g. Neurovitan tabs, Becozyme tabs and vitamin B12 tabs, at the level of the importer and not the pharmacist; the JFDA are monitoring them continuously to spot any mal practices or over pricing.
- 9) If a category of drugs is liberated then it will be subject to a 16% customs tax.
- 10) In the years 2007-2008 , around 60% of price increase applications have been accepted and 40% were denied the latter lacking a justified reason for the application.
- 11) Price increase application process is through writing a letter asking for the increase including the reason behind the request, the committee studies the application and depending on how convincing the reason / reasons are a decision is taken to accept or deny. There is no law or standard governing the increase of drugs prices process and it was not handled by the committee that first put the laws governing the pricing or the policy.
- 12) Price increase applications stand in a queue and every Sunday they are discussed by the current committee namely the committee of pricing comprised of Drug Department president, head of pricing department at JFDA, Supply department head, MD internist selected by the Minister of Health, Clinical pharmacist selected by the Minister of Health and two experts selected by president one of them should be an expert on cost analysis.
- 13) The JFDA has recently accepted that every local manufacturer is allowed to select 10 molecules to apply for price increase request and increases with different percentages would be granted not necessarily the 80% depending on the decision of the committee and the justification for the request explained by the manufacturer in the application.
- 14) The number of applications for price increase in the year 2003 were 31 applications
- 15) In the year 2007 there were 49 applications for price increase.

- 16) In 2008 there are more than 200 applications for price increase
- 17) The government is inclined to raise the prices of some locally manufactured drugs but sensibly and in the best interest of the Jordanian patients
- 18) A suggestion and a study has been done to make profits on drugs in tiers i.e. The higher the price of the drug the lower is the percentage of profit but till now there is no sound study done and JFDA would prefer to wait until a full and comprehensive study is done to effect this change. Saudi Arabia has this manner of pricing and the average profit of the pharmacist is 15% and the average profit of the importer is also 15% may be this model can be studied and suggested?
- 19) The JFDA pointed out and strongly that their goal is providing the medicine to the patient at a suitable price and under no condition they are concerned to increase the profit margins of importers, manufacturers or pharmacies.
- 20) There was no inclusion whatsoever in the pricing policy for the price increase or the right of any drug to increase the price of drugs to reach the 80% of the originator in order not for any party to consider it as a right and argue against it in a court of law and in many applications submitted to increase prices to the 80% the increase granted is not the one requested unless it's a compelling case example being that the generic is the only alternative to the originator, or if it's a life saving drug....etc.

MEETING WITH COMPANY A

Date 4/9/2008

Following are the main points raised during the meeting”

- 1) 90% of Company A sales by value is for export
- 2) 80% of pharmaceutical production in Jordan is designated to export markets mainly Saudi Arabia, Egypt and North Africa
- 3) Amoclan antibiotic has a lower price than identical generic originating from Saudi Arabia manufactured by Spimaco reason being that Saudi Arabia government support the pharma industry there and give them high prices in country of origin in order to obtain high prices in export market.
- 4) In the pricing policy the policy states that the generic whether local or other takes 80% of the originator price at registration or re-registration whichever is lowest however in practice and it happened that if an Indian or local generic is registered at 70% or originator price a new locally manufactured drug that comes after it in registration the price ceiling would be the Indian or old registered Generic price! Example, Originator is Plavex is registered at JD 72. Company C registered a generic product at 45 JD when Company A applied for registration the price granted was not 80% of the originator formula but the same price of Company C got.
- 5) To tie the prices of locally manufactured drugs continuously is not fair as Originator prices keep going down due to many reasons one being change of manufacturing site or other this will reflect on lowering the locally manufactured drugs prices. Even if the price of originator goes up due to currency the locally manufactured drug price does not go up accordingly.
- 6) The under license issue: this is when a patented drug file is purchased by the local industry to be manufactured here in Jordan upon presenting the file to JFDA it is requested that two certificates be presented
 - Price certificate in the country of origin
 - Ex factory price
- 7) This field of under license drugs is quite important economically as the company will obtain patency for 5 years, it is the import of new technology and opens up export markets and builds the product portfolio of the local company in export markets
- 8) Licensees prefer to give license to companies in Saudi Arabia or Algeria due to bigger markets and higher sales additionally Jordanian market is considered small so there should be special treatment for under license drugs if obtained.
- 9) The major problem here is that once a price is obtained for an under license product no revision of prices in terms of increase is allowed at JFDA , however in the under license agreement it is obligatory that the local company purchases raw material from licensees and the exchange rate prices are fluctuating which renders the product not profitable.
- 10) If a comparison with other sectors is conducted it is noted that all sectors have been granted price increases except for the pharma sector, although this sector has suffered from increases in salaries, energy, inflation rate of 15% and fluctuation in prices of raw materials

- 11) It is important to note that keeping the status quo will affect negatively on other sectors directly related to the pharma industry e.g. packaging, designers, transportation...etc.
- 12) Company A management clarified that keeping the status quo will compel them to reduce their manufacturing activities in Jordan and transfer it to their other manufacturing sites outside Jordan to obtain better prices reflecting negatively on employment and affecting the sector, in fact 4-5 products are currently being redirected to other manufacturing sites to obtain better prices.
- 13) The fee for price increase is 100 JD per strength and not per molecule which incurs extra expenses on local manufacturers especially when these requests are rejected or not studied, the recent approval from Prime Minister to increase prices of 10 molecules per company is under study and three Sundays have elapsed with no results as the committee never seems to convene!

MEETING WITH COMPANY A

Date 7/9/2008

Evaluation of the pricing policy in Jordan from the perspective of Company A:

- 1) The new generic product takes 80% of the lowest registered originator price. If we take the fact that, the price of the originator is changed as per export currency price. We should also take into consideration that generics are using active ingredients that are imported and any change in the currency exchange rate will affect the cost directly since 40 % of a medicinal cost is imported raw material.

Generics are granted 80% from the lowest originator price and not the current market price. This action is considered biased and it is not reasonable to give originator flexible margin related to currency price.

According to the law some of the generic prices are around 60% of the originator price, below are some examples

Originator Product	Current price (JD)	Local Generic	Price (JD)	% of originator
Plavix 75 mg tabs	73.83	Cloplav tabs	45.43	61
Lipitor 40 mg tabs	65.27	Vastor 40 mg tabs	31.86	49
Lipitor 20 mg tabs	57.15	Vastor 20 mg tabs	27.23	47
Lipitor 10 mg tabs	36.91	Vastor 10 mg tabs	19.31	52

Company A recommendation: is to give the generic product 80% of the current registered and marketed originator as one to one action between originator and generic.

- 2) Comparison of the prices of originators with prices in Saudi Arabia market. The mark up in Saudi Arabian market for the stores and the pharmacists is not fixed; as in Jordan, this means that the mark up for the higher prices is lower for lower prices and vice versa.
- 3) the effect of the local price in Jordan on the given price in export countries; Due to the fact that investment volume in Jordan is small compared to other markets, the Jordanian pharmaceuticals industries move to the vital markets in the middle east and north Africa countries as their target market.
And based on that the reference for the health authorities upon pricing of new product is the price in the country of origin, this will add extra load on Jordanian manufacturer to compete other foreign products in term of profit and volume of share.

Company A recommendation: is to give the Jordanian product alternative price called export price this will give a superior chance to have reasonable price for export.

- 4) the Jordanian manufacturer submit several requests to the Jordanian food and drug administration to increase the price of old products and under license products which their prices were given before the huge revolution in prices of active ingredients and the prices of originator, and due to the fact that the Jordanian pharmacists are originator oriented that lead to high mark up, they sales of local products is highly effected with this.

The fee for increase request is 50 JDs per strength and not per molecule. And the fee for objection in given price is 100 JDs also per strength. Two local companies submitted a request to JFDA to increase prices of 10 products; the fees were 4200 JDs for 20 products without any official feedback.

MEETING WITH COMPANY B

Date 10/9/2008

- 1) 72% of Jordanian pharmaceutical market is imported medicines value wise and 28% is local medicaments 30% of this 28% is for tender business where the local industry is giving away products at cost or lower to fight competition, fill capacity or simply exist. It is strange that the JFDA is concerned for the welfare of the Jordanian patient and bringing down locally manufactured medicines prices for the 28% of the market, leaving the 72% value to prosper!
- 2) It is noticed that the trend of treating originators with respect at the expense of generics is a worldwide trend due to the originators being powerful and generic

industry are easier to attack. Moreover, originators are always attacking the generics industry for the sole purpose of shutting it down.

- 3) The regulatory scene is changing nowadays for the industry , the cost of keeping plants and products GMP compliance is increasing whether locally or internationally to stay with the pace a manufacturer has a lot of expenditures to make, example being the DOP tests which were carried out once a year now it should be done 3 times year a fact which involves purchasing the machine and employing a full timer to keep it rather than the usual outsourcing of the task. Another example is the particle counter which also incur more expenditure and therefore the cost of keeping a GMP plant has tangibly gone up.
- 4) The first foreign drug that gets registered is considered the originator in Jordan e.g. Boehringer Ingleheim is the originator of Mucosolvan but it has been preceded by an Italian company Kasai with the same product Flubiron which took the place of the originator and considered the limit for pricing.
- 5) Company B export markets are Saudi Arabia, Algeria and Sudan. They have 50 products in their portfolio of which 20% are their main sources of income.
- 6) The Jordanian pharmaceutical industry gained legitimacy with what it offered to the community and was not supported by the government, it has lowered the government expenditure on medicines and will keep on being a main economic driver as long as it exists so it should not be taken lightly.
- 7) Company B refrained from giving us any examples on drugs that were priced below the 80% limit and preferred to wait until the results of the 10 molecules price increase requests are out.

MEETING WITH COMPANY C

Date 12/9/2008

- 1- It is evident that neighboring countries such as Saudi Arabia, Syria, and Egypt are not adhering to WTO regulations and there is some sort of protection on their local pharmaceutical industry in the sense that they reduce each generic price by 10% from the preceding one to discourage registration whereas the locally manufactured drugs prices are not decreased.
- 2- The pricing policy should take into account the increase or decrease on prices as is the trend worldwide.
- 3- There is no mechanism that looks into price increase requests?
- 4- There are no clear policy for price increase requests and each request is studied on an ad hoc basis and there is an evident discrimination against the Jordanian products
- 5- Company C has 35 products and exports to Lebanon, Yemen, Libya and Europe and they are registering in Saudi Arabia.
- 6- One example of a product being unjustly priced is Peptacid Effervescent tablets. This product has no equivalent form in Jordanian market as effervescent but there are oral tablets containing the same active ingredient Ranitidine 100mg. The product was priced based on Ranitidine 100 mg oral tablets not taking into account all the research and development put in the product and packaging ...etc.
- 7- Floxar (Ciproflaxacillin) 1000 mg Sustained Release tablets was also developed in Company C's R&D labs and there is no similar drug in terms of form and dosage the price given by JFDA was calculated on 750 mg originator plus 25% for dose and it obtained JD 6.00 price not taking into account the sustained release mechanism or the research put into developing it, on the other hand Sandoz brought into the market a form of Ciproflaxzcillin 500 mg and this obtained JD 8.5 depending on price in the country of origin!
- 8- Panda Strong (1000 mg paracetamol) was considered as an originator due to lack of similar product in the market and Company C had to pay the registration fee of originators (JD 1000), while generics pay JD 300). Upon pricing it got the price of normal generic.

9- Paracetamol example

Origin	Drug	No of tabs	Pack price JD	Unit price JD
Saudi	Omol extra	20	0.77	0.0385
Jordanian	Panda Extra	36	0.90	0.0250
Originator	Panadol Extra GSK	24	1.94	0.0808

10- Alantronate example

Origin	Drug	Price of pack JD
Jordan	Alandomax	13.00
Originator	Fasomax	24.00

11- Anti hypertensive drug

Origin	Drug	Price of pack 30 tabs JD
Jordan	Arbiten	21.00
Originator	Diovan	39.00

- 12- Operational expenses energy takes about 5% from cost of production now and after oil price increase the impact on cost of production due to energy prices increase has gone up by 30%
- 13- RPM (Raw material and packaging) cost generally for drugs is 45-50% from the cost of any drug.
- 14- Sectors impacted by the pharmaceutical industry are:
- a- CRO(s)
 - b- Packaging (glass , tubes, plastic)
 - c- Designing
 - d- Cartons
 - e- Training and consultancy
 - f- Transportation
 - g- Banking
 - h- Drugstores
 - i- Pharmacies

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