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Investigating the Effect of Data Exclusivity on the Pharmaceutical Sector in Jordan

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ABSTRACT

Multinational pharmaceutical companies and generic drug manufacturers have long been at odds over "data exclusivity" regulations. The latter requires a waiting period of at least five years before they can access valuable clinical trial data necessary to bring less expensive forms of innovative drugs to market. Jordan has implemented Data exclusivity since joining the World Trade Organization and signing Free Trade Agreement with the United State in 2001. Before 2001 Jordan allowed Jordanian Pharmaceutical companies to "copy" molecules of Multinational Pharmaceutical companies and sell them under their own trade names. The arrival of the product patent and data exclusivity meant that Jordanian pharmaceutical companies could no longer copy. This has created lot of problems for the Jordanian Pharmaceutical companies as their Research & Development for new molecules is at a very emerging stage. The purpose of this study was to find out what is the effect of the application of data exclusivity on the pharmaceutical sector in Jordan.

After analyzing 140 medicines used in treating chronic diseases in Jordan in the period between 2004 & 2010 in Jordan. It was found that at least 16 % of these 140 medicines had no competition from a generic equivalent as a result of data exclusivity. This was perceived negatively by local pharmaceutical companies as the originator companies were relying mainly on the use of data exclusivity instead of patents to preclude generic competition. Data exclusivity was one of the main reasons behind the delay of the presence of the equivalent generic drug in Jordan contributed to rising of the pharmaceutical expenditure in Jordan.

Keywords: Data Exclusivity, Pharmaceutical Sector, Jordan.

1. INTRODUCTION

The Pharmaceutical Industry has a vital role within the world economy, as well as ensuring the welfare of humans worldwide. The pharmaceutical industry develops, produces and markets drugs licensed for use as medication, which could be generic and or brand medication. The pharmaceutical industry is subject to a verity of laws and regulations regarding patenting, testing and marketing drugs. In today's society, drugs are major source of relief for many illnesses. According to the World Health Organization (WHO), one-third of the world population cannot access medicines they need. An important reason for this is that prices are often too high for people or government-funded health systems to afford. In developing countries, most people who need medical drugs have to pay for them out of their own pockets. Where the cost of drugs is covered by health systems, spending on medicines is a major part of the total healthcare budget[(1)].

Two major forms of drugs are sold, patented drugs that are protected either through product or process patent and known by their trade name, and a generic medicine that means a prescription medicine based on an active

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substance that is out of patent and marketed under a different name from that of the original branded medicine[2]. The generic medicine manufacturers play an important role in offering affordable medicines to patients after the expiry of the patent protection period as generic drugs are seen predominantly as a low-cost alternative to patented drugs[3].

Jordan is classified as a lower- middle income country in which the largest provider of health care is the public sector via the Ministry of Health (MOH), providing insurance to 40% of the population, followed by the Royal Medical Services (RMS), covering 27.5% of the population. In addition, Jordan University Hospital (JUH) and King Abdullah University Hospital (KAUH) provide health care services for the Universities employees and dependents and also serve as referral centers. The remaining is covered by insurance companies associated with banks, professional syndicates, universities or private companies. Being successful in dealing with communicable diseases and with its economic manifestations, the burden of disease in Jordan has shifted toward non-communicable diseases (NCD). This is reflected in the Jordan national health priorities list: (Cardiovascular diseases, Cancer, diabetes, Osteoporosis and Neuropsychiatric disorders)[4].

Although patients seeking treatment in the public sector have to pay very small charges of the prescribed drugs as copayment, some drugs are routinely out-of-stock in the public sector with no substitutes available, forcing the patients to pay for the drugs out-of-pocket from retail pharmacies in the private sector. The latter provides primary, secondary, tertiary & quaternary services through a network of private clinics, polyclinics, and hospitals. Patients seeking treatment in the private sector purchase their drugs directly from the private health center, or its retail pharmacies[5].

Jordan has a fairly well developed high quality local pharmaceutical manufacturing sector. Currently, there are 16 companies which manufacture mostly generics or branded generics. The local manufacturers engage in contract manufacturing for global pharmaceutical companies, currently contributing to less than 5% of the overall pharmaceutical sector revenue. Given the relatively small size of the Jordanian market compared to minimum efficient plant size in pharmaceutical production, most of these companies are export- oriented, with more than70% of their production sold in more than 65 countries worldwide. As one of the biggest producers of pharmaceutical products in the Middle East, Jordan has a positive trade balance in pharmaceuticals[6]. Despite of this, it mostly depends on Europe for patented drugs.

In order to market a new drug in Jordan, it has to be approved by Jordan Food & Drug Administration (JFDA). Originator drugs applicant should submit toxicological, pharmacological and clinical data about this new drug, whereas generic drug companies can make abridged applications to get market approval for their products demonstrating that their product is bioequivalent to the original drug. Generic applicant does not need to repeat the clinical safety and efficacy trials performed by the originator company[7]. In many countries, health authorities don't allow the use of originator's data as a reference by generic companies for a period (usually 6 - 10 years) after the original product gets approval[8]. The latter is called data exclusivity (not a patent) which refers to a practice whereby, for a fixed period of time, drug regulatory authorities do not allow the registration files of an originator to be used for application for a therapeutically equivalent generic version of that medicine. In fact, the strongest impact may be felt in a country where there is no patent for a medicine (if data exclusivity is granted) this will provide a monopoly for a set period (e.g. five years).

Jordan's pharmaceutical industry has grown rapidly during the 1990s, partly as a result of a "copycat" strategy that emphasized simple adaptations of global pharmaceutical innovations over local innovation. Jordan's accession to the World Trade Organization (WTO) in 2000 put an end to this practice and raised the pressure on Jordan's manufacturers to reinvent their strategies. Jordan joined the WTO as the 136th member in 2000, and then continued a decade-long reform process of upgrading its intellectual property laws under the U.S./Jordan Free Trade Agreement (USJFTA) in 2001[9].

Trade Related Intellectual Property Rights (TRIPS) brings in uniformity in the standards of intellectual property rights among the member countries of the WTO irrespective of their developmental status. While this is expected to result in free flow of technology and investment among the member countries, yet the extent to which the benefits will accrue depend on the domestic industry and the developmental status of the country that is undertaking the reform measures. The claimed benefits of data exclusivity relate, to a great extent, to the additional incentives offered to companies in the long and expensive process of pharmaceutical Research & Development (R&D). Data exclusivity gives companies an incentive to extend the original use of the product (for example, to a wider population, by age or geography, or in new indications for therapeutic use) where, for one reason or another, no patent protection is available. Data exclusivity provides an additional opportunity for originator companies to recoup their investments where marketing approval is given late in the patent life, so that the protection afforded extends beyond patent expiry[10].

In many developing countries there are numerous medicines that are not patented (even if they are patented in developed countries). In addition, even where there are patent laws, companies may not have considered the market sufficiently valuable to justify the expense and administrative cost of securing patents.

Like most developing countries, Jordan relied heavily on generic medicines, until the country implemented the TRIPS agreement in 2000. Under the terms of its accession to the World Trade Organization WTO in 2000, Jordan was required to introduce TRIPS-plus provisions in its national patent laws in 2004. The latter supposed to improve the ability to develop generic medicine and engage in new innovative research, as well as increasing the presence of and collaboration with multinational drug makers, but indeed TRIPS plus tend to increase the price of new medicines, which keeps them out of reach for all but the elite in developing countries.

Jordan was the first Arab country that signed a free trade agreement FTA with the USA in 2001 allowing for more intellectual property protection in which parallel importation without patent holder's prior consent is forbidden.

The goal of this research was to determine the effect of data exclusivity on the pharmaceutical sector in Jordan after 10 years of implementing TRIPS plus, it is expected that this study could inform decision makers in both public and private sectors while establishing future strategies toward more developed pharmaceutical industry. As being the first of its nature in Jordan; this comparative descriptive study is trying to analyze the effect of data exclusivity on the pharmaceutical sector in Jordan before and after the implementation of data exclusivity.

Methodology

Sales of all pharmaceutical products in Jordan, including all dosage forms, expressed as quantities as well as values were obtained either from JPD or from International Medical Statistics (IMS) quarterly Jordan market reports (2010); the top five selling groups out of the 16 available groups (groups are classified according to The Anatomical therapeutic code ATC-WHO) were selected as they represent 66% of total sales by value in 2010 focusing in non-communicable diseases (NCD) or chronic diseases such as hypertension, coronary heart disease, diabetes mellitus, etc. Two groups were excluded as they are out of the scope of this research i.e. not chronic mostly (anti-infective and Miscellaneous).

The three selected groups (Alimentary & Metabolism, Cardiovascular and Nervous system) included 140 products (Details are available as Tables upon request). Data collected included: drug name, strength, price, quantities sold in the private or purchased in tenders, number of equivalent generics available for the originator, date of launch for originator & first generic and data exclusivity expiration date for the originator. The latter was collected for the 140 products for both private (IMS Jordan 2005-2010), and tender (MoH website, Joint Procurement Department (JPD) 2004-2010 and JFDA) markets for 5 & 6 years respectively. Those 140 products accounted for 36.8% of total sales value in the private market for the year 2010.

In order to avoid packaging and strengths variation per each product, if any, an internationally accepted unit of measurement: "Defined Daily Dose" (DDD) was used. WHO defines DDD as the assumed average maintenance dose per day for a drug used for its main indication in adults (11); DDD for each product was obtained.

A. Tenders:

- Actual purchased quantities in tenders for the period 2004-2010 were converted to DDD for each dosage form for each product.
- Cost per DDD was calculated by dividing total sales value for each product in each year by total DDD quantities for the same.
- Estimated cost difference (savings) were calculated for each product by subtracting cost of DDD for the first generic launched from cost of DDD of its equivalent originator.

B. Private: Data collection tool spreadsheets were created to record the prices of originators and its equivalent generics for each product.

- Prices of originator and its equivalent generic (s) were obtained from IMS Jordan for the year 2010.
- Price differences between originator and generic were calculated in order to estimate cost saving.

Results

During the analysis of the 140 products that were awarded in Jordan Tenders (2004-2010), four different groups were evolved. Data was categorized accordingly:

1. Group 1 (originator to generic): drugs where originator was awarded at the start then equivalent generic was awarded in the following year.
2. Group 2 (Only originator): Only one bidder: the originator i.e. No generics available.
3. Group 3 (Generic to originator): Generic was awarded at the beginning, and then equivalent originator was awarded also.
4. Group 4 (Only generic): Only generic participate in the bidding; no equivalent originator.

Details are shown in Table 1.

Table 1. Group categorization sales (tender 2010)

Study group	Number of products/140 (%)	% of sales (value)
Originator to generic	13 (9%)	10.7%
Only originator	69 (49%)	52.1%
Generic to originator	1 (1%)	0.4%
Only generic	57 (41%)	36.8%

1- Group 1 (originator to generic):

In order to investigate if there is any difference in cost/DDD when the generic entered the market, the total DDD purchased per each product belongs to the (originator to generic) group and cost per each DDD for the years 2004-2010 were calculated as shown in Table 2.

In addition,, registration dates for originator and the date of registration & launch for its first equivalent generic (2004-2010) were categorized in Table 3.

The cost/DDD was decreased once the equivalent generic entered the market; the trend analysis showed a continuous decrease since 2004 till 2010 and presence of equivalent generic reduced the cost/DDD.

As shown in Table 3, three products (valsartan, leviteracitam, celecoxib) from this group were selected for trend analysis in the private market as they were under data exclusivity during 7 years of the study period and the generic entry date was 2009 & 2010 for these products (Table 4).

Table 2. Originator to generic group Total DDD purchased and cost/DDD (Jordanian Dinars) for the years 2004-2010 (Qty=DDD purchased, cost=cost/DDD) (Tenders=Public sector)

			2004		2005		2006		2007		2008		2009		2010	
	Product	**DDD**	**Qty**	**Cost**	**Qty**	**Cost**	**Qty**	**Cost**	**Qty**	**Cost**	**Qty**	**Cost**	**Qty**	**Cost**	**Qty**	**Cost**
CNS	Lamotrigine	300 mg	54,160	2,166	65,580	2182	53,350	1.794	158,333	1.161	-	-	278,425	0.503	52,165	0.352
	Gabapentin	1800 mg	22,222	3,051	44,444	2648	122,222	1.618	155,561	0.853	-	-	313,222	0.346	460,556	0.236
	Clozapine	300 mg	101,667	1,435	133,333	0702	-	-	-		1,000	1.483	3,667	0.811	208	1.078
	Phenytoin Oral	300 mg	333,333	0,112	-	-	166,667	0.114	500,000	0.121	-	-	564,167	0.091	-	-
	Parenteral	300 mg	16,667		-	-	16,667	3.962	20,833	3.705	-	-	6,250	3.681	26,250	3.519
	Haloperidol Oral	8	377,250	0249	457,550	0,179	1,253,750	0.057	1,941,250	0.056	1,041,250	0.056	8,438	0.261	12,031	0.243
	Parenteral	8	318,182	0264	681,818	0273	454,545	0.248	915,341	0.295	188,068	1.377	184,333	1.083	3,109	0.457
	Levetiracetam	300 mg	-	-	35,700	2520	-	-	33,333	3.557	-	-	81,160	2.335	113,767	2.212
CVS	Betaxolol	20 mg	149,996	0,151	149,996	0,178	75,012	0.202	299,992	0.198	194,768	0.198	294,000	0.148	123,990	0.125
	Pravastatin	30 mg	-	-	526,940	0740	-	-	800,000	0.690	40,000	0.600	1,319,980	0.550	-	-
	Carvidilol	37.5 mg	145,4045	0,570	275,000	0430	462,525	0.270	741,667	0.080	1,039,167	0.060	1,063,167	0.050	464,667	0.040
	Valsartan	80 mg	1,400,000	0373	1,400,000	0373	1,000,000	0.200	1,400,000	0.065	2,130,000	0.044	2,071,328	0.040	1,092,000	0.023
DM	Gliclazide MR	60 mg	-	-	-	-	-	-	-	-	-	-	25,005	0.211	162,495	0.139
MSCL	Celecoxib	200 mg	-	-	-	-	-	-	-	-	180,000	0.486	-	-	15,000	0.300

NB: Valsartan + Hydrochlothiazide combination was excluded as DDD is unavailable due to complexity of calculation

Table 3. Originator to generic group cost trend analysis for tenders (2004-2010) (values in Jordanian Dinars)

Originator to generic group	Regist date of Orig	Launch date of Orig	Regist date of 1st gen	Launch date of 1st gen	Data exclusivity expiration	Generic entry date	2004	2005	2006	2007	2008	2009	2010	Total	% cost /DDD trend
CNS															
Lamotrigine	1994	1995	2006	2007	1999	2006	117,3	19,67	9 5,686	183,782	-	140,058	1 8,364	574,888	-84%
Gabapentin	1997	1998	2006	2006	2002	2006	67,80	117,7	197,760	132,738	-	108,260	108,79	733,063	-92%
Clozapine	1994	NA	2003	2008	1999	2005	145,8	93,60	-	-	1,483	2,974	225	244,169	-25%
Phenytoin	1995	NA	2005	NA	2000	2006	37,23	-	8 5,072	137,552	-	74,277	9 2,378	Oral	-19%
														Parenteral	-11%
Haloperidol	1975	NA	2006	2007	1980	2006	178,2	267,8	184,270	378,839	317,08	201,768	4,344	Oral	-3%
														Parenteral	-73%
Levetiraceta	2002	2004	2008	2008	2007	2009	-	89,96	-	118,560	-	189,468	251,66	649,660	-12%
CVS															
Betaxolol	1997	1998	2009	2009	2002	2009	22,65	26,63	1 5,158	59,501	38,606	43,512	1 5,499	221,556	-17%
Pravastatin	1994	1994	2008	NA	1999	2009	-	388,5	-	553,384	24,130	727,218	-	1	-25%
Carvidilol	1996	1996	2005	2006	2001	2007	82,18	117,6	122,857	61,120	63,092	56,434	1 8,835	522,138	-93%
Valsartan/HZ	2000	2000	2008	2008	2005	2010	-	-	231,076	-	-	-	2,250	233,326	-78%
Valsartan	2001	2000	2006	2007	2006	2006	521,5	521,5	200,000	91,000	92,940	82,372	2 5,184	1	-94%
DM															
Gliclazide	2002	2002	2008	2009	2007	2010	-	-	-	-	-	5,286	2 2,533	27,819	-34%
MSKL															
Celecoxib	2000	2000	2009	NA	2005	2010	-	-	-	-	87,428	-	4,500	91,928	-38%
Total							1,172	1	1,131,88	1,716,476	624,76	1	564,57	6	

Regist.= registration, orig.=originator, gen.=generic, NA=not available, % cost trend in DDD=difference of bidding price between first year and last year, HCZ=hydrochlorothiazide

Table 4. IMS data for the products under data exclusivity

Year	**Celecoxib**		**Valsartan**		**Leviteracitam**	
Sales (,000)	**Unit**	**Value (JD)**	**Unit**	**Value (JD)**	**Unit**	**Value (JD)**
2004	54.5	413.8	10.2	194.3	0.2	6.5
2005	26.8	202.4	14.1	273.6	0.9	33.5
2006	30.3	229.1	9.9	194.7	1.5	55.0
2007	36.9	277.4	14.0	279.7	2.2	82.0
2008	43.2	308.4	15.2	318.9	2.2	90.7
2009	57.9	351.5	17.9	363.3	1.3	55.0
2010	56.9	345.6	19.7	415.0	2.5	140.6
Total						**2,967.9**

The pharmacy prices in the Jordanian private sector for the three products (valsartan, leviteracitam & celecoxib) as originator brand and available generics (IMS-2010) are shown in Table 5.

Table 5. Pharmacy prices in Jordan in 2010

		Concentration	Pack Size	Pharmacy Price JD
Valsartan	**Generic 1**	160 MG	30 Tablets	14.75
		80 MG	30 Tablets	11.80
	Generic 2	320 MG	30 Tablets	17.37
		160 MG	30 Tablets	15.17
		80 MG	30 Tablets	10.53
	Generic 3	160 MG	30 Tablets	14.05
		80 MG	30 Tablets	11.68
	Originator	320 MG	**28 tablets**	28.89
		160 MG	28 capsules	26.34
		80 MG	28 capsules	20.86
		40 MG	28 capsules	12.36
Leviteracitam	**Generic 1**	100 MG /ML	240 Ml Syrup	41,000.00
		750 MG	30 Tablet	39,790.00
		500 MG	30 Tablet	27,260.00
		250 MG	30 Tablet	14,210.00
	Originator	**500 MG 100**	**100 Tablet**	**111,220.00**
		100 MG /ML	300ml Oral	76,310.00
		500 MG	30 Tablet	38,800.00
Celecoxib	**Generic 1**	400 MG	10 Capsules	7.14
		200 MG	10 Capsules	4.76
	Originator	100 MG	20 Capsules	7.17
		200 MG	10 Capsules	5.99

2- Group 2: Only Originator:

This group included 57 products, in which the main reason for absence of generic (from 2004-2010) for 19 of them was the data exclusivity which means the originator only was in the market for five years from date of registration. Tenders cumulative sales values for the 19 products are shown in Figure 1 (in Jordanian Dinars).

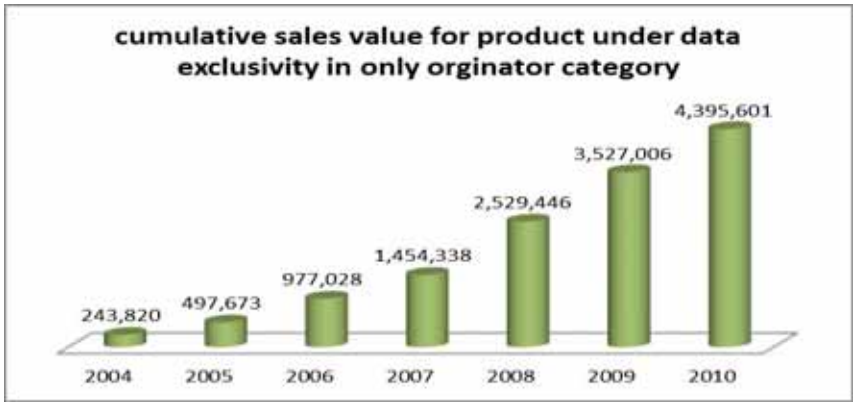

Figure 1: Tenders cumulative sales value for products under data exclusivity (JDs)

In the private market, only 14 products out of the 19 were available as the others are mainly hospital products-and the products in hospital are not included in IMS Jordan data-. Figure 2 shows sales value in the private market for products in group only originator from 2005-2010.

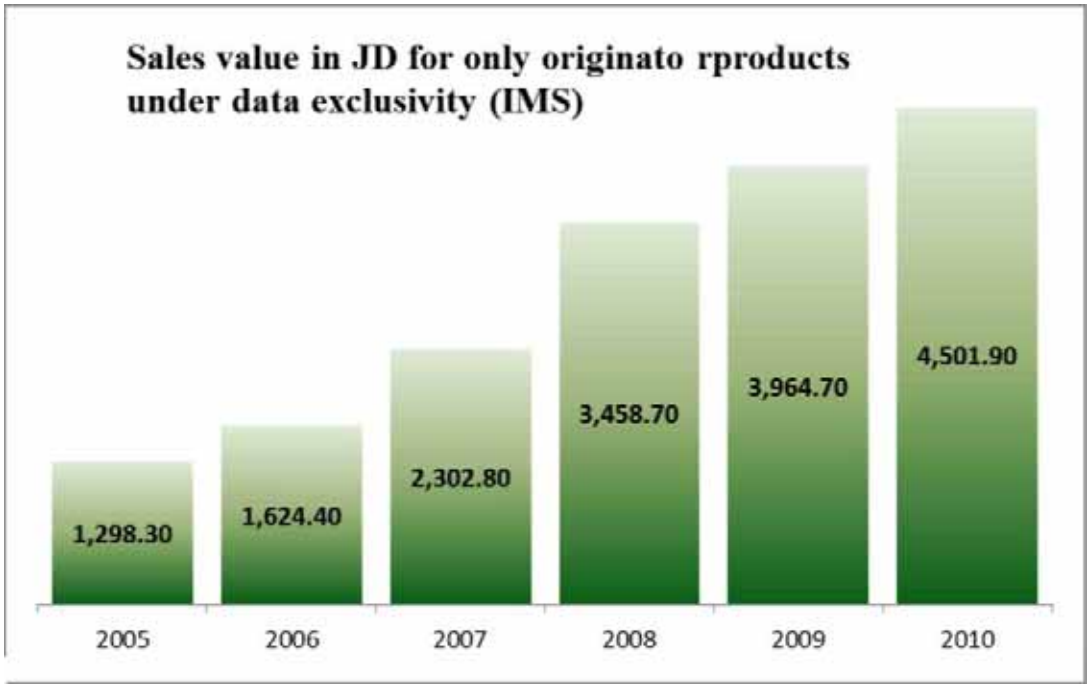

Figure 2: Sales value in private market for 14 products in only originator

The cumulative sales value for the 14 products (rosuvastatin, pioglitazone, ramipril,, nebivolol, telmisartan, quetiapine, ezetimibe, zolpidem, moxonidine, rivastigmine, eprosartan, atomoxetine, infliximab, nitroprusside) under data exclusivity in group only originator was 17,150,900 JDs in the private market. The latter high expenditure will be much less if generics were available.

3- Group 3: Generic to originator:

This group includes only one drug (clopidogrel) as originator brand was awarded in the tender after the generic was awarded before, the reason for this may be due to clinical guidelines that recommended the use of the originator brand immediately after catheterization for 3 months followed by a generic regardless of the price. The letter increased the cost/ DDD by 141% as the originator was much more expensive than the generic.

Due to a price difference of 37.4 JD in 2010 (originator awarded) over 2009 (generic awarded), the cost to the government increased by extra 179,829 JD in 2010.

On the other hand, in the private sector, Table 6 shows the pharmacy prices after expiration of data exclusivity and generics entered the market in which prices were much less by 56%.

Table 6. Clopidogrel pharmacy prices in Jordan 2010

Clopidogrel	Concentration	Pack	Pharmacy Price (JD)	Launch date
Generic 1	75 MG	**28 Tablet**	33,650	7/2009
Generic 2	75 MG	**30 Tablet**	30,950	2/2007
Generic 3	75 MG	**30 Tablet**	36,050	1/2007
Generic 4	75 MG	**30 Tablet**	36,050	10/2008
Generic 5	75 MG	**30 Tablet**	36,050	2/2008
Generic 6	75 MG	**30 Tablet**	36,050	12/2010
Originator	75 MG	**28 Tablet**	48,310	8/2001

4- Group 4: Only Generic

Only Generic group was not studied as the equivalent generic for the originator was already available in the market which means that no data exclusivity hinders their presence.

On summary, results of this research found that the total products under data exclusivity were 22 out of the 140 representing 16% of the total studied products in term of unit sales and 9.4% of total sales value which equal to 5,734,673 JD.

Table 7 shows the overall trend analysis summary for the studied groups.

Table 7. Estimated savings (JDs) averted due to data exclusivity in tenders and cost in the private market

Group	Tender Cost before generic entry	Tender estimated savings if generics awarded	Private Cost
originator to generic	1,330,000	1,244,723	2,968,000
only originator	4,395,000	1,450,350	17,100,000
generic -originator	2,967,900	170,829	6,526,425

Discussion

Authors would like to acknowledge that although this is a retrospective observational type of study. With the inherited limitations with this design a causal relationship can't be well established.

One important point worth mentioning before starting the discussion; generics were not available although data exclusivity was expired for some years. The latter was attributed to many reasons; sometimes products were not feasible economically i.e. not attractive to be marketed (low sales value), others are available in dosage forms that cannot be produced by local generic companies (e.g. injectable).

Over the years, the TRIPS-plus FTAs have been much criticized for their possible conflict with TRIPS norms and their potential negative impact on access to medicine for developing countries[12].

Moreover the protections resulted from FTA

negatively impacted affordability and availability of medicines in Jordan. It also challenged the claim that stronger IP protection leads to greater foreign direct investment which was not the case in the pharmaceutical industry in Jordan. Besides, there is no evidence to support claims that the FTA has enhanced availability and accessibility of medicines in Jordan. As stricter IP rules led to dramatic increases in the price of key medicines to treat cancer and heart disease, which are the main causes of death in the country. Furthermore, it neither attracted foreign investment, nor improved local manufacturers' R&D capacity or led to more collaboration between national and multinational pharmaceutical companies[13].

On the other hand, medicines prices have continued to rise in Jordan after IP rules, but Jordan was not able to use TRIPS safeguards to reduce their cost. Also, Jordanian generic companies have not developed any new medicines since the Free Trade Agreement (FTA). While new medicines were frequently unavailable or unaffordable in Jordan[14].

The research-based pharmaceutical industry claims that data exclusivity provides incentives for companies to generate the necessary data, since without marketing exclusivity, brand-name companies would not want to conduct expensive preclinical tests and clinical trials[15]. The argument that data exclusivity laws will encourage the introduction of new medicines into the market betrays a misunderstanding of their implications. In fact, there is a possibility that data exclusivity would actually provide incentives to delay the entry of new products for multinational companies would prefer to keep prices high in developed markets by delaying their entry into the developing world at lower prices[16].

The tension between patent law and public health concerns such as access to medicine has long been an issue of much debate. The requirement of patent protection for pharmaceutical products and various other relevant provisions under the TRIPS agreement signifies this tension as they have created considerable difficulties for developing countries acquiring the medicines needed to address their public health concerns, despite the flexibilities that had been built into the agreement. Hence, the Doha Declaration on the TRIPS agreement and public health has been adopted in 2001 to address this issue, hoping to provide relief to this tension between public health policies and intellectual property rights legislations. Nevertheless, this tension seems to have been further heightened with the proliferation of the FTAs, through which developed countries such as the US and the EU have introduced TRIPS-plus obligations that go beyond the minimum standards set by TRIPS, further exacerbating the tension. Over the years, these TRIPS-plus FTAs have been much criticized for their possible conflict with TRIPS norms and their potential negative impact on access to medicines.

Data exclusivity did not affect only Jordan, but also its export market, as the local Jordanian manufacturers will be out of their export markets at least for 7 years;(5 years protection due to data exclusivity, 1 year registration time in Jordan and at least one year registration in export market).

One of the perceived gains of data exclusivity is an increase in foreign direct investment in the pharmaceutical sector and the arrival of newer medicines for Jordanian patients, but in reality this did not happen, most licensing agreements in effect today were signed before 1999, and transfer little know-how to local manufacturers. Furthermore, Egypt, in contrast to Jordan, has no TRIPS-Plus provisions in its IPR law yet still enjoys a significant amount of foreign investment in its pharmaceuticals industry.

Conclusion

This study indicated that data exclusivity for the pharmaceutical products seems likely to generate negative impacts on Jordan in terms of higher drug prices. It is also suggested that data exclusivity, on one hand, would have no relation whatsoever to the rate of R&D and foreign investment, but, on the other hand, is likely to impede the industrial development process of the country. Additional expenditure for medicine with no generic equivalent was resulted from the enforcement of data exclusivity.

This is a clear incentive for local pharmaceutical manufacturers to work smart to establish their own R & D toward developing new drug entities and innovative products.

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دراسة أثر "نظام حماية البيانات" على قطاع الأدوية في الأردن

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ملخص

لقد شكل موضوع "نظام حماية البيانات" محور جدل بين مصنعي الأدوية الجنيسة وشركات الأدوية لوقت طويل. ومن ناحيتهم في الوقت الحالي، يحتاج مصنعو الأدوية الجنيسة لفترة تمتد حوالي خمس سنوات على الأقل قبل أن يتمكنوا من الحصول على نتائج التجارب المخبرية الخاصة بالأدوية الجديدة حتى يستطيعوا تقديم الأدوية الجنيسة لمنظمة الغذاء والدواء الأردنية ليتم قبولها وتسجيلها، وهو ما يعد في نظرهم وقتاً طويلاً نسبياً ليكونوا قادرين على تزويد العالم بدواء طبق الأصل (جنيس) للدواء الأصيل لكن بأسعار أقل نسبياً.

طبق الأردن نظام "نظام حماية البيانات" منذ انضمامه لمنظمة التجارة العالمية وعند توقيعه على اتفاقية التجارة الحرة مع الولايات المتحدة الأمريكية في 2001. في السابق، سمحت السلطات الصحية الأردنية لشركات الأدوية المحلية لنسخ ما يعرف بالجزيئات "molecules" المشكلة لمنتجات شركات الأدوية العالمية وبيعها تحت أسمائها التجارية المحلية. لكن تطبيق نظام حماية البيانات منع شركات الأدوية الأردنية من نسخ الجزيئات مما خلق مشكلة لهذه الشركات نظراً لأن أقسام البحث والتطوير فيها لا زالت بدائية بالمعنى الدولي وليست بقادرة على خلق أدوية جديدة.

هدفت هذه الدراسة للتحقق من أثر "نظام حماية البيانات" على القطاع الدوائي في الأردن. وأظهرت نتائج الدراسة أن هذا النظام أسهم في ارتفاع فاتورة الرعاية الصحية التي تتكبدها الحكومة الأردنية سنويا بحوالي 47% من ذي قبل.

الكلمات الدالة: حماية البيانات، قطاع الأدوية، مصنعي الأدوية الجنيسة، الأردن.

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