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# The price of medicines in Jordan: the cost of trade-based intellectual property

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**Abstract**

Jordan dramatically strengthened the level of intellectual property protection it provides for pharmaceutical products in consequence of joining the World Trade Organization in 2000 and signing a Free Trade Agreement with the United States in 2001. This study assesses the impact of higher levels of intellectual property protection on access to medicines by quantifying the effects on the private retail pharmaceutical market of delayed market entry of generic products. Adjusted for increased sales volume and inflation, from 1999 to 2004 there was a 17% increase in total annual expenditure for medicines in Jordan. When assessing originator medicines that were marketed in both 1999 and 2004, and for which there were generic equivalents, the weighted average price of originator medicines increased while the weighted average price of equivalent generic medicines decreased. Delayed market entry of generics due to enhanced intellectual property protection is estimated to have cost Jordanian private consumers approximately 18 million U.S. dollars in 2004. Jordan should consider amending its current regulatory scheme on data protection and amending the Unfair Competition and Trade Secrets Law of 2000. Jordan should also consider increased spending on public health to offset the adverse impact on consumers of strengthening its intellectual property protection relevant to pharmaceutical products.

**Keywords**

Access to medicines, intellectual property, US–Jordan free trade agreement

## Introduction

### *Intellectual property rights and access to medicines*

Intellectual property rights (IPRs), which include patents, trademarks, and copyrights, convey legal ownership over certain intangible assets, including technologies used in pharmaceutical drugs and production methods. IPRs provide innovators with economic incentives to develop and share ideas through a form of temporary monopoly. Patents, for example, may be granted to the inventor of a new, inventive and useful product or process, and generally prevent others from making, using, selling or importing the invention during the patent term.[1] In the United States, a strong patent system has been credited as a crucial driver of innovation, economic development, and trade.

While IPRs create incentives for development and commercialization of useful inventions, they also create obstacles to accessing new technologies. In the case of pharmaceuticals, patent protection promotes investment in research and development (R&D) for the creation of new drugs. However, these same protections may limit access to medicines, particularly in developing countries. Deciding on the appropriate level of protection for intellectual property involves striking a balance between innovation and access.[2]

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## The Trade-Related Aspects of Intellectual Property Rights agreement

The agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an international agreement adopted within the framework of World Trade Organization (WTO) that provides requirements for national legislation in the area of intellectual property, as well as enforcement procedures, remedies, and dispute resolution procedures. The TRIPS agreement is the most comprehensive international agreement on intellectual property.

TRIPS establishes minimum standards for patent protection of pharmaceuticals, and this protection may present a barrier for access to medicines. While the granting of patents may encourage innovation, patents establish exclusive rights that allow pharmaceutical companies to set and maintain high prices. Patents may delay the release of lower-price generic equivalents that have traditionally met the needs of developing countries.

## TRIPS flexibilities and 'TRIPS-plus' provisions

The TRIPS agreement contains flexibilities for governments to the balance interests of IP holders against the interests of public health. These flexibilities include, but are not limited to, permitting adequate transition periods, experimental uses, parallel imports, and compulsory licences. Reports have found that the use of TRIPS flexibilities can promote access to medicines, but that these flexibilities are often inadequately utilized.[3,4]

The ability to implement TRIPS flexibilities may be compromised by bilateral or regional trade agreements that create more restrictive patent rules and medicines regulations ('TRIPS-plus' provisions). TRIPS-plus provisions may include stronger protections for pharmaceuticals that restrict certain experimental uses, limit compulsory licenses, constrain parallel imports, and provide protection based on data exclusivity. Protection based on data exclusivity, for example, hinders competition because it creates a type of monopoly for medicines not protected by patents. In general, IPR standards beyond those agreed to in TRIPS create additional barriers for access to medicines.[5]

The United States currently has free trade agreements (FTAs) with 17 countries.[6] Other industrialized countries and regions, such as Japan and the European Union, also have FTAs with both developed and developing partners. Proponents of TRIPS-plus provisions in bilateral/regional agreements argue that stronger IP protections lead to new export opportunities, improved national R&D, increased transfer and dissemination of technology, and increased foreign direct investment. Critics argue that these provisions are one-sided and support the multinational pharmaceutical industry at the expense of public health.[7]

## Jordan's accession to the World Trade Organization and FTA with the United States

Jordan joined the WTO in 2000.[8] Membership in the WTO confers a variety of benefits, including lower tariffs and reduced trade barriers to exports, more access to foreign products, and potentially improved international relations. However, applying to the WTO for membership is a lengthy and complex process, and Jordan was required to commit to substantial new obligations in areas such as tariff reductions, services, agriculture, and transparency. Jordan was also required to enhance protection for intellectual property and to become compliant with TRIPS, an obligation for all WTO members.

Jordan entered into a bilateral FTA with the United States which took effect on 17 December 2001.[9] The FTA commits Jordan to TRIPS-plus provisions for IP protection, particularly in the pharmaceutical sector.[10] FTA requirements include expanded data protection, extension of patent term, notification requirements, elimination of exclusions from patentability for biotechnology inventions, limitations on parallel imports, and limitations on compulsory licenses.

Jordan ratified a new Patent Law in 1999 (amended in 2001 and 2007), patent regulations in 2000 and an unfair competition and trade secrets law in 2000.[11] These acts of legislation fulfilled some of Jordan's obligations arising from its accession to the WTO and its FTA with the United States.

## Medicines in the public sector

Medicines in Jordan are generally obtained through either a public or a private system. The public sector involves state providers: the Ministry of Health, Royal Medical Services, King Hussein Cancer Center, Prince Hamzah Hospital, and the Jordanian Universities. Currently, medicines for these institutions are obtained through the Joint Procurement Department (JPD). The JPD combines estimated medicines requirements annually and publishes a combined tender offer. Private companies registered in Jordan may then place bids on the tender. Tender bids must not exceed 85% of private market wholesale pharmacy prices.

The JPD was established in 2004, and all public institutions have participated fully in the JPD since 2009. Prior to universal participation, public

institutions obtained medicines individually through 'direct purchases.' This process remained distinct from the private market.

## Medicines in the private sector

In the private sector, the Jordan Food and Drug Administration (JFDA) establishes fixed national retail prices. Originator medicines must be sold at the lowest of the following prices: (a) the price requested by the seller based on cost, insurance and freight export price, (b) the price in the country of origin, (c) the export price to Saudi Arabia, and (d) the median price in a basket of at least three out of seven European countries. Similar price controls apply to generic medications, which are additionally limited to a ceiling of 80% of the originator price. This means that, *at most*, a generic medicines will sell for 80% of the bioequivalent originator medicine's price (at the time of registration, re-registration or the day of pricing, whichever is less). Generics are therefore always available at lower price, although in some cases physicians may continue to prescribe higher priced originator medicines despite the presence of generics.

Specialized agents/distributers are the only parties permitted to coordinate sales between medicines manufacturers/importers and pharmacies. The profit margin for agents and retail outlets is set by the government as a fixed percentage of the sales price. Agents and pharmacies therefore make more money when selling more expensive medicines. Pharmacies are not permitted to charge a fee for professional services or to give discounts on the retail price of medicines, although some may do so in violation of law.

## Pharmaceutical IP protections in Jordan

Domestically patented pharmaceutical drugs now receive 20 years of market exclusivity without generic competition from the date of patent application. However, multinational pharmaceutical companies have tended to forgo patent protection in favor of 5 years of data protection automatically associated with registration of a new medicine.[12] There are many reasons a company may choose not to file for a pharmaceutical patent. For example, a foreign manufacturer may decide the limited size of the Jordanian market does not justify the cost and time necessary for patent application.

Jordan has applied a 5-year data protection regime since April 2000 when the unfair competition and trade secrets law was adopted. When the law was adopted, data exclusivity was applied retroactively to medicines that had already been approved by the state. So, for example, a medicines approved in 1998 received market exclusivity until 2003. Data exclusivity is applied automatically for any new medicines that are registered with the JFDA, and the definition of 'new' was under debate until June 2009. Now, to be considered new, medicines must be submitted for registration within 18 months of approval anywhere in the world. Previously, medicines already available in generic form elsewhere in the world, such as Metformin and Meropenem, were approved as new products in Jordan and received 5 years of national data protection.

The JFDA does not check to see whether data submitted for regulatory approval has been previously disclosed. The TRIPS agreement only requires protection of *undisclosed* confidential commercial information submitted for regulatory approval.[13]

Originator medicines also receive 3 years of data protection for approved new uses of an existing medication. This system has been in effect since December 2004, as Jordan had a 3 year grace period to apply this commitment. In June 2006, 'new uses' was defined as new indications. Previously, there had been considerable disagreement regarding how the term should be interpreted (whether it should apply to new dosages, etc.). This protection prevents generics from mentioning the new indication in the insert leaflet or in promotional material. Although against regulations, in practice, a generic may still be substituted for the originator medicine in what is termed 'off-label' use.

While IPRs raise the price of medicines in Jordan, they do so less directly than in the USA and some other developed countries. In the USA, for example, originator companies can generally charge high prices for their medicines regardless of what the medicines are selling for elsewhere in the world. However, in Jordan where the JFDA sets fixed private market prices, the price of medicines is dependent on prices in other countries, particularly in Saudi Arabia. Saudi Arabia in turn sets fixed medicines prices based on drug prices in more than 30 other countries (including low, middle, and high income nations). IPRs therefore generally raise prices indirectly, by virtue of raising the price of medicines in other countries. To the extent that generic companies may be permitted to charge a maximum of 80% of a high-priced originator medicine's price, IPRs can produce higher profits for local industry as well.

## Studies of the effects of increased IP protections in Jordan

A report by the International Intellectual Property Institute in August 2004 stated that, 'contrary to

conventional wisdom, globalization has benefitted Jordan. The results [of the FTA] included increased economic growth generally, and in particular, benefits for Jordan's pharmaceutical and bio-medical technology industries'.[14] As evidence to support this claim, the report noted that Jordan's economy expanded significantly between 1998 and 2001, which it attributed to improved protection for IPRs. The report noted that health-service contributions to the Jordanian gross domestic product grew from 2.8% in 1997 to 3.5% in 2001, and health-services employment grew 52% since 1997.

On the other hand, a 2007 article analyzed the TRIPS-plus provisions of the Jordan–United States FTA and found that the claimed benefits from the FTA have been exaggerated and the costs underestimated.[12] It concluded there is no evidence to support claims that the FTA has enhanced availability and accessibility of medicines in Jordan, attracted foreign investment, improved R&D capacity of local manufacturers or led to more collaboration between national and multinational pharmaceutical companies.

Another study of the FTA in 2007 by Oxfam[15] reported that medicines prices have increased significantly in Jordan since the FTA, partly as a result of TRIPS-plus rules. Stronger IP protections have produced minimal benefits to foreign direct investment, domestic R&D, and the introduction of new medicines. The report predicted that medicines prices will continue to rise in Jordan, and the country will be unable to use certain TRIPS flexibilities.

Original data are not presented in this report on the availability of medicines in Jordan, although research has suggested that local availability issues exist.[16] Regarding affordability, enhanced IP protections delay the entry of generics which raises the price of medicines.[17] Where national spending on medicines is limited, higher prices restrict access.[18]

### *Study objectives*

The current analysis is designed to assess the impact of Jordan's increased intellectual property protection, as a result of WTO accession and the US–Jordan FTA, on access to medicines. The effect of these events is not considered individually because they occurred during an overlapping time period, and because domestic laws and regulations were adopted in Jordan to comply with both its WTO membership and the FTA at the same time.

This study quantifies the impact from delaying the entry of generics due to IP protections on the private retail market.

## Methods

### *Data collection*

A subset of 46 of the most essential medicines used in Jordan from all of the drugs approved by the JFDA was identified by a national multidisciplinary research team composed of representatives from the Jordanian government, originator and generics industries, academics, and healthcare providers. None of the medicines selected, based on the top selling oral drug entities within each class, have been protected by patent in Jordan. Data for these drugs was then obtained from IMS-Jordan for retail prices in Jordan (denominated in Jordanian dinars), units sold in the private market for 1999 and 2004, as well as total sales in US dollars (USDs).

Units sold were then converted to defined daily dose (DDD)—as an internationally accepted unit of measurement—and cost per DDD was calculated if two or more different dosage forms for the same drug entity were available at different prices. Cost per DDD was calculated based on a weighted average price for those dosage forms.

Data collected by the Jordanian Association of Pharmaceutical Manufacturers (JAPM) from the Jordan Patent Office (JPO) gives the annual number of pharmaceutical-based patent applications, which includes both products and processes. The JPO database is not currently automated or searchable, and these data were obtained through careful examination of all patents filed during this study time period. Although exact data are not available regarding the number of patents that were approved, the national research team is not aware of any rejected applications. This data has not previously been released.

Data are presented from 1999, which pre-dates strong intellectual property protection for pharmaceuticals in Jordan, and 2004, which post-dates strong intellectual property protection. Data are presented for total private market sales in both of these years, for both total units sold and total sales in USD. In addition, the average price of both originator and generic medicines is presented for 1999 and 2004. These prices are estimated based on the subset of 46 medicines selected by the national research team. Only medicines sold in 1999 and 2004 in both originator and generic form were included in this analysis, which resulted in an analyzable group of 23 medicines.

To adjust for inflation, inflation rates were obtained from 1999 to 2004 from the Central Bank of Jordan's online statistical database.[19] Since 1995, the exchange rate between Jordan dinars and USD has been fixed at 0.709 dinars to 1 dollar.

### Outcome measures

To measure the effect of delayed market entry of generics, the number of registered new chemical entities (NCEs) in 2004 was first determined. Second, the JFDA independently determined the number of these medicines which were likely within the ability of generics manufacturers to produce. To do this, the JFDA excluded medicines created by biological processes (biologics, such as monoclonal antibodies) as well as chemical drugs which, in the opinion of the JFDA, had very difficult active pharmaceutical ingredients to manufacture.

Third, the average total price of an originator medicine in 2004 was calculated based on the subset of 46 medicines. Fourth, the average difference in price between an originator and generic medicine in 2004 was calculated based on the subset of 46 medicines (data were available for 29 of the 46 medicines subset, which were originator medicines with generic equivalent in 2004).

Finally, because protection in Jordan based on data protection extends for 5 years, NCEs registered in 2003, 2002, 2001, and 2000 were included. The impact of these earlier drug registrations is based on the previous analysis from 2004, including the percentage of NCEs within the ability of generics manufacturers to produce, the average total price of an originator medicine, and the average difference in price between an originator and generic medicine.

Based on these calculations, the study estimated the additional cost in the private market due to delayed entry of generics from 5 years of data protection.

Data are also presented on the current number of Jordanian pharmaceutical companies undertaking R&D, as well as the annual number of pharmaceutical-based patent applications, medicines without generic equivalents, and new pharmaceutical product registrations.

## Results

### Total private market sales

Between 1999 and 2004, both the total units of medicines sold and the total price of medicines increased significantly (Figures 1 and 2). In 1999, 26 billion units of medicines were sold at a price of 81 million USD. In 2004, 32 billion units of medicines were sold at a price of 125 million USD. This represents an increase of 24% in the number of units sold and a 53% increase in the total price of medicines. Adjusting for increased sales volume and inflation, this represents an increase of 17% in the total price of medicines.

### Changing originator vs generic price

Examining originator medicines on the market in both 1999 and 2004 with generic equivalents, the weighted average price of originator medicines increased from 2.09 USD/DDD in 1999 to 2.40 USD/DDD in 2004. During the same period, the weighted average price of generic medicines decreased from 1.30 USD/DDD in 1999 to 0.99 USD/DDD in 2004.

Because originator medicines have increased in price over time while generics have decreased, the difference in price between originator and generic medicines has grown (Figure 3). In 1999, the weighted average difference in price between an originator medicine and its generic equivalent was 0.79 USD/DDD. That means, on average, patients paid an additional 79 cents a day to take an originator medicine, which was 60.4% more expensive than its generic equivalent. In 2004, the weighted average difference

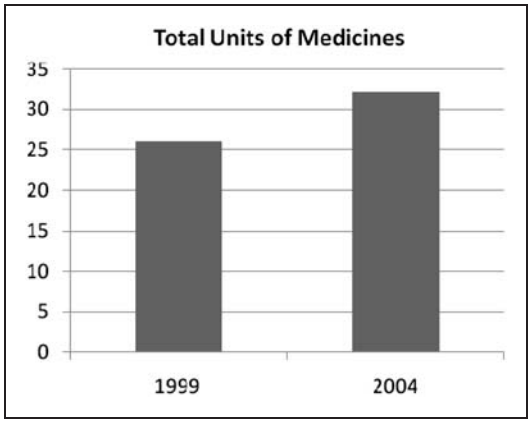


**Figure 1.** Total units of medicines sold in Jordan's private sector in billions.

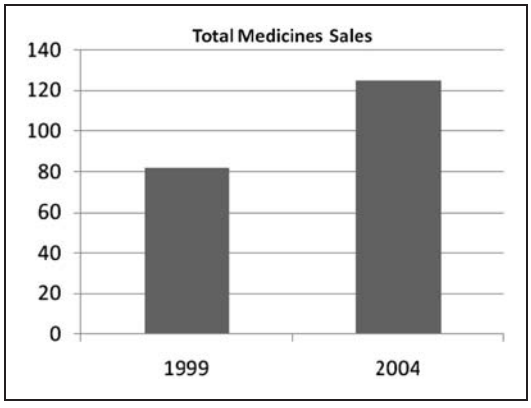


**Figure 2.** Total medicines sales in Jordan's private sector in millions of USDs.

in price between an originator medicine and its generic equivalent was 1.41 USD/DDD. Patients paid an additional 1.41 dollars a day to take an originator medicine, which was 144% more expensive than its generic equivalent.

## Pharmaceutical-based patent applications

Data obtained from the JPO provides the number of pharmaceutical-based patent applications between 1990 and 2008 (Figure 4). According to information provided by the JAPM, 17 Jordanian pharmaceutical companies currently undertake R&D.

## JFDA submissions

Data are presented on the number of pharmaceutical products registered and approved for domestic sale by the JFDA from 1998 until 2005 (Table 1). New drug registrations include NCEs, as well as new dosage forms, new concentrations, etc.

## Effect of delayed market entry of generics

In 2004, 20 originator NCEs were registered with the JFDA. According to the JFDA, 13 of these medicines were within the ability of generics manufacturers to produce (65%). Based on the subset of 46 originator medicines, the average total annual retail expenditure on an originator medicine was approximately 466,000 USD (one originator medicine without sales in 2004 was excluded). In 2004, the weighted average generic medicine price was 45% the price of its originator counterpart. This data suggests that 1

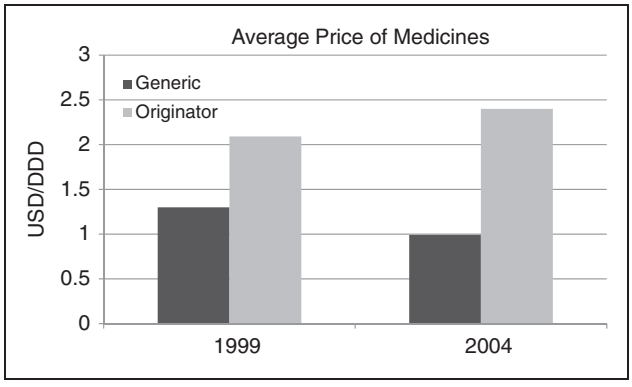


**Figure 3.** Price of originator medicines compared to their generic equivalents in Jordan's private sector.

**Table 1.** Pharmaceutical products registered with the Jordan Food and Drug Administration (JFDA) from 1998–2005

| Year | All new registrations | NCEs | Originator registrations | Generic registrations |
|---|---|---|---|---|
| 1998 | 122 | 14 | 60 | 62 |
| 1999 | 59 | 9 | 14 | 45 |
| 2000 | 282 | 18 | 97 | 185 |
| 2001 | 458 | 20 | 138 | 320 |
| 2002 | 327 | 26 | 122 | 205 |
| 2003 | 336 | 26 | 134 | 202 |
| 2004 | 245 | 20 | 107 | 138 |
| 2005 | 279 | 14 | 90 | 189 |
| Total | 2108 | 147 | 762 | 1346 |

NCEs: new chemical entities; originator registrations include NCEs.

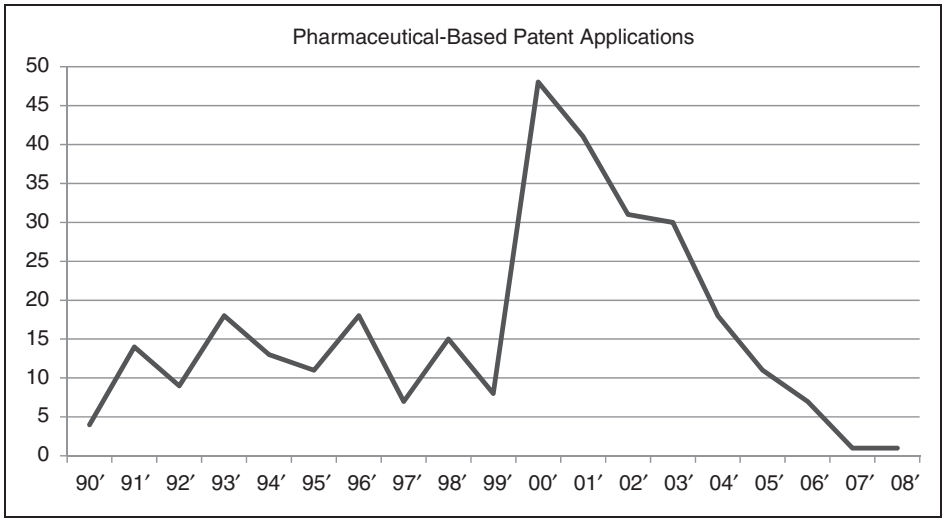


**Figure 4.** Number of pharmaceutical-based patent applications in Jordan by year from 1990–2008.

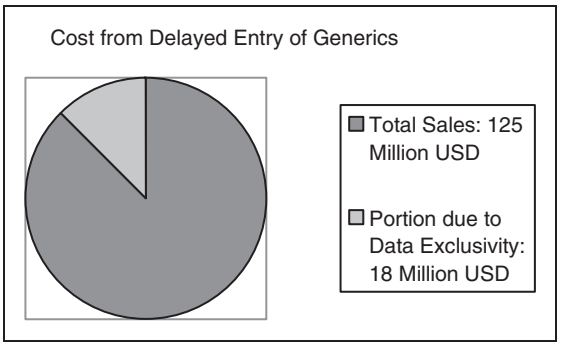


**Figure 5.** Percentage of total annual pharmaceutical spending in Jordan's private sector due to data exclusivity.

year of data exclusivity for NCEs registered in 2004 cost Jordan's retail market approximately 3.3 million USD.

Extrapolating these numbers based on these calculations to include the 90 NCEs registered with the JFDA between 2000 and 2003, which were also protected by data protection in 2004, it is estimated that delayed market entry of generics due to enhanced IP protections cost Jordan's retail market approximately 18 million USD in 2004. This represents approximately 14% of the total annual pharmaceutical spending in Jordan's private sector (Figure 5).

## Discussion

### *Study limitations*

The price of medicines is the result of a number of factors. In addition to IPRs, drug prices are influenced by global, domestic and local economic factors, inflation, government price controls and procurement strategies, changes in population demographics, and changes in disease prevalence. As with most cases of statistical or economic analysis, it is difficult to correlate the effect of one variable on a complex result.

The estimation methodology utilized by this study may under- or overestimate the impact of delayed market entry of generics. In terms of underestimation, this report has only considered private market data, which ignores purchases made in the public sector. Estimation relied on the difference in price between originator and generic medicines; however, these data were only available for medicines with generic equivalents in Jordan. Originator medicines without competition may be significantly higher priced by virtue of their ability to charge monopoly prices, and may drop in price once generics are available.

In addition, this study did not consider all of the IP-related changes that occurred as a result of Jordan's WTO membership and the FTA. None of the medicines selected for inclusion by the national research team were under patent protection. However, research suggests that patent protection significantly increases price.[20,21] Also, the FTA restricts parallel importation (Jordanian law currently requires prior consent of a patent holder to engage in parallel importation) and compulsory licensing, practices which otherwise might be used to lower the price of medicines domestically. Finally, the FTA requires Jordan to make efforts to accede to the Patent Cooperation Treaty. Although Jordan has not yet done so, it is likely that Jordan will see a substantial increase in the number of pharmaceutical-related patents if it joins this treaty.

Conversely, the methodology may have resulted in overestimating impact. The estimation relies on the assumption that generics would be purchased instead of originator medicines, if available. In practice, physicians may continue to prescribe higher priced originator medicines. In addition, the average total annual retail expenditure on an originator medicine was based on the top selling oral drug entities within each class, which may have resulted in overestimating the average price. It is also possible that the timeframe considered by this study may have had a relatively larger number of NCE registrations. From 2000 to 2004 there was an average of 22 NCE registrations, compared with an average of 18.4 NCE registrations from 1998 to 2005.

### *Comparison to the Oxfam study*

The Oxfam study estimated that, between 2002 and mid-2006, enforcement of data exclusivity resulted in additional expenditures between 6.3 and 22.04 million USD in Jordan. This study estimates a loss of 18 million USD in 2004, which is larger than the impact found by the Oxfam study.

The Oxfam study identified 260 medicines available in Jordan with no generic equivalent from IMS Health data, and then based calculations on 108 of these medicines launched by the 21 largest multinational pharmaceutical companies. Oxfam excluded 152 medicines from their analysis due to 'the difficulty of identifying patent applications and interpreting patent data'.[15] This exclusion was not adjusted for in later calculations. Five of the 108 medicines found to be under patent were also excluded. The present study based its calculations on 110 NCE registrations from 2000 to 2004.

The Oxfam study estimated 21% of medicines would not be available in a generic form regardless of data exclusivity because of technology barriers. It based this estimate on the availability of generics in India and elsewhere. This study relied on a

determination by the JFDA that 35% of medicines would not be available in a generic form because of technology barriers.

Finally, the Oxfam study estimated a difference in price of 30–80% between originators and generics. It based this determination on Jordan's pricing policies and earlier studies of generic competition. This study based its calculations on an actual price difference of 55% between originator medicines and their generic equivalents.

The Oxfam study did not consider the impact of patent protection. The study authors reported that they found only three medicines were under patent protection. However, they noted that patent applications were being filed for medicines not yet on the market, and they felt that patents would eventually have a significant impact on medicines prices. Because none of the medicines selected in this study had patent protection, this study also did not consider that impact.

## Mitigating the impact of data protection

Of all the current forms of intellectual property protection in Jordan, the provision for data protection has the most significant effect on the price of medicines. However, neither the TRIPS agreement nor the FTA obligate Jordan to maintain its current regulatory scheme. Under these agreements, if applications for generic drug approval do not make actual use of test data submitted by originators, but only rely on the fact that an originator medicine has been approved in Jordan, the government has no obligation to delay generic applications.[22] However, the JFDA is currently required by Article 8 of Jordan's unfair competition and trade secrets law to prevent approval of generic applications that rely on originator approval.[10] Jordan should consider eliminating this requirement from its unfair competition and trade secrets law.

Less ambitiously, the TRIPS agreement and FTA only require Jordan to protect *undisclosed* data (and prevent follow-on generic registration when originator approval is based on foreign regulatory approval). The JFDA could stop universally applying data protection to originator applications, and require applicants to report whether data submitted for regulatory approval remains confidential. The JFDA does not rely on foreign regulatory approval for its originator approval.

Finally, the unfair competition and trade secrets law could be amended to permit generic applicants to apply for approval of bioequivalence studies and marketing at any time during an originator's period of data protection. Under the current law, the JFDA is not able to issue approvals until expiration of an originator's period of data protection.

## Concluding thoughts

This study, along with a substantial body of evidence, supports the assertion that when developing countries strengthen intellectual property protection it may have a negative impact on access to medicines. Jordan is already committed to the strong intellectual property protection mandated by WTO membership and the US–Jordan FTA. However, Jordan has recently taken promising initiative to promote generic competition within the framework of its international obligations. This has included restricting data protection to a narrow definition of 'new' uses and limiting applications for data protection to a short period following market approval in the originator country.

As concluded in this study, Jordan should now consider amending its current regulatory scheme on data protection and amending its unfair competition and trade secrets law. Jordan should also consider increasing spending on public health to offset the impact of strengthening its intellectual property protection.

Domestic patents do not currently appear to have a substantial impact on access to medicines, so restricting the scope of patentability is unlikely to have a major impact if conditions remain unchanged. It is possible that the effects from patents have not yet been felt, as it takes years for a patented NCE to receive market approval. Regardless, Jordan should continue to resist entry into the Patent Cooperation Treaty, which will likely result in a much higher number of patent applications from multinational pharmaceutical companies.

Nations considering agreements that would strengthen their intellectual property protection for pharmaceuticals should be aware that this is likely to have a negative impact on access to medicines. This risk should be carefully balanced against possible benefits such as tariff reductions and increased foreign direct investment.

In order to make rational decisions and negotiate effectively, governments need accurate information on the likely effects of intellectual property obligations. Because international negotiations involving intellectual property are ongoing, there is a constant need for up-to-date research to assess risks and benefits prior to engaging in multilateral and bilateral negotiations.

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## Author's Biographies

Ryan B. Abbott, MD, JD, MTOM, lead researcher of this study, is Associate Professor of Law at Southwestern Law School. He has served as a consultant on health care financing and regulation, intellectual property, and public health for international organizations, academic institutions, and private enterprises including the World Health Organization, World Intellectual Property Organization, and University of California, Los Angeles. Professor Abbott has published widely on issues associated with health care law and intellectual property protection in legal, medical, and scientific peer-reviewed journals. He is a graduate of the Yale Law School and the University of California, San Diego School of Medicine. Professor Abbott is a member of the California State Bar and a registered patent attorney with the U.S. Patent and Trademark Office. www.DrRyanAbbott.com.

Rania Bader holds a bachelor's degree in pharmacy and a master's degree in pharmaceutical technology and quality assurance. She obtained her pharmacy degree in 1993, and practiced community pharmacy at R&M and clinical pharmacy at KGH Hospital in Kingston, Ontario, Canada. Ms. Bader has gained significant experience through her participation in a number of international projects over nearly seventeen years; most of these projects have focused on issues surrounding pharmaceutical sector regulations and policies. She has worked extensively in the area of policy surrounding generic medicines, prices of medicines and assessment of different procurement systems, regulations and processes in Jordan and the

MENA region. Her most recent project measured the integrity level in the health sector, a UNDP project for the Anti-Corruption Commission in Jordan. She has worked as a Consultant for the Medicine Transparency Alliance (MeTA) supported by the WHO, World Bank and Department for International Development (DFID) UK, and has also participated in the design of a Compulsory Health Insurance Scheme for the Government of Dubai. She has successfully managed an international World Bank Health Reform Project with a project output of eleven pharmaceutical policy studies. She also participated in Health Assessment of Displaced Iraqis in Jordan, funded by the WHO, and provided technical guidance in survey design, sampling methodology and field implementation of population-based surveys using health assessment tools. She was assigned through the WB to assess the effectiveness of the Joint Procurement Authority in Jordan. Rania has worked with the Health Action International and the World Health Organization (HAI/WHO) on a medicines prices, availability and affordability project. She supports civil society organizations in Jordan, mainly in building capacity in the area of pharmaceutical and health policies. Dr. Bader is currently the Director of Medical Applications at Electronic Health Solutions, where she is implementing a national health information system: "Hakeem," the first national e-Health initiative in Jordan. The program aims to facilitate and improve healthcare services by providing real time and up-to-date electronic medical information throughout the public health system.

Lina Bajjali has a bachelor's degree in pharmacy, and is currently the head of the Drug Registration Department at the JFDA. She has been in this position since 2005, prior to which she worked as the head of Drug Registration Unit, and before that as an employee at the drug registration department since 1992. She is currently a member of many committees within the JFDA, including drug registration committees.

Taher Abu El-Samen is a medical doctor, and specialist in hospitals and health facilities administration from Leeds University. Currently, he is the Secretary General of the High Health Council (HHC) in Jordan. He is involved directly in the national health policy process, and in collaborating efforts among all health sectors in Jordan, with his main focus on national health priority issues: health insurance reform to attain comprehensive coverage, medical liability, joint procurement of drugs, continuing medical education, and establishing an emergency and first aid commission. He is the team leader of National Health Accounts (NHA), which is considered an important instrument for drawing up the national health policy. Also, he is the chairman of the steering committee of the Medicines Transparency Alliance (MeTA) Project in Jordan. He worked in the MOH in many areas, initially as a medical doctor, hospital director, assistant secretary general of planning, general director of health insurance, then finally as Secretary General of the High Health Council. Also, he worked on health sector reform issues with the MOH through collaboration with the World Bank and USAID health projects. He has extensive experience in improving the national health system. He has worked with the WHO in several health consultancies.

Thamer Obeidat graduated with a bachelor's degree in pharmacy from the University of Jordan in 1994, and a master's degree in intellectual property rights from the German Jordan University in 2009. He worked in pharmaceutical marketing from 1994 to 1999, and has been Secretary General of the Drugstore Owners Association since 2000.

Hanan Sboul, MBA, CAE, is Secretary General of the Jordanian Association of Pharmaceutical Manufacturers, and represents the Jordanian pharmaceutical industry at the national and international level. She served on the Higher Committee for Drugs and was part of the negotiations for Jordan's accession into the WTO. Dr. Sboul is a Board member of Jordan Pharmaceutical Center of Excellence, the Jordanian Intellectual Property Association, Employment - Technical Vocational Education and Training Fund (E-TVET Fund), Scientific Research Support Fund, and a member of the Board of Trustees at the Hashemite University in Jordan. Dr. Sboul obtained her MBA from Jordan University, and holds a bachelor's degree in pharmacy from Yarmouk University. She is also a Certified Association Executive (CAE) from the American Society of Association Executives.

Mustafa Shwayat has a bachelor's degree in pharmacy and is Business Development Manager at Safa Company in the Kingdom of Saudi Arabia.

Ibrahim Alabbadi has been a qualified pharmacist since his graduation in 1987, and is experienced in pharmaceutical marketing (Middle East; ASTRA & Advanced). Dr. Alabbadi got his MBA-Marketing (pharmaceutical pricing) in 2001, when he started lecturing, training and consulting. In 2006, he completed his PhD in PharmacoEconomics from Queen's University in the United Kingdom. He developed an internationally published model for drug selection for

formulary inclusion. Dr. Alabbadi is currently an Associate Professor in the Clinical Pharmacy department at the University of Jordan. He is the former Director of Scientific Research Documentation Office, and he is currently Deputy General Director for Administrative Affairs at the Jordan University Hospital. Dr. Alabbadi has more than 13 international publications, and has participated in many regional and international conferences as an invited speaker. Furthermore, Dr. Alabbadi has been an active member in many international and national associations and committees, for example, JFDA, MoH, ISPOR, MeTA and HHC. He is the Jordan ISPOR chapter co-founder and current president.