

A Comparison of Generic and Originator Brand Drug Prices between Jordan and the United Kingdom

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ABSTRACT

When a pharmaceutical patent expires, generic companies may enter the market and start selling copies of the original drug. As generic drugs contain exactly the same active ingredient, they are certified to be perfect substitutes to the originator branded drugs. In competitive markets, entry of generics would trigger fierce price competition, hence decreasing the monopoly enjoyed by the original patent holder.

The study aims at comparing the retail prices of generics and originator brand for five drugs between Jordan and the United Kingdom and to investigate the relation between the number of generics available, retail price of originator & generic (s) and the effect of time in the market on these prices.

Prices of originators and generics and the number of generics available in each market were obtained from the Jordanian Food and Drug Administration, Royal Pharmaceutical Society of Great Britain, British National Formulary and Chemist & Druggist generics list. The prices were converted to British Pounds expressed per one dose unit. All data were tabulated in spreadsheets; prices were compared between the two countries at different preset times.

The generics of all drugs investigated appeared in the Jordanian market before the patent expiry of their originator worldwide due to lack of patency regulations in Jordan at the launch time of drugs under investigation (before 2004). Unlike the UK, the prices of originator drugs in Jordan did not change when the first generic was introduced to the market. The price of generic drugs has dropped dramatically in the UK at the time of the first generic launch approximately by 90% compared to 15% in Jordan. There was no apparent correlation between the numbers of generics available or the number of years of the first generic being in the market and the prices of the drugs investigated in both countries. The current prices of all investigated drugs in Jordan are higher than the UK particularly for the generics.

Although the income is much lower per capita in Jordan, generic drugs are more expensive than the equivalent prices of the same drugs in the UK.

Keywords: Jordan, United Kingdom, Drug Prices, Originator, Generic.

INTRODUCTION

Drug discovery is a long, difficult, expensive and high-risk process. It begins with basic research, which expands the fundamental understanding of disease pathways, identifies and characterizes new drug candidates. When a pharmaceutical company identifies a New Chemical Entity (NCE), patent protection needs to

be acquired. According to the United Kingdom (UK) Intellectual Property Office¹ patent is “An intellectual property right, granted by a country’s government as a territorial right for a limited period. Patent rights make it illegal for anyone except the owner or someone with the owner’s permission to make, use, import or sell the invention in the country where the patent was granted. As long as renewal fees are paid every year, a UK patent has a life of 20 years and provides protection throughout the UK, but no further”. After the patent expiry of the

Received on 10/4/2010 and Accepted for Publication on 21/6/2010.

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originator brand, a generic drug of the same active constituent that is bioequivalent to the originator is allowed to enter the market². Simply, generic product is a copy of an original product whose patent has expired. A patent protects branded drugs from generic competition.

Many studies have explained the effect of patents and other legislation on the returns to innovation, Research and Development (R&D) and market outcomes³⁻⁶. In general, companies' strategic decisions regarding pricing and investment aim to maximize the profit. Patents are vital for manufacturing in view of the fact that they give the innovator a period during which copying can be excluded and the investment in R&D can be recovered. The manufacturing expenditure of a pharmaceutical is only a small part of the selling price, therefore, an imitator who has no R&D costs to recover can sell a product at a cheaper price and still make a profit⁷. Generics promote innovation as they remove the permanent monopoly on pharmaceutical products. The latter would encourage the originator companies to discover new medicines, and both originator and generic companies to develop new generic equivalents, new formulations, new dosage regimes and new methods of delivery.

After patent expiry, originator drug manufacturers do not necessarily compete on price at the time when generic competitors enter the market, in spite of generic prices being lower than the originator price, the originator price may increase rather than decrease after patent expiry^{5, 8, 9}. Even if generics are price competitive, consumers may have loyalty to the originator brand or to another in-patent product⁹.

The continuous demand for originator branded drugs while a cheaper generic drug is available means that physicians and patients develop choice habits that are not easily changed¹⁰. Although residual loyalty remains to the brand after patent expiry, it does not completely deter generic competition¹¹⁻¹². This gives a rise to the term 'generics paradox' which predicts that a higher penetration by generics would not necessarily lead to a reduction in originator drug prices¹³; however, it may only prevent a price increase of originator³. Patent expiration need not to be the end of the product but with

smart marketing it can be a beginning¹⁴.

While it has been concluded that countries with strict price regulation (e.g. France, Italy, Spain) have lower prices for generic drugs compared with countries with less strict regulation (e.g. Germany, Sweden, UK), using cross country data suggested that regulations weaken competition in off-patent markets and that the potential cost-saving out of post-patent competition is not fully realized in countries with tough price regulations¹⁵⁻¹⁸.

Patent expiry does not at all times lead to the entry of generics, and when it does, there is usually a lag time for a few years. After generic entry, the originator pharmaceutical company will not lose all the sales immediately, but only over a period of time. Thus, the value of a patent extends beyond the actual period of patent protection. In addition, the speed with which the original brand loses revenue would appear to be directly proportional to both the size of the market and the price of the original brand prior to generic entry¹⁹.

Entry of generic pharmaceutical products into the market was described as simultaneous rather than sequential¹². Generic entries are slower on average in markets where there are more brand-name products competing. Furthermore, generic drug entry is faster on average in larger markets, and that entry is faster for drugs that mainly treat chronic diseases²⁰.

In Jordan, pharmacists are not permitted legally to make any change or substitution to prescriptions, although in practice this happens frequently. If the pharmacist call the doctor and requests the change, then the alternative drug can be dispensed.

The Jordan Food and Drug Administration (JFDA) is in charge for setting the prices of medicines for sale in community pharmacies and private hospitals, but it is not involved in the pricing of medicines obtained through tenders for the public sector. The price of a NCE (originator brand) is allocated based on lowest price resulted out of the following²²: Cost, Insurance and Freight (CIF) basis, the selling price to the public in the country of origin, the median price in at least 3 countries out of (Britain, France, Spain, Italy, Germany, Greece and the Netherlands), the export price to the Saudi Arabia; a

neighbor country with better negotiating power. The same was applied for generic equivalents provided that it should not exceed 80% of the registered price of the originator (exchange rates were considered and reviewed periodically). Prices were revised after two years of registration and the price of all products are reviewed upon renewal of registration every five years. 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.

In the UK, the price of a new pharmaceutical product is indirectly regulated by the Pharmaceutical Price Regulation Scheme (PPRS); a voluntary scheme between companies supplying branded licensed National Health Services (NHS) medicines and the Department of Health

(DH)²³. Through this scheme, the pharmaceutical companies conclude an agreement enabling them to gain a specific return on capital which is set equal to profits from sales to the NHS minus allowable costs. Companies are liberated to set launch prices of new medicines only if they do not exceed the target rate of return on capital. This scheme does not apply to generic medicines and companies are free to set prices of generic medicines. In response to this, the British government introduced a statutory price ceiling for the main generic medicines in 2000²³. Companies that choose not to become members of the PPRS are subject to statutory price control under section 34 of the Health Act 1999²⁴.

A comparison between Jordan and UK regarding health and health related issues is illustrated in Table (1).

Table 1: A comparison between the UK and Jordan²¹

Comparison Criteria	UK	Jordan
Population (2006)	60,512,000	5,729,000
Population annual growth rate (%) (2006)	0.4	3.3
Area (sq km)	244,820	92,300
Life expectancy (years) for both sexes (2006)	79	71
Healthy life expectancy at birth both sexes (2003)	71	61
Gross national income per capita (PPP international \$) (2006)	33650	4820
Population living below the poverty line (% living on or less than US\$1 per day) (2003)	0	<2.0
General government expenditure on health as percentage of total government expenditure (2005)	16	9.5
General government expenditure on health as percentage of total expenditure on health (2005)	87.1	45.3
Private expenditure on health as percentage of total expenditure on health (2005)	12.9	54.7
Private prepaid plans as percentage of private expenditure on health (2005)	7.9	7.4
Social security expenditure on health as percentage of general government expenditure on health (2005)	0	0.7
Per capita total expenditure on health (PPP int. \$) (2005)	2598	649
Per capita government expenditure on health (PPP int. \$) (2005)	2262	294
External resources for health as percentage of total expenditure on health (2005)	0	4.5

Aims and Objectives

The study aimed to compare the retail prices of generics and originator brands of five drugs from three different classes (omeprazole, lansoprazole, simvastatin, enalapril and lisinopril) in Jordan and UK; particularly:

- compare originator prices at the time of launch and at the time of the first appearance of generic in the market.
- compare current prices of originator brands and generics and their prices at the time of the first generic launch.
- investigate whether there is a correlation between number of generics available and the price change of both originator brand and its equivalent generic.
- investigate whether there is a correlation between number of years originators and generics have been in the market and their prices' change in Jordan and the UK.

Methodology

Data was collected for the five drugs for a maximum period of 23 years (including drug name, strength, price

of originator at the time of registration, prices of originator and generics at the time of generic launch, number of generics currently available and current prices for both originator and generics) and obtained from the Royal Pharmaceutical Society of Great Britain, British National Formulary (BNF), updated Chemist and Druggist generic list, JFDA and AstraZeneca-Jordan was also contacted in order to get the price of originator omeprazole at the time of launch.

Two tables were created as excel spreadsheets, one for the UK data and the other for the Jordanian data. In order to avoid package variation in the two countries-if any, prices were set to be as per unit dose using a unified currency for comparison; the Sterling Pound (£) referring to the monthly average exchange rate published by the Central Bank of Jordan²⁵.

Results: (Prices were in £ per unit dose were mentioned throughout the manuscript).

Generic products of drugs investigated appeared much earlier in Jordan than in the UK e.g. first generic of omeprazole appeared in Jordan 10 years earlier than its equivalent in the UK (1993 vs. 2003) (Table 2).

Table 2: Dates of launch of originator and first generic in Jordan and UK

Drug name	originator launch date		first generic launch date	
	Jordan	UK	Jordan	UK
Omeprazole	1993	1989	1993	2003
Lansoprazole	1996	1994	1997	2006
Simvastatin	1991	1989	1997	2004
Enalapril	1987	1985	1989	2000
Lisinopril	1991	1988	1994	2003

- **Originator Prices At The Time of Launch and At The Time of the first Appearance of Generic in the**

Market In Jordan and the UK

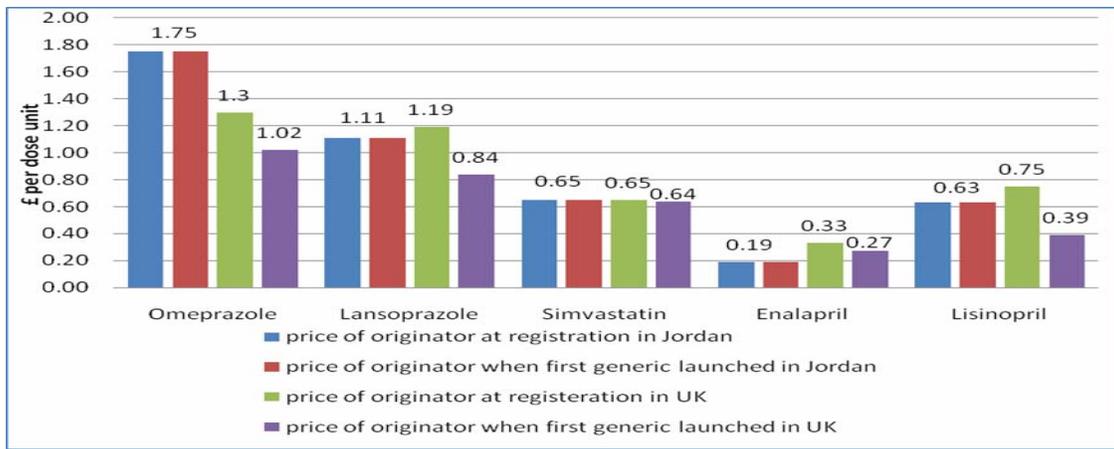


Figure 1: Prices of originators at the time of launch and at the time of the first appearance of generic in the market in Jordan and the UK

As illustrated in Figure 1, the results showed that prices of originators at the time of launch were slightly higher in the UK than in Jordan for lansoprazole, enalapril and lisinopril, with a maximum difference of £0.14 per unit dose for enalapril. The price for simvastatin was the same in both countries, while it was £0.45 higher for omeprazole in Jordan than in the UK. The prices of originator brands in Jordan did not change from the time of the first registration till the time of the first generic launched, however, in the UK the prices of originator drugs fell down when a generic was launched (with the exception of simvastatin in which there was no feasible change). The price of originator brand drugs at the time of launch of the first generic in the market for all

investigated drugs except enalapril was higher in Jordan than the corresponding price in the UK. The increase ranged from £0.73 per unit dose for omeprazole to £0.01 per unit dose for simvastatin. The price per unit dose for enalapril in Jordan was £0.08 less than in the UK.

The prices of generic omeprazole, simvastatin and enalapril at the time of the first launch in the UK was higher than the corresponding price in Jordan. This latter increase ranged from £0.11 for enalapril to £0.29 for simvastatin per unit dose. On the contrary, the price for lansoprazole and lisinopril in Jordan was higher than in the UK (£0.79 per unit dose for lansoprazole and just £0.08 per unit dose for lisinopril) (Figure 2).

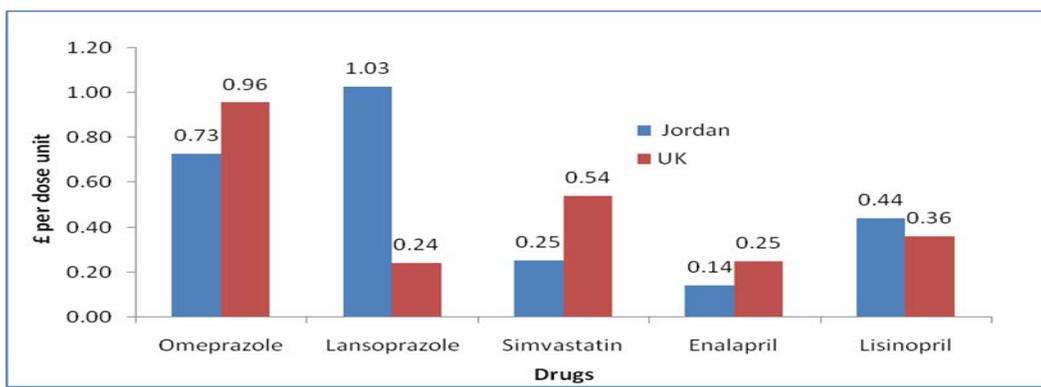


Figure 2: First generic price at the time of the first launch in Jordan compared to the UK

- **Current prices of originator brands and generics and their prices at the time of the first generic launched in Jordan and in the UK**

Generic prices are currently much higher in Jordan than in the UK (Figure 3).

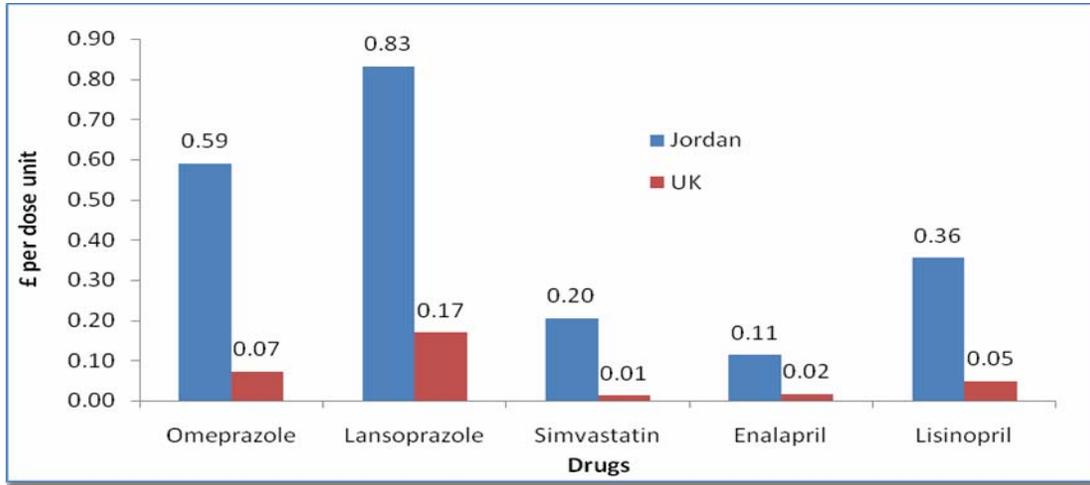


Figure 3: Current prices of generics in Jordan compared to the UK

The current prices of originator brands for omeprazole, lansoprazole and lisinopril in Jordan are higher than their equivalent prices in the UK (Figure 4). However, with the exception of lansoprazole, the current originator prices of the other four drugs under investigation has decreased in Jordan when compared to their equivalent prices at the time of the first generic was launched (Figure 5). For example, the price per unit dose of omeprazole in Jordan was £1.75 at the time

of the first generic was launched where it is currently £1.50. While in the UK, the prices of these four drugs were mostly unchanged (Figure 6). On the other hand, unexpectedly there was a big price drop (£0.45 per unit dose) for the originator brand of lansoprazole at the time of the first generic launched in the UK while there was a very slight increase in Jordan for the same brand (£0.06 per unit dose) (Figure 6).

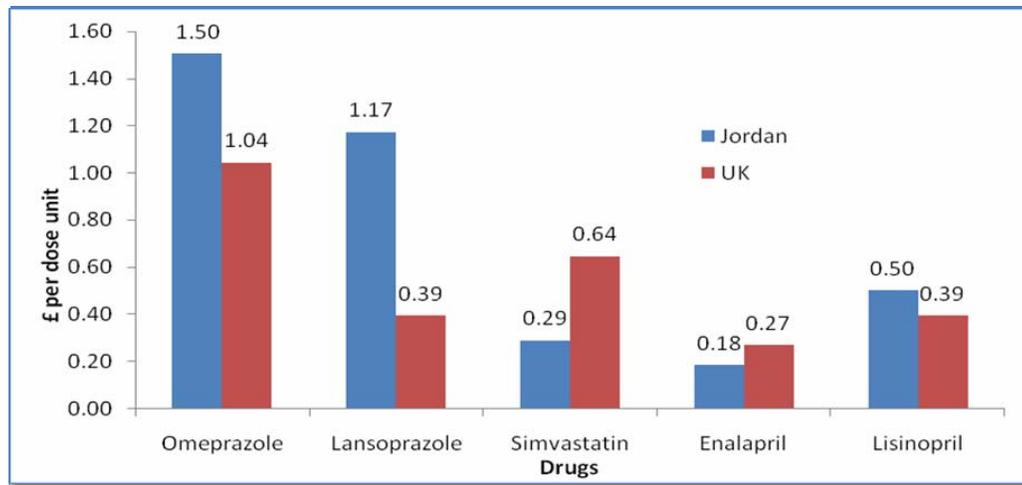


Figure 4: Current prices of originator brand in Jordan compared to the UK

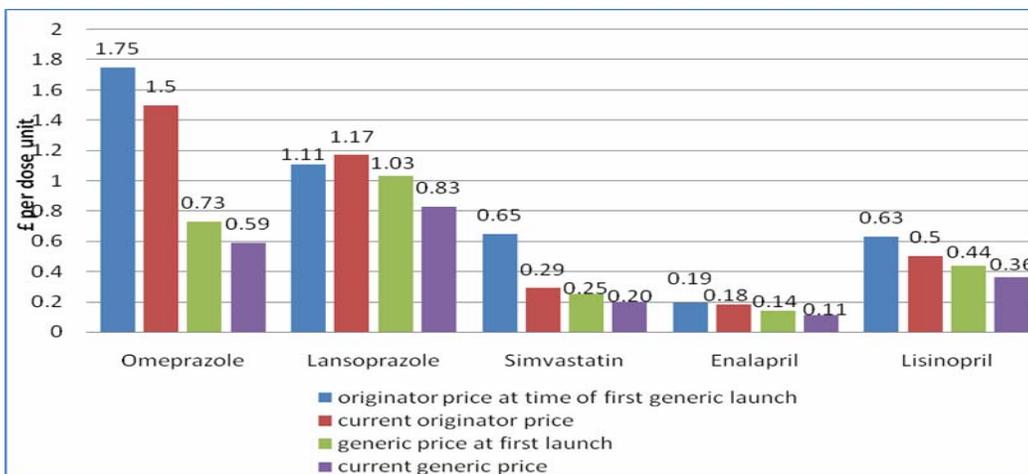


Figure 5: Current prices of originators and generics and their prices at the time of the first generic launched in Jordan

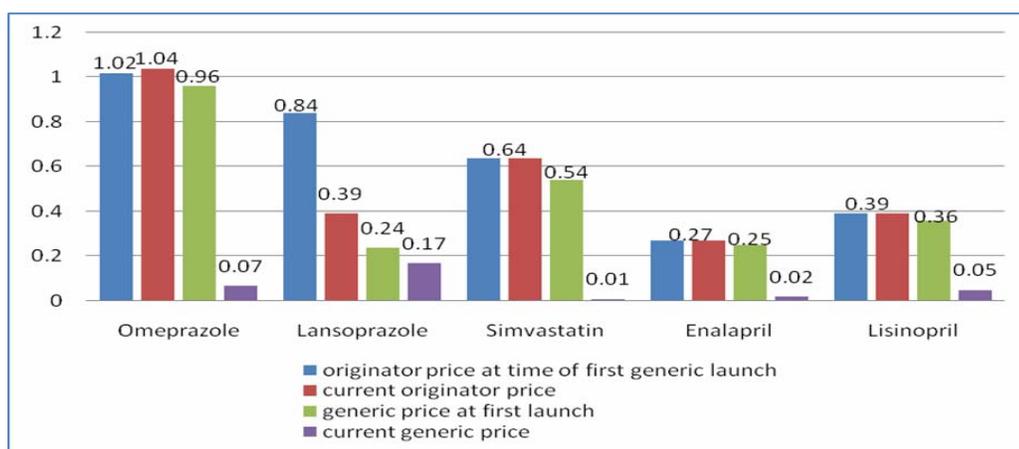


Figure 6: Current prices of originators and generics and their prices at the time of the first generic launched in the UK

Figures 3, 4, 5 and 6 also showed that the current prices of originator simvastatin and enalapril in Jordan are lower than their equivalents in the UK while, the originator enalapril maintained the same price in both countries from time of the first generic launched.

Although the prices for generics dropped in both countries from time of the first launch (Figure 5 and 6), the drop in price per unit dose is substantially greater in the UK than in Jordan. For example, omeprazole price of the first generic launched in the UK was £0.96 compared to £0.73 in Jordan; the corresponding current prices are £0.07 and 0.59, respectively (85% and 19% drop).

For all the five drugs investigated, the originator brand prices at the time first generic was launched were higher in Jordan than the equivalent generic prices. In general, the current prices of both generic and originator drugs in Jordan were less than those at the time of the first launch (Figure 5). As in Jordan, the prices of the originator brands in the UK were higher than the equivalent generics at the time of the first launch (Figure 6).

• **The Correlation between The Number of Generics Available and Price Change of Both Originator Brand and Its Equivalent Generic in Jordan and the UK**

Results showed that prices of originators did not change at the time of the launch/ registration compared to the time of the first generic launched in Jordan while they

were decreased in the UK (Figure 1); the percentage of decrease ranged from 67% for lansoprazole to 1.4% for simvastatin (Table 3).

Table 3: Correlation between number of years the originators have been in the market and their prices' change in Jordan and in the UK

Drug name	Jordan		UK	
	% change in price	No. of years	% change in price	No. of years
Omeprazole	+9.0%	15 years	-19.6%	19 years
Lansoprazole	-7.2%	12 years	-67.0%	14 years
Simvastatin	-64.0%	17 years	-1.4%	19 years
Enalapril	+2.5%	21 years	-17.6%	23 years
Lisinopril	-31.4%	17 years	-47.7%	20 years

Although there were a considerable number of generics available as alternatives to the originator brand in Jordan; there was no correlation between the number of generics available and price change of that brand (Figure 7). For example, the price of originator

omeprazole which has the highest number of generics available (10 generics) increased by 9%, while the originator simvastatin which has the second lowest number of equivalent generics available (7 generics) showed the highest decrease in price by 64% (Table 3).

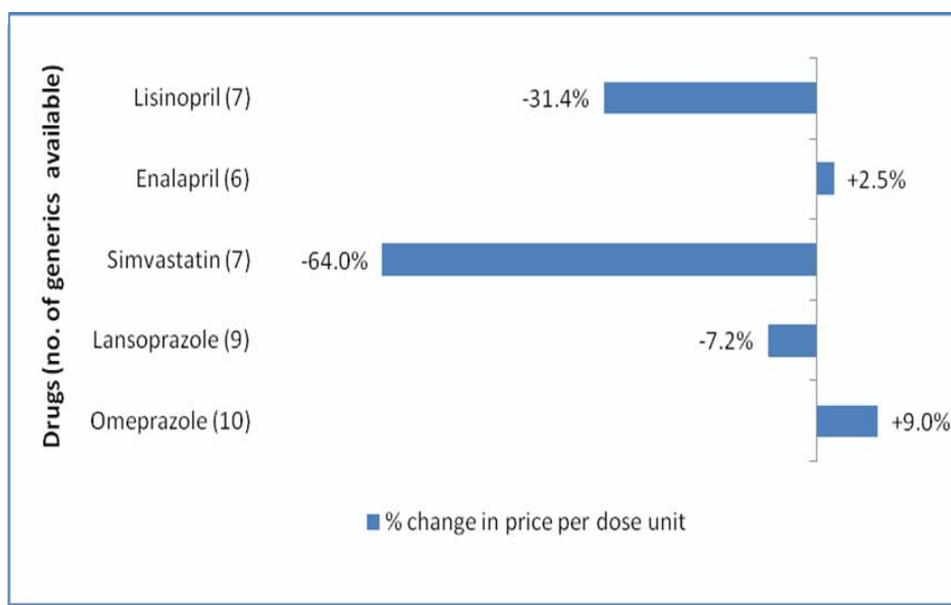


Figure 7: Percentage change in the price of originators from time of the first generic launched in Jordan

The same results were seen in the UK; for example the price of the originator omeprazole which has the highest number of generics available (22 generics) increased by 2.3% while originator lansoprazole which

has the lowest number of equivalent generics available (12 generics) showed the highest decrease in price by 53.5% as shown in Figure 8.



Figure 8: Percentage change in the price of originators from time of the first generic launched in the UK

Again, there seems to be no correlation the between number of generics currently available and the change in generic prices in Jordan. For example, the price of omeprazole did not change despite having the highest number of generics available (10 generics), while prices

of enalapril, lisinopril and simvastatin which have the lowest number of generics available showed a considerable price drop (16.7%, 30% and 64.5%, respectively) (Figure 9).

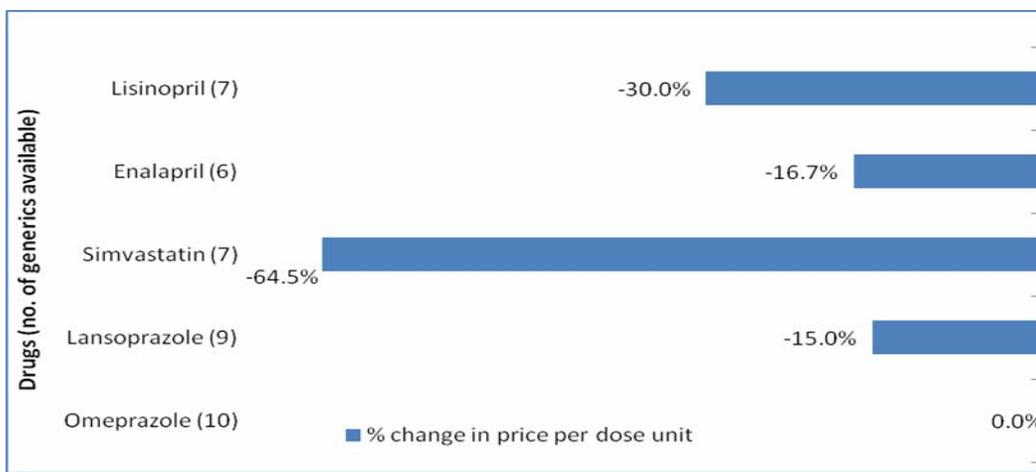


Figure 9: Percentage change in the price of generics from time of the first generic launched in Jordan

Interestingly, for most of the investigated drugs, the drop in the prices of originator brands was much less than the drop in the prices of their equivalent generics in Jordan from time of the first generic launched. For example, originator lansoprazole price drop was 7.2%, when its equivalent generic price drop was 15% and while enalapril originator price increased by 2.5%, there

was a 16.7% drop of its equivalent generic price in Jordan (Figures 7 and 9).

On the contrary, with the exception of lansoprazole; while all generics' prices studied decreased much in the UK, the originator prices remained the same (Figure 8 and 10).

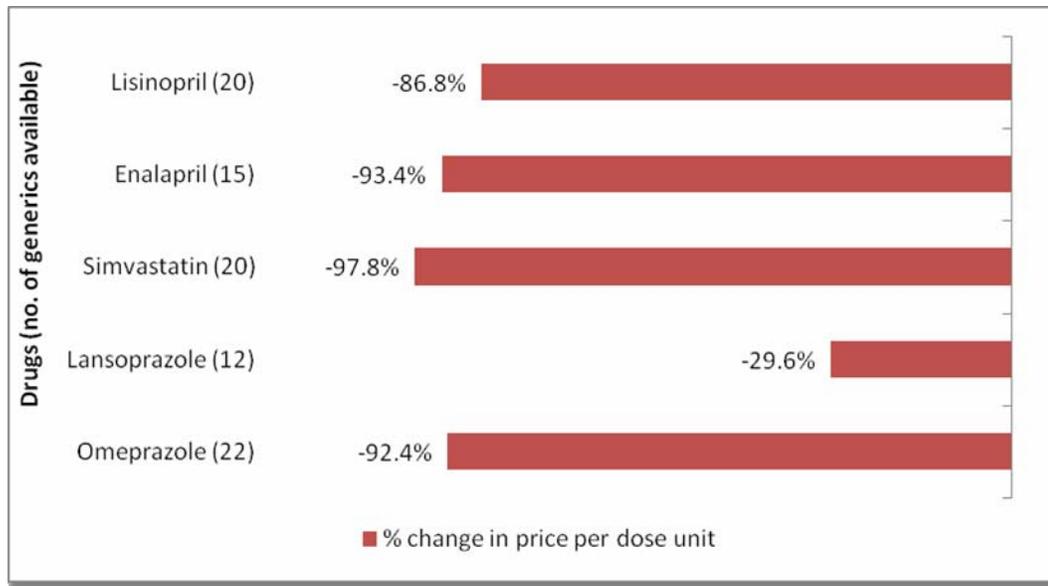


Figure 10: Percentage change in the price of generics from time of the first generic launched in the UK

• **Correlation between the Number of Years Originators and Generics have been in the Market and their Prices' Change in Jordan and in the UK**

As shown in Table (3), there is no correlation between the number of years originators have been available in Jordan and the change in their prices. For example, lisinopril and simvastatin originator brands have been available in the Jordanian market for the same period (17 years) while their prices dropped by 31.4% and 64.0%, respectively.

The same results were observed in the UK; for example enalapril originator which has been available for 23 years in the UK market showed 17.6% drop in its

price while lansoprazole which has been in the market for 14 years showed a 67% drop in its price (Table 3).

Regarding generics, the same results were observed. For example, in Jordan enalapril generic was introduced into the market for 19 years in which its price dropped by 16.7%, while simvastatin generic price fell by 64.5% despite being available for only 11 years (Table 4). In the UK, there does not seem to be a clear cut correlation between the number of years a generic is available and the percentage price reduction, however lansoprazole generic which has only been available for 2 years did show the smallest drop in its price (Table 4).

Table 4: Correlation between the number of years generics have been in the market and their prices' change in Jordan and in the UK

Drug	Jordan		UK	
	% change in price	No. of years	% change in price	No. of years
Omeprazole	0.0%	15 years	-92.4%	5 years
Lansoprazole	-15%	11 years	-29.6%	2 years
Simvastatin	-64.5%	11 years	-97.8%	4 years
Enalapril	-16.7%	19 years	-93.4%	8 years
Lisinopril	-30%	14 years	-86.8%	5 years

DISCUSSION

Jordan joined the World Trade Organisation (WTO) in 2000²⁶ in which countries have to recognise product protection throughout the patent period which is normally 20 years. Jordan also signed a Free Trade Agreement (FTA) with the USA in the same year²⁷, the FTA provides protection for trademarks, copyrights and patents with specific attention to pharmaceuticals, as patents are especially prone to violation. As part of its trade commitments, Jordan accepted the World Intellectual Property Organization (WIPO) Copyrights and Patents Treaty, this came into effect from April 2004 resulting in new patency regulations in Jordan²⁸. Prior to signing the WTO agreement, local companies in Jordan were able to produce generic equivalents of new drugs before patency expiration. The latter explains the availability of generics in Jordan at a much earlier time (Table 2) than in the UK, and may explain why the originator prices did not change after the launch of the first generic in Jordan during that period (Figure 1).

On the contrary, UK has been applying the patency regulations a long time earlier than Jordan. This explains the originator drug prices' being less at the time of the first generic was launched in the UK. This is true for omeprazole, lansoprazole and lisinopril. However, the price of enalapril originator has been found to be less in Jordan and the price of simvastatin originator did not show any change (Figure 1). The latter was explained by that the JFDA is applying pharmaceutical pricing

instructions based –in portion- on referring to the drug price in the country of origin which was Netherlands for these two drugs. Another portion of the Jordanian pharmaceutical pricing instructions were stated to refer to a median price of originators in at least three countries out of UK, France, Spain, Italy, Germany, Greece and the Netherlands, this explains the lower prices of enalapril and simvastatin originators in Jordan than the UK (Figure 4). Accordingly, it is worth mentioning that those countries were selected to be as references in drugs' pricing in Jordan and which are the most similar to Jordan in terms of the level of development, income, population, capabilities and health care system.

Although the number of generics available for an individual drug and the number of years since originator or generic was launched, this has been thought to play a big role in dictating drug prices; there was no clear correlation between those factors and price change in Jordan as well as in the UK (Figures 7-10 and Tables 2-3).

Although originator prices in Jordan either decreased or increased after their equivalent generics were introduced into the market (Figure 7), the case is different in the UK in which higher penetration by generics would not necessarily lead to a reduction in originator drug prices¹³ (this has been usually called the "generic paradox"); however, it may only prevent a price increase of originator³ (Figure 8).

Although lower income per capita (Table 1), generics' prices in Jordan are higher than in the UK, this can be

explained by: first; local pharmaceutical manufacturers in Jordan gained an excellent reputation for their good quality products since they have been in the market for more than 45 years that allows them to export for more than 65 countries all over the world including USA and Europe (accounting for 70% of their business), most of which require that exported products should be registered and freely sold in the country of origin (Jordan is the case here) at a price that is considered as a reference price in those export markets, so to encourage export, higher prices at country of origin (Jordan). Second; strict pricing regulations weakens the competition in off-patent time and reduces the potential cost saving from generic drugs¹⁸; this is the case in Jordan in which current pricing instructions allow what is called branded generic a price ceiling up to 80% of the originator price (Figure 5). Also, lower generic prices in the UK can be explained by the lack of R&D costs for generic manufacturing.

Although lansoprazole generic has been available only for two years, a lansoprazole originator price in the UK was the only one that showed a drop which is considered relatively high (53.5%) (Figure 8), this could be explained by launching FasTab (orodispersible tablet)

dosage form besides the capsules.

CONCLUSION AND RECOMMENDATION

Although many limitations were faced in this study; such as lack of published research comparing originator drug prices with generics' drug prices either locally or regionally, limited number of observations (5 drugs investigated), shortage in data (limited number of years) and many differences between the two countries in their level of development, income and health care settings, it can be concluded that a wider extensive study should be conducted in the near future to include more therapeutic classes with different dosage forms for longer time periods with better matching countries that have similar levels of socioeconomic and demographic characteristics of Jordan. Also, it was concluded that the current pharmaceutical pricing instructions in Jordan need to be revised in order to add evidence-based pharmacoeconomic evaluations including cost-effectiveness studies to be required for any new drug entity asks for premium prices, and need to balance the need for lesser generic prices without negatively influencing the local pharmaceutical industry; differential pricing may be an option.

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