



SUPPORT FOR LEBANON'S ACCESSION TO THE WORLD TRADE ORGANIZATION (WTO)

Regulatory Impact Analysis Report A New Interpretation of Article 47

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OCTOBER 2012

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SUPPORT FOR LEBANON'S ACCESSION TO THE WORLD TRADE ORGANIZATION (WTO)

REGULATORY IMPACT ANALYSIS REPORT Regulatory Impact
Analysis of a New Interpretation of Article 47

USAID SUPPORT FOR LEBANON'S ACCESSION TO THE WORLD
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FROM: BOOZ ALLEN HAMILTON

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Executive Summary

On August 14, 2000, the Lebanese authorities passed a new patent law (law No. 240) replacing the old patent law dating back to 1924. The new patent law provides for the protection of pharmaceutical products on the basis of a patent, prohibiting the unauthorized use of the confidential data generated and used by the original inventor or patent holder. Article 47 of this Patent Law, is meant to specifically address issues of data exclusivity in the pharmaceutical industry, requiring the Lebanese government to protect regulatory data provided by pharmaceutical companies for registration purposes from other companies trying to use this information to replicate the products in the production of generic substitutes.

Most data exclusivity regimes grant a period of reasonable exclusive rights to the originator during which generic manufacturers are banned from relying on the original data to meet registration standards of safety and efficacy, so that drug manufacturers can be assured that they will have time to make money back on their investments once they are registered with the government. Resulting from a lack of consensus on the interpretation of Article 47, in Lebanon generic manufactures are not banned from relying on original data to register competing products that are identical to the original products.

A newly proposed “Draft of Article 47” aims at defining exclusive data in a way that would protect the research based pharmaceutical companies from making investments in Lebanon. The American Chamber of Commerce in Beirut gathered a working group to conduct a regulatory Impact Analysis (RIA) to measure the impact of implementing a new interpretation of Article 47 on private companies, healthcare costs and Lebanon’s economy.

Results of this analysis identified that imposing stricter Data Exclusivity (DE) regulation is likely to show an overall benefit to the Lebanese economy. The overall benefits associated with implementing a new interpretation of Article 47 will outweigh the anticipated costs by a factor of approximately 2.8/1 (Table 5) over the initial five years after the implementation of the new interpretation for Article 47. Based on literature outlining DE regulation recently implemented in India, Jordan and Turkey, Lebanon is expected to see increases in pharmaceutical production by generic and innovative pharmaceutical manufacturers, reductions in health care expenditures to both consumers and the government, and an enhanced business environment witnessed through increases in Foreign Direct Investment (FDI) and R&D expenditures for the pharmaceutical industries. The primary overall cost bearers of this regulation will be the manufacturers, importers, and exporters of illegally produced copycat drugs, which represent less than 10% of the pharmaceutical industry in Lebanon today. Any lost revenue by these companies is expected to be outweighed by increased investment and collaboration activities between legitimate domestic manufacturers, importers, exporters, and international manufacturers.



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I. Introduction

Regulations perform an important role in society, ensuring that society functions properly, that resources are not “squandered,” and that laws are obeyed. Policy makers in government develop regulations with certain goals or intentions in mind: such as ensuring the delivery of only safe pharmaceutical products and that domestic industries are able to compete in a fair and transparent business environment.

On August 14, 2000, the Lebanese authorities passed a new patent law (law No. 240) replacing the old patent law dating back to 1924. The new patent law provides for the protection of pharmaceutical products on the basis of a patent, prohibiting the unauthorized use of the confidential data generated and used by the original inventor or patent holder. Article 47 of this Patent Law, specifically addresses issues of data exclusivity in the pharmaceutical industry requiring the Lebanese government to protect, for a specified number of years, regulatory data provided by pharmaceutical companies for registration purposes, from other companies trying to use this information to replicate the products in the production of generic substitutes. Regulatory data refers to test and clinical trial data generated by drug developers and submitted as necessary evidence of safety and efficacy for the successful registration of a product.

The full drug development process from discovery to marketing may take as long as fifteen years and the "fully capitalized cost to develop a new drug, including studies conducted after receiving regulatory approval, averages \$897 million"¹. Most data exclusivity regimes grant a period of reasonable exclusive rights to the originator during which generic manufacturers are banned from relying on the original data to meet registration standards of safety and efficacy, so that drug manufacturers can be incentivized to invest in research and development related activities assured that they will have time to recoup the cost of their investments once they are registered with the government.

In Lebanon, generic manufactures are not banned from relying on original data (published on FDA website for example) to register competing products that are identical to the original products. As a result, innovative pharmaceutical manufacturers are not protected in Lebanon for the following 2 limitations:

- Lebanese patents will not be granted after the passage of one year from the date of the filing of the application for the initial patent. Due to the nature of the pharmaceutical products that require between eight to twelve years of research and testing (research,

¹ E. Bale, Jr., *Encouragement of new Clinical Drug Development: The Role Of DE*, Director-General, IFPM, 2000



- animal testing, human testing, large scale trials, published studies, regulatory approval, launch) before they are marketed, those products cannot obtain a Lebanese patent within said one year delay. In fact, since for one of every hundred compounds discovered only makes it to the market, the companies cannot rush and file patent applications for all one hundred compounds in Lebanon.
- Despite the existence of a data protection provision in article 47 of the new patent law, the Ministry of Health is ignoring it and allowing Lebanese companies to register copycat products using the confidential data generated by the original patent holder and used either by it or by its licensed manufacturer. The registration of a product with the Ministry of Health constitutes a license to market that product in Lebanon.

A newly proposed “Draft of Article 47” aims at defining exclusive data in a way that would protect the research based pharmaceutical companies from making investments in Lebanon. The American Chamber of Commerce in Beirut has gather a working group to conduct a regulatory impact analysis (outlined in this report) to measure the impact of implementing the updated draft of Article 47 on private companies, foreign direct investment, healthcare costs and the Lebanese economy as a whole.

II. Background

a. Discussion of Article 47 of Law No.240/2000 and its legal relevance to the Pharmaceutical industry

Article 47 of the patent law provides for the protection of confidential information required by the Ministry of Health (“MOH”) in order to obtain a marketing license within the country of Lebanon. In fact, the last two paragraphs of article 47 provide as follows:

- “...The manufacturing methods as well as the results of research and experiments are considered as confidential information.
- The confidential information that the administration requires to be disclosed in order to authorize dealing with pharmaceutical products or chemical products used in agriculture cannot be used illegitimately for commercial purposes; they also cannot be disclosed unless the protection of the public requires it.”

A careful reading of the last two paragraphs of article 47 reveals that article 47 provides a definition of the type of confidential information that should be protected. It consists of the manufacturing methods, and the results of research and experiments. It should be noted that the definition of the confidential information of article 47 does not distinguish between published and unpublished information. One of the basic principles for the interpretation of the laws provides that when interpreting a text of law one should not distinguish where said text does not



provide for a distinction. Therefore, since the definition of the confidential information of article 47 does not distinguish between published and unpublished information, then both published and unpublished manufacturing methods and the results of research and experiments are captured by the definition of confidential information of article 47. The definition of the confidential information that does not create any distinction between published and unpublished data was not accidental. It was carefully assessed by the legislator and found to be necessary in view of the major efforts and substantial investments² made by the innovators to find new drugs. Therefore, the Lebanese authorities including the MOH and the Ministry of Economy and Trade should protect both the published and unpublished results of the research and experiments and the manufacturing methods.

The last paragraph of article 47 prohibits in essence the use for commercial purposes of the confidential information (as defined in the preceding paragraph) that the MOH requires for the registration of a pharmaceutical product. Since the application to register a copycat filed with the MOH is aimed at obtaining the MOH'S authorization to import and distribute the copycat, then such application is certainly aimed at using the confidential information for commercial purposes. Such use is prohibited by the last paragraph of article 47. Any other interpretation would lead to a very unfair, unjust and illogical result as it would allow a competitor of the innovator to use the innovator's own confidential information (that would have cost the innovator a fortune) to register the copycat product and compete against the innovator's product.

It should be noted that the last paragraph of article 47 does not prohibit the use of said information for non-commercial purposes such as education etc.

The above interpretation of article 47 gives a meaning to the last two paragraphs of article 47, as any other interpretation including that of the Ministry of Economy³ would render the last two paragraphs inapplicable. An interpretation of a text of law should always be done in a manner that gives the text of law a logical and reasonable interpretation. If there are two possible interpretations of a text of law, one that renders the text inapplicable and the other that gives the text a reasonable and logical meaning, then the latter interpretation should be adopted. Needless to say here, that if we were to adopt the interpretation of the Ministry of Economy, the last two paragraphs of article 47 would become inapplicable as all the data derived from the clinical studies is either published in the medical journals or on the FDA website.

b. RIA methodology

² It is estimated that the cost of finding and testing a new drug ranges from US\$800,000,000 to US\$1,000,000,000

³ The Ministry of Economy and Trade does not share this interpretation. It has taken the position that any published data would no longer be considered as confidential and therefore should no longer be protected in accordance with the provisions of article 47.



The Regulatory Impact Analysis (RIA) is a policy tool for providing detailed information on the potential effects of regulatory measures of both the intended and actual effects- in terms of costs and benefits to all parties affected by the regulation. It facilitates careful consideration of the details that should be taken into account when designing and implementing a regulation. In addition, RIA's can help to ensure that government regulations are effective, efficient, and result in the greatest net public benefit. It also helps to ensure that stakeholders are informed of the benefits and costs that are likely to result from the proposed regulation. An RIA is performed to fully evaluate the costs and benefits, both actual and intended of a regulation. This information can be helpful in advocating either for or against a regulation.

For this particular RIA, identifying the direct costs and benefits of such a regulation was challenging because not a lot of domestic public health and pharmaceutical data exists on the topic. As a result the team structured an approach guided by a literature review, focusing on other examples of DE regulatory implementation in countries with similar economies to that of Lebanon. Major findings were leveraged from studies on this topic focusing on Turkey, Jordan, India, all having undergone. Data from these examples was used as proxies to help estimate the potential costs and benefits for Lebanon under similar regulation.

With a good indication of potential costs and benefits from international examples, we deepened our research focusing on specific topics included in our Cost Benefit Analysis. These included the specificities of the Lebanese Patent Law and its main differences with international trade treaties, the effects involved with the substitution of NTI drugs and other complex topics, but also researching Data we can use to later quantify the effects we find (prices of Lebanese medicines, healthcare costs in Lebanon, etc.,)

Once the literature review was completed, we summarized our findings for the projected costs and benefits that are expected to arise from the implementation of Article 47 and confirmed these assumptions with a working group of Pharmaceutical Industry Leaders in Lebanon. This was done to ensure we fully captured the dynamics of the Lebanese pharmaceutical industry in our analysis, ensuring that the assumptions we made were timely, credible and relevant to the Lebanese business environment.

c. Working Group

The Working Group included the following participants and members of the Lebanese Pharmaceutical Association:

- **Mr. Walid Nasser** - Nasser & Associates Law Office- Attorney at law
- **Linda Daou**- Eli Lilly - Corporate Affairs Director
- **Fady G. Khayat** – Janssen - Area General Manager



- **Hassan Bibi**

- Janssen - Regional Regulatory Affairs Director

- **Fady Koussa** - Sanofi Aventis - Near East Head of Regulatory Affairs

III. Lebanese Baseline Data

a. Lebanese Economy

Below is a summary of data associated with Lebanon’s economy, pharmaceutical industry and how they compare to that of Jordan, Turkey, and India. These countries were chosen for comparison because they represent comparable economic environments that have recently undergone DE regulatory reform. As part of the literature review, pre and post DE regulatory reform data was compiled from these countries and used to provide insight on what is likely to take place in Lebanon under similar circumstances.

Table 1: Lebanon Economy and Comparisons⁴

2010	Lebanon	Jordan	Turkey	India
GDP/Capita (current US\$)	9,904	4,666	10,498	1,489
GDP growth (annual %)	7.00	2.30	9.16	9.55
Private capital flows, total (% of GDP)	5.34	9.06	3.24	2.96
Foreign direct investment, net inflows (% of GDP)	10.97	6.44	1.24	1.43
R&D Spending (% of GDP)	N/A	.42	.85	.76

Of these countries, Lebanon’s economy is closest to that of Turkey with a GDP per capita of approximately \$9900 in 2010, significantly greater than those of Jordan and India at \$4700 and \$1500 respectively. GDP growth in Lebanon has also seen recent growth rates (7%) that have been on par with that of Turkey and India, both experiencing economic growth as a result of DE regulation. Among these countries, private capital flows, and foreign direct investment (FDI) in Lebanon represent large components relative to their GDP at approximately 11% and 5.3% respectively. This compares to an average for the other three of 3% and 5.1% respectively, signaling that Lebanon’s economy is already very sensitivity to capital flows, and could significantly benefit from increased investment and partnership opportunities.

⁴ World Bank Databank – Lebanon - <http://data.worldbank.org/country/lebanon>



b. Lebanese Pharmaceutical Industry

In 2012, in Lebanon there were 131 Drug Importers, 39 Drug Stores, and 2,490 Pharmacies in Lebanon with 6,059 drugs currently present in the Lebanese Market. Of these 6,059 drugs, 1,218 are of Lebanese origin and the rest (4,841) produced in the United Kingdom, France and Germany. From the 1,218 products originating in Lebanon, only 196 are sold with licenses from the innovative brand companies. The remaining 1,022 are classified as generic drugs.⁵

c. Lebanese Health Expenditures

Similar to India; in Lebanon, the majority share (60%) of health care spending is paid for by the Private sector. This means significant implications for long-term economic growth if health care costs could be reduced (Table 2).

Table 2: Lebanon Health Expenditures and comparison

2010	Lebanon	Jordan	Turkey	India
Health expenditure, total (% of GDP)	7.03	8.04	6.74	4.05
Health expenditure, public total health expenditure)	39.16	67.66	75.20	29.17
Health expenditure, private total health expenditure)	60.84	32.34	24.80	70.83
Health expenditure, total US\$)/ Capita	651	357	678	54

Health Expenditures in Lebanon are already much higher as a % of GDP than Turkey and India. Although Total Health Expenditure (THE) as a percentage of GDP has been decreasing steadily for the last 8 years, signifying that GDP growth has been outpacing the growth in THE, THE per capita has actually been increasing (Table 3).

Table 3: Lebanon Total Health Expenditures Historical Time Series

Years	2002	2003	2004	2005	2006	2007	2008	2009	2010
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⁵ Based on proprietary data provided by Working Group members on all pharmaceutical drugs sold in Lebanon.



Total health expenditure (THE) % Gross Domestic Product (GDP)	9	8	8	8	8	8	8	7	7
General government expenditure on health (GGHE) as % of THE	44	41	43	46	43	42	43	42	39
Private expenditure on health (PvtHE) as % of THE	56	59	57	54	57	58	57	58	61
Total expenditure on health / capita at exchange rate	427	420	453	434	446	510	556	617	651

IV. Literature Review

A new pharmaceutical discovery is not sufficient to bring a safe and effective product to the market, for use by patients. Rather, the public reaps the benefits of an innovative drug or vaccine only after relevant data, generated in extensive preclinical and clinical trials, demonstrate the drug’s safety, quality and efficacy to the satisfaction of regulatory authorities. The generation of this confidential registration data involves a substantial amount of time and expense for the originator. The full drug development process from discovery to marketing may take as long as fifteen years and the "fully capitalized cost to develop a new drug, including studies conducted after receiving regulatory approval, averages \$897 million"⁶ to originator pharmaceutical industries. Despite being a primary beneficiary of potential DE regulation, additional beneficiaries and cost bearers must be considered as part of any DE regulatory reform.

a. Health, Safety, and Regulatory Benefits from the Introduction of DE

Expected changes to life expectancy

In 2007, the National Academies Committee on Science, Engineering and Public Policy called for extending the data exclusivity term in Europe to a longer period from the current 10 to 11 years. The researchers estimated that extending the term of data exclusivity to 12 years would lead to an additional 228 drug approvals over the next 50 years and an increase of 1.7 months in average life expectancy, according to the study.⁷

Comparing the European Medicines Agency (EMA) drug approval rate (27 per year)⁸ to that of the Lebanese Health Agencies (23) we can apply the relative change to the Life expectancy in Lebanon. Conducting this comparison identifies that for every 1-1.5 year increase (currently at 0)

⁶ E. Bale, Jr., Director-General, IFPM, ENCOURAGEMENT OF NEW CLINICAL DRUG DEVELOPMENT: THE ROLE OF DE, 2000

⁷ <http://news.usc.edu/#!/article/27869/How-Do-Data-Exclusivity-Periods-Affect-Pharmaceutical-Innovation/>

⁸ http://www.f.u-tokyo.ac.jp/~utdpm/paper2/2010_newdrug1999-2007.pdf



in the DE period would result in a 1.4 month increase in the average life expectancy for Lebanon.⁹

Consumer Safety from a contained production process

Other than providing incentives for innovation, by requiring generic companies to provide their own studies and manufacturing methods, DE plays a role in ensuring bioequivalence and safety in the production of Biosimilar (Biologics) drugs, promoting safe production and consumption by Lebanese consumers.

The production of Biologics is a complex process where reverse engineered generics might not have the same effects on the human body as the original ones. Unlike the straightforward industrial chemistry techniques used to make small-molecule drugs, the methods of producing and isolating ‘biologics’¹⁰ can be complex and fickle. “The process is the product” was the mantra of the biopharmaceutical world. Even those who developed drugs in the first place were loath to play around with their methods. “We were deathly afraid of changing anything because we couldn’t tell where it would lead”¹¹ said Craig Wheeler, President of Chiron BioPharmaceuticals.

Therefore, safety regulators, by not requiring generic manufacturers to provide their own manufacturing methods while registering a new drug, might be taking a risk because generic manufacturers may not realize that they are not producing the same drug as the original and this could create safety issues for consumers.

An example of the complexities associated with biologics was shown in 1998, when European Regulators asked Johnson & Johnson to remove human serum albumin, which was purified from human blood at the time, from its brand of EPO called Eprex. Serum albumin was present in the drug to stabilize the protein during storage and regulators wanted to eliminate the risk that Eprex might spread infectious agents. In response, J&J replaced it with polysorbate 80, a detergent and emulsifier commonly used to keep proteins in solution. This substitution had tragic results: users of Eprex started experiencing bizarre side effects with at least 200 cases in which the immune system branded Eprex as a foreign invader and started producing antibodies to neutralize the drug. The antibodies not only rendered the therapy useless but also attacked the endogenous protein erythropoietin causing a life-threatening anemia.³

Improvements in the Regulatory Process by Lebanese Health Authorities (HAs)

If DE regulations are applied in Lebanon, many multinational pharmaceutical companies are expected to introduce their products in Lebanon, and in order to do so they are likely to choose a

⁹ <http://news.usc.edu/#!/article/27869/How-Do-Data-Exclusivity-Periods-Affect-Pharmaceutical-Innovation/>

¹⁰ Complex drugs, vaccines or antitoxins made by or from living cells

¹¹ Heidi Ledford, THE SAME BUT DIFFERENT, NATURE|Vol 449|20 September 2007



domestic partner for the importation, production or sale of their product. When these multinationals decide which local company to partner with, the choice will be the one with the most existing potential to produce at internationally required quality standards.

To explain this phenomenon we pulled from a report by the World Health Organization highlighting examples of technology companies looking to produce their products in international economies. “Technology holders often select transferees based in part on their existing or potential capacity to produce at international quality standards. Furthermore, training in Good Manufacturing Practice (GMP) and producing the documentation required to meet regulatory standards is often a core part of local production initiatives. In addition, one interviewee commented that effective enforcement by national regulatory authorities was essential to providing local producers with the incentive to comply with higher quality standards; in the absence of fair, effective regulation, a firm adhering to costly quality standards would be at a competitive disadvantage.”¹²

Furthermore, according to members of the working group, incentivizing the introduction and participation of multinational pharmaceutical firms and their advanced safety quality assurance processes, would allow the Lebanese Ministry of Health to expand and improve its own regulatory processes based on the requirements imposed on these multinational firms in western countries. For example, when DE regulations are applied in Lebanon, multinational pharmaceuticals looking to register new drugs with the HAs will be submitting testing documentation that will identify their own Qualitative Assurance processes that they undergo. These standards will likely be much higher than the standards and requirements currently being imposed by Lebanese HA’s. As a result, HA’s may actually improve their requirements to be more in line with international standards. Such a process would impose stricter guidelines and QA requirements on domestic manufacturers and promote overall consumer safety.

Increased Access to New Medicines

A study on Turkey’s DE regulatory reform highlighted that the implementation of DE would likely result in a higher number of new molecules coming to Turkey, providing patients with better access to innovative products, improved medication and overall reductions in healthcare expenditures.¹³

b. Changes in Health Care Costs

¹² WHO, Pharmaceutical Production and Related Technology Transfers, 2011.

¹³ Monitor Group, Developing a Common Understanding of the Impact of DE on Pharmaceutical Industry and Health Care Economics in Turkey, June 2003



While DE regulations seem to imply a tradeoff between innovation and the high cost of healthcare, the numbers do not confirm this inference. A primary concern for Governments weighing the impacts of stricter DE regulation may be the high cost of healthcare associated with stricter DE in the sense that residents of Lebanon would have to pay a higher price for brand name medicines rather than generic ones. In the example of Turkey, with the introduction of DE, over a six-year period, health care costs were estimated to increase between \$600 million and \$1.2 billion. However, this remains a small proportion (2–5%) of total expenditures on pharmaceuticals over the same period.⁵

Furthermore, according to the United Nations, Office on Drugs and Crime “The buying of fraudulent pharmaceuticals can obscure the long-term risks: there are numerous examples of disability and death caused by tainted medication, and such pharmaceuticals contribute to the growth of drug resistant diseases.”¹⁴

In fact, the following table summarizes the results of a study conducted on the risks and costs of multiple-generic substitution of Topiramate.¹⁵ Those numbers represent before and after DE implementation costs. Before DE costs are represented by the generic column and after DE costs are represented by the brand use column, indicating the use of generic drugs actually resulted in higher overall healthcare costs (approximately 30% higher) versus the brand name drugs that were used after DE regulation.

Table 4: Pharmaceutical Costs - Brand Name vs. Generic

Healthcare Indicators	Brand Use	Generic
Hospitalization rates visits per p/y	0.48	0.83
Mean Hospital Stays days per p/y	3.88	2.55
Risk of hospitalization following generic-to-generic substitution	-	2 times higher

¹⁴ <http://www.unodc.org/toe/en/crimes/counterfeit-goods.html>

¹⁵ M. S. Duh, P. E. Paradis, D. Latrémouille-Viau, P. E. Greenberg, S. P. Lee, M. B. Durkin, G. J. Wan, M.F.T. Rupnow and J. LeLorier, The risks and costs of multiple-generic substitution of Topiramate, American Academy of Neurology, 2009.



observed medical services costs and total health care costs of topiramate therapy in \$	677	719
Observed medical services costs and total health care costs of topiramate therapy in \$		21% higher total health care costs
Total \$ health care costs of topiramate	1,418	1,716

According to a study by Jeremy Wilson of the University of Michigan, “the greatest toll that counterfeit pharmaceuticals take is on public health”. “Of the one million malaria deaths that occur worldwide each year, 20% or 200,000 are the result of counterfeit anti-malarial drugs”¹⁶

According to the National Library of Medicine under the National institutes of Health the range for the percentage of counterfeit drugs on the market can represent <10% (developed countries) and >30% (developing countries) of the total pharmaceutical sold in the world.¹⁷

The World Health Organization also highlights that although the actual impact on the use of counterfeit drugs is high; counterfeiting is greatest in those regions where the regulatory and legal oversight is weakest, such as Lebanon.¹⁸

c. Increases in Pharmaceutical Production

A recent study conducted by the Monitor Group in 2003, identified that the implementation of DE in Turkey would result in an annual revenue loss of approximately \$11 million for Turkish generic companies, and a \$17 million revenue gain for original companies (annualized sales, ex-factory prices, using 2002 sales figures). These figures represent less than 1% of original or generics overall revenues thus making the impact on health care costs likewise insignificant.⁵

It should be noted however, that the implementation of DE may change the dynamics of the market in the long run, by removing generic competition that would otherwise have been present for specific original products, or through original companies choosing to launch more products in Turkey now that they will benefit from the protection of DE. Looking at the sixth year after the application of DE the overall impact on pharmaceutical healthcare costs could range between \$200 and \$500 million depending on the scenario, with these figures representing between 4%

¹⁶ Wilson, Jeremy, M. *The Health and Economic Effects of Counterfeit Pharmaceuticals in Africa*, March 2011. <http://a-cappp.msu.edu/sites/default/files/files/AFRICABACKGROUNDERfinal.pdf>

¹⁷ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2845817/>

¹⁸ <http://www.who.int/impact/FinalBrochureWHA2008a.pdf>,



and 10% of overall expenditure on pharmaceutical products in 2009. This ignores the potential benefits of the availability of new medications which would otherwise not have been launched in Turkey.⁵

The value shift (or future opportunity shift) from generics to originals in 2009 also falls into a wide range. The opportunity loss to generics could range between \$100 and \$270 million (on an ex-factory price basis) in 2009, which might represent between 5% and 18% of generic revenue in that year, depending on whether and how the generic sector has grown. The opportunity gain to original manufacturers could range between \$270M and \$600M, or between 8% and 22% of originals revenue in that year, depending on how the original manufacturing companies revenues has grown.

d. Changes in Research and Development (R&D), Foreign Direct Investment (FDI), and Innovation

Expected benefits of DE also relate to the additional incentives offered to innovators in the long and expensive process of pharmaceutical R&D. Additionally, experts argue that DE offers benefits to domestic innovators in developing countries, as it provides incentives for research to identify new uses for existing unpatented products and for originator companies to introduce products in those markets, because exclusivity would protect the companies from generic competition.¹⁹

Confirming this assumption, for India, Linton and Corrado identified that “FDI inflows increased by 463 percent over 2003 levels, due in large part to anticipation of the “advent of the product patent era.” However, ongoing uncertainty, perhaps attributable to perceived inadequacies in India’s law in the areas of data protection, the standards for patentability, and compulsory licensing, appears to have tamped down FDI in 2005 and 2006.”²⁰ By 2007, Indian domestic manufacturers began undertaking serious drug discovery contract research, with the top 10 firms spending as much as \$170 million on R&D related activities. India represented the highest number of US Food and Drug Administration (FDA) approved active pharmaceutical ingredient (API) and formulation plants outside the US, with 85. In the past many of India’s chemists ended up abroad; 15% of scientists working in the American pharmaceutical industry were of Indian origin. In 2005, after implementing DE regulation, evidence had shown that they were slowly being lured back to India.²¹

¹⁹ Heidi Ledford, *THE SAME BUT DIFFERENT*, *NATURE*/Vol 449/20 September 2007

²⁰ Linton, Katherine, C. and Nicholas Corrado, *A “Calibrated Approach”: Pharmaceutical FDI and the Evolution of Indian Patent Law*, August 2007, http://www.usitc.gov/publications/332/journals/pharm_fdi_indian_patent_law.pdf

²¹ The Economist, A survey of pharmaceuticals, June 18 2005.



For Turkey, it was expected that the full implementation of intellectual property rights in pharmaceutical industry would result in increased Foreign Direct Investment (FDI). Innovators have argued that the lack of DE was the single biggest reason for their reluctance to invest in Turkey. In general, the global companies view economies which adhere to the intellectual property protection in a more positive way.⁷

Jordan also strengthened its IP system as a result of joining WTO as the 136th Member in 2000 and signing an FTA with the US in 2001. “Contrary to conventional wisdom, globalization has benefited Jordan. The results include increased economic growth generally, and in particular, benefits for Jordan’s pharmaceutical and bio-medical technology industries. New health sectors, including contract clinical research, have spurred a new focus on research-based innovation for Jordanian pharmaceutical companies, there is a growing multinational presence, medical tourism has taken on new importance, and the number of clinical trials has multiplied. This in turn has fueled job growth and launched Jordan as the leading knowledge economy in the Middle East”.²² Since the implementation of in-house R&D conducted by the local pharmaceutical industry is of a modest nature and scale, most of the local firms established and still maintain R&D units. The local firms have been successful under DE regulatory reform because these units undertake research in three areas, namely, formulation and stability studies, bio-equivalence studies, and, in a later stage, process development. They developed their capacities in these areas in order to reverse-engineer and thus understand advanced technology developed elsewhere in the world, diversify their products portfolio, and to develop alternative manufacturing processes to produce new drugs without infringing on those of patentees.

Moreover, Fink argues that for developing countries (like Jordan or India), stronger intellectual property rights bring about benefits in terms of increased trade, FDI and technology transfer. However, these benefits mainly accrue to middle income countries (like Lebanon) and the size of the benefits depends on complementary policy reforms, notably improvements in other aspects of the investment climate.²³ Confirming this assumption, Lebanon has a better transportation infrastructure with a higher percentage of paved roads, a better telecommunications infrastructure with 5.07 out of 100 people being fixed broadband Internet subscribers versus 1.03 for India. Lebanon also has a better rated educational system than India with 24% of the Lebanese Labor Force achieving a tertiary education level, a number similar to that of Australia, France, Germany, Greece and Singapore.²⁴

e. Domestic Pharmaceutical Production post DE

²² Felix Rozanski, *Developing Countries and Pharmaceutical Intellectual Property Rights: Myths and Reality*, Stockholm Network, 2007

²³ Fink, Carsten, *Intellectual Property and the WTO*, November 2004;

²⁴ World Bank Databank – Lebanon - <http://data.worldbank.org/country/lebanon>



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The Indian pharmaceutical industry has shown steady growth during the last three decades and has emerged as one of the leading global players in generics. India is one of the major drug producing countries in the world (the fourth largest producer by volume and the thirteen largest by value) holding approximately a 20-22% share in global generic production.¹⁴

The Indian pharmaceutical industry that worked on the basis of reverse engineering and process innovation achieved self-sufficiency in technology, and has been strengthening export orientation in the tide of economic liberalization since the early 1980s. The industry started to show good promise of global competitiveness, and today continues to expand its presence worldwide. As a result the trade surplus of the pharmaceutical products has been increasing since 1987. In the late 1990s, India achieved favorable pharmaceutical trade balance all over the world. The industry has emerged as the seventeenth largest drug exporters in the world and with exports representing approximately 40% of total production.

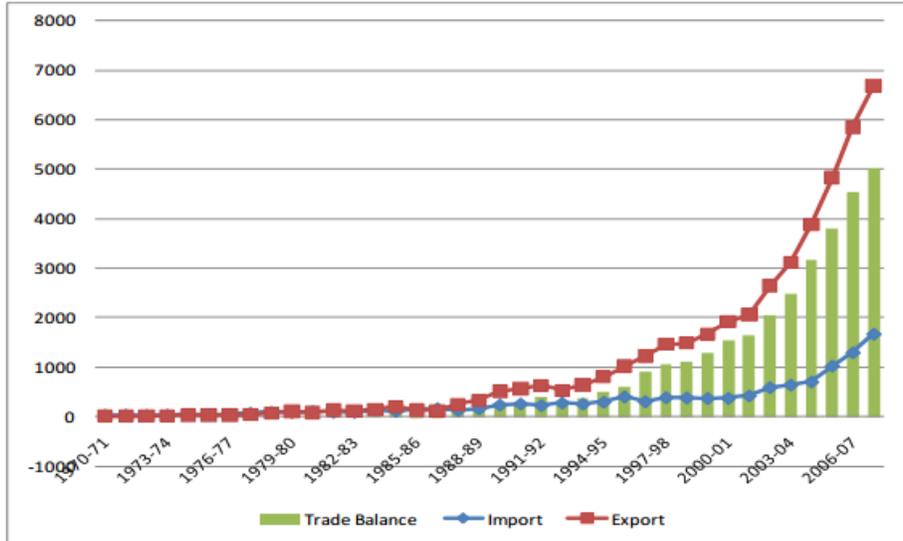
Nevertheless, the introduction of pharmaceutical product patent was supposed to have negative overall impacts on the domestic pharmaceutical industry. Under the assumption that the industry could no longer manufacture by reverse engineering and exporting generic drugs, the introduction of pharmaceutical patent was expected to hamper the growth of the Indian pharmaceutical industry²⁵.

Contrary to expectations, after the introduction of DE, the Indian pharmaceutical industry was successfully able to shift its activities from reverse engineering to innovation and emerge unexpectedly as a leader with the trade balance increasing exponentially since the application of DE at a rate of 60% per year. The domestic and export markets have been growing steadily. While the industry has been growing at annual growth rate of 10%, exports have increased by an annual rate of approximately 20%. Growth is largely driven by R&D expenditures in the domestic pharmaceutical sector that has increased by approximately 40% annually between 2001 and 2006²⁶. The following graphs summarize the state of the Indian economy historically, leading up to, and after DE regulations were implemented in 2005.

Figure 1: Exports and Imports of Pharmaceutical Products in India

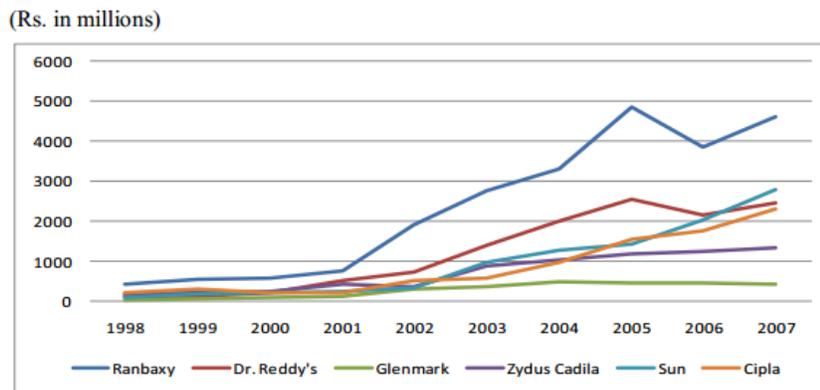
²⁵ Atsuko Kamiike and Takahiro Sato, *The TRIPs agreement and the pharmaceutical industry: The Indian Experience*, 31 August 2011

²⁶ Atsuko Kamiike and Takahiro Sato, *The TRIPs agreement and the pharmaceutical industry: The Indian Experience*, 31 August 2011



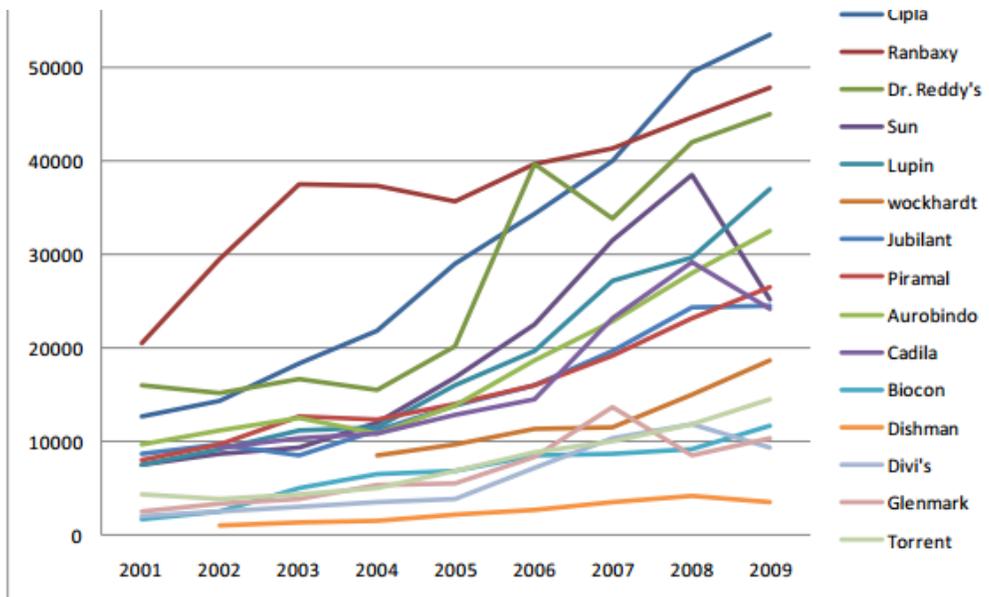
Source: RBI (2009), Pharmexcil (2009), Department of Pharmaceuticals (2010).

Figure 2: R&D Expenditures at Leading Indian Pharmaceutical Companies



Source: Company's Annual Report, various years, Cygnus Business Consulting &

Figure 3: Sales for Leading Indian Pharmaceutical Companies



Source: Company's Annual Reports, various years.



f. Outsourcing Opportunities for Domestic Firms

While many blockbuster drugs will generate more than \$1 US billion in revenue each year, as the DE and patent life of drugs is reduced; increasing R&D costs have made it difficult for multinational pharmaceutical companies specializing on the whole pharmaceutical supply chain to generate profits. “The global industry saw 24 new drugs approved by the US Food and Drug Administration in 1998 with \$27 billion R&D investment. In 2006, only 13 new drugs were approved, but investments in R&D rose to \$64 billion. As a result the business model of a vertically integrated approach to developing, manufacturing and selling drugs has changed in favor of outsourcing. This new model favors developing countries that are able to attract investments i.e. those with strong IP systems.”²⁷ Since the application of DE, India has specifically benefited from such outsourcing business opportunities.

In the past, foreign pharmaceutical companies were hesitant to manufacture new drugs in India because of the Patent Act of 1970, which did not recognize product patents on pharmaceutical products. The implementation of stricter DE regulation in 2005 removed any incentive for Indian companies to leverage data attained from contractors (foreign companies) for the production of illegal copycat drugs. As a result, this amendment also lowered the risk of outsourcing to Indian companies who have been eager to outsource the labor intensive portions of the new drug manufacturing process to India.

India has distinct advantages as an outsourcing destination. These advantages include excellent development and manufacturing skills, low R&D cost, low manufacturing cost (manufacturing cost in India is 40-50 per cent lower as compared to western countries), a large number of trained chemists and biologist, over 80 USFDA approved plants, abundant English speaking skilled manpower, large patient population providing a diverse pool for clinical trials for NCEs, and IT industry”²⁸ If we compare some key indicators between Lebanon and India mainly the levels of

²⁷ Felix Rozanski, *Developing Countries and Pharmaceutical Intellectual Property Rights: Myths and Reality*, Stockholm Network, 2007

²⁸ *Atsuko Kamiike and Takahiro Sato, The TRIPs agreement and the pharmaceutical industry: The Indian Experience, 31 August 2011*



education and infrastructure, we can assume similar if not greater potential for increases in R&D related activities and investment in Lebanon.²⁹

g. Negative Impact on Local Manufacturing of Active Pharmaceutical Ingredients:

Not all of the examples outlined positive impacts on Local Manufacturing activity. In the case of turkey, prior to the implementation of DE regulation there were twelve local companies in Turkey with manufacturing facilities, producing around fifty different active pharmaceutical ingredients. Although the total amount of production has been in decline for the past decade, exports were steadily increasing. As many of these manufacturing facilities rely heavily on the domestic market, the implementation of DE and subsequent withdrawal of a number of copycat generic drugs from the market forced closure of these facilities. However, given that the immediate impact of DE is likely to be low, the direct impact on local manufacturing was also correspondingly small.”⁶ Similar assumptions can be made for Lebanon where the copycat manufacturing industry represents approximately 10% of total pharmaceutical production³⁰. Although these companies will likely have to modify their operations or go out of business, they are not projected to have a large impact on overall pharmaceutical production in Lebanon.

h. Potential Increased Dependence on Imports

The Turkish example also highlights that a transition to DE, if not properly managed, could lead to increased dependence on imports, a drop in local demand and in turn the cost competitiveness of locally produced active ingredients. Such a result in Lebanon could reduce the possibility of Lebanon developing in new areas such as bio generics after the implementation of stricter DE regulation.⁶

V. Identification of Affected Stakeholders

Article 47 addresses issues of DE in the pharmaceutical industry which requires the Lebanese government to protect the information provided by pharmaceutical companies for a certain number of years from other companies trying to use this information to replicate the products of an innovating company.

a. Intended Stakeholders

²⁹ See section on “Changes in Research and Development (R&D), Foreign Direct Investment (FDI), and Innovation”, page 14.

³⁰ Estimates of the size of the Lebanese Copy-Cat Pharmaceutical industry relative to the all pharmaceutical production in Lebanon was provided by Working Group participants based on their internal proprietary data.



As one would expect the intended stakeholders are the innovating pharmaceutical companies, Brand Pharmaceutical Importers and Distributors, generic pharmaceutical companies, generic exporters, Innovating Lebanese Pharmaceutical Companies, and the Lebanese public (through increased access to new drugs and costs savings)).

b. Unintended Stakeholders:

The Unintended Stakeholders are importers and exporters benefiting from increases in trade through trade agreements that might arise from adopting stricter DE Regulation, the Lebanese Government and Public through increases in FDI and its implications to regional output and employment. Government is also an unintended stakeholder because of the costs they will have to incur as they work to implement a new interpretation of article 47.

HAs are unintended stakeholders because they will be able to improve on their own regulatory process of domestic manufacturers thus promoting more safety and stability in this sector.

Domestic Manufacturers may develop partnerships with multinational firms to develop legal generics in country that some of these larger companies are already selling in other parts of the world, but producing themselves.

VI. Quantification of Impact

In order to quantify the impact associated with stricter DE regulation, the working group researched literature on similar economies that have recently undergone DE regulations, and made conservative assumptions about their applications to the country of Lebanon. All assumptions, calculations and impacts for each of the projected changes associated with the implementation of stricter DE regulation are included below.

a. Cost Bearers

i. Direct Cost Bearers

Lebanese Copy-Cat Producers:

The main cost bearers are the Lebanese generic pharmaceutical companies, who will lose their right to use the data submitted by the innovating companies to produce generic products prior to expiration of the manufacturing patent. This will significantly impact their operations, since these companies' general business plan is to produce drugs with the exact composition as those produced by the innovating companies. They do so by getting the information they need from



the Lebanese Government since the government doesn't offer protection to the data presented by those innovating companies during the registration process of new drugs.

If copycat generic manufacturing do not modify their operations, they are expected to go out of business under the implementation of the new interpretation of article 47. Currently it is estimated that 10% of drug producers in Lebanon are copycat producers, indicating that once the new interpretation of article 47 is implemented, the domestic pharmaceutical industry is expected to realize average losses of approximately \$80 million / year in revenue over the first 5 years (10% of the Lebanese pharmaceutical revenues)³¹ after the implementation of DE regulation.

Under a stricter regulatory environment they have the option to refocus their operations in the short term towards producing legal generic drugs, or working to develop partnerships with multinational manufacturers, where the multinational firms would outsource a large chunk of the production process to Lebanese firms, thus reducing the cost of labor and transportation within their supply chains. This trend was noted earlier in India. Lebanon, like India, could also benefit from outsourcing opportunities by leveraging its lower manufacturing costs and labor costs, the high number of trained scientists and a Trilingual skilled manpower.³²

Generic Drug Importers and Exporters:

With stricter DE regulation prohibiting the manufacturing of generic drugs, the Lebanese Importers and Exporters of generic pharmaceutical products are affected indirectly as cost bearers as well

As discussed earlier, Article 47 affects generic drug companies significantly and forces them to either change their business activities or go out of business. If those companies go out of business, exporters of generic drugs would also be negatively impacted.

Based on our assumption that copy cats represent approximately 10% of the Lebanese pharmaceutical industry, it is fair to assume that they also represent 10% of current drug exports totaling approximately \$202 million. The projected annual revenue reduction associated with copycat exports is thus estimated at \$20.2 million for the first year and growing at an annual rate of 5%, proportional to the growth of the Lebanese pharmaceutical industry.

ii. Indirect Cost Bearers:

³¹ Estimates of the size of the Lebanese Copy-Cat Pharmaceutical industry relative to the all pharmaceutical production in Lebanon was provided by Working Group participants based on their internal proprietary data.

³² World Bank Databank – Lebanon - <http://data.worldbank.org/country/lebanon>



cost bearer is the Lebanese Government.

The Lebanese Government:

The Lebanese government will have to incur additional costs to ensure proper compliance with article 47. These include inspection costs to ensure that pharmaceutical data is properly protected for an appropriate protection period through both the health and court related authorities. Furthermore, some additional costs will have to be incurred to ensure that all drug manufacturing labs stop manufacturing generic drugs for products still under data protection. These procedures should cover the 6,059 drugs currently sold on the Lebanese Market.

With little to no government data currently available on government expenditures associated with the regulation of pharmaceutical products in Lebanon, conservative assumptions were made about the potential increase in government oversight required for the successful implementation of stricter DE regulation. In order to quantify this effect we assumed that the government budget associated with the oversight and regulation of pharmaceutical products will have to be proportionately equal as a percentage of the total government budget to that of the Food and Drug Administration in the United States. Of the 2012 annual budget of approximately \$3.8 trillion, the US Food and Drug Administration budget for oversight of human drugs, biologics and animal drugs will represent approximately 0.03%³³ or \$1 billion.

Applying the 0.03% multiplier to the estimated 2012 Lebanese Budget of approximately \$12 Billion³⁴, we could expect the Health Administration budget to be approximately \$3.6 million \$FY 2012. Assuming a growth rate in the budget that is proportional to the 7% growth rate in GDP, this increase in the overall budget over the next 5 years would be approximately \$20 million. Given that Lebanon is not currently overseeing the patent review process, it is assumed that whatever budget Lebanon will need to incur is an increase above what they are currently spending on pharmaceutical regulation.

b. Beneficiaries

iii. Direct Beneficiaries:

The direct beneficiaries are the innovative pharmaceutical companies; local Lebanese companies that partner with multinationals, and the Lebanese public.

³³ Based on the FDA FY 2012 Presidents Budget Request. \$1 billion for oversight of Human Drugs, Biologics, and Animal Drugs and Feed.

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM243370.pdf>

³⁴ World Bank Databank – Lebanon - <http://data.worldbank.org/country/lebanon>



The Lebanese Public

With the implementation of a new interpretation for article 47, the Lebanese public will reap the benefit of wider access to new pharmaceutical products. Innovating pharmaceutical companies insured by the fact that legislative action has been implemented in order to protect the proprietary data they provide in the registration process, are projected to issue a wider array of products increasing access to pharmaceutical products in Lebanon by an estimated average of 12% each year.

A new interpretation of Article 47 is also projected to results in long-term reductions in healthcare expenditures. Our literature review identified that generic drug use leads to higher healthcare costs and because generic drug users tend to switch between generic brands which proves to be, as this study shows, quite dangerous with significant side effects (as mentioned in the costs savings associated with DE section).

In 2012, Lebanon's THE is estimated at approximately 7 percent of GDP (Table 3), or approximately \$3 billion³⁵. According to the Patient Protection and Affordable Care Act pharmaceuticals are expected to represent approximately 12.5 percent of total health care spending in the U.S.³⁶ Assuming a similar proportion for Lebanon we arrive at an annual rate of spending on Pharmaceuticals that is approximately \$375 million. Our research also identified that the percentage of pharmaceutical drugs in the developed and developing countries could range between 5 percent and 30 percent, highly dependent on the level of regulatory oversight. Although, Lebanon does not have DE regulation in place, nor the court system in place to punish abusers, we can conservative assume that approximately 17 percent of Pharmaceutical products in Lebanon could be considered generic/counterfeit. Multiplying the 17 percent * 12.5 percent we arrive at a total cost of THE associated with Generic/Pharmaceutical products of approximately 2.1 percent of THE.

Given that not every generic/counterfeit drug will cause harm to consumers, this 2.1 percent is used as a conservative estimate on the cost that generic/counterfeit drugs represent for THE. As a result, the reduction in THE associated with the implementation of a new interpretation of article 47 is estimated at approximately \$74 million per year for the initial five years.³⁷

Based on the share of costs subsidized by the Lebanese government as outlined in Table 2, 40% of these savings will be foregone by the government and 60% by the private sector. For the

³⁵ Assumes an Annual GDP in Lebanon of approximately \$42 B in 2012, World Bank Databank – Lebanon - <http://data.worldbank.org/country/lebanon>

³⁶ <http://hbswk.hbs.edu/item/6832.html>

³⁷ Projected to increase at a slower rate than GDP (Table 3), growth in THE is estimated at approximately 4.2% annually based on the relative increase in THE to GDP.



private sector this could mean a reduction in production costs for industries subsidizing the cost of health care, and an increase in disposable personal income.

International and Local Lebanese Companies

Article 47 provides an incentive for innovating companies to market and sell their products without the risk of competing against copycat manufacturers that do not have to price in the cost of research and development into their retail prices. This ensures a bigger market share and increases in revenues for the research related pharmaceutical industry.

Local Lebanese pharmaceutical companies stand to benefit substantially from article 47 as well. Interested in introducing their products to the Lebanese Market, multinational companies will look for regional partners to outsource components of their operations that may be too costly or risky to invest in on their own. As seen in India, the Lebanese pharmaceutical industry is expected to grow by a conservative estimated average of 10 percent per year as a result of these outsourcing opportunities. Based on its current size of approximately \$680 million, with a new interpretation for article 47, the Lebanese pharmaceutical industry will increase by an average of approximately \$80 million per year for the initial five years after the new interpretation is implemented.

A new interpretation of Article 47 is projected to increase FDI for the pharmaceutical industry in Lebanon on average by an estimated 300 percent per year³⁸. Assuming that THE represents approximately seven percent of GDP and the current level of FDI across all industries in Lebanon is approximately \$3.8 Billion³⁹, we conservatively assumed that FDI associated with healthcare spending in Lebanon is approximately \$266 million and with pharmaceuticals is approximately \$33 million (Pharmaceuticals represent 12.5 percent of THE⁴⁰). Assuming that FDI increases by approximately 300 percent we can conservatively estimate the increase in FDI associated with the implementation of stricter DE regulation at approximately \$74 million per year for the initial five years after the new interpretation is implemented.

Assuming conservatively that Lebanon will fare as well India under DE regulatory reform, the local pharmaceutical industry is also projected to increase R&D expenditures by approximately 40% per year. Based on estimates of R&D spending within similar economies to that of Lebanon, the current estimate for annual R&D expenditures in Lebanon is approximately \$35 million (Table 1)⁴¹. With the implementation of new interpretation for Article 47, R&D

³⁸ http://www.usitc.gov/publications/332/journals/pharm_fdi_indian_patent_law.pdf

³⁹ World Bank Databank – Lebanon - <http://data.worldbank.org/country/lebanon>

⁴⁰ <http://hbswk.hbs.edu/item/6832.html>

⁴¹ R&D expenditures were calculated by taking the average for Turkey, Jordan, India as a percentage of GDP. A pharmaceutical R&D spending was assumed to represent roughly 12.5% of the total R&D spending in Lebanon,



expenditures in the domestic pharmaceutical sector are projected to increase by approximately \$19 million on average annually for the first five years.

iv. Indirect Beneficiaries:

Licensed Dealers of innovative pharmaceutical companies

Indirect beneficiaries are licensed dealers of innovative pharmaceutical companies who will benefit from large brand name companies introducing their products on the Lebanese Markets. Once those products are introduced, dealers will have the opportunity to sell a new host of products, increasing their profits. The dealers can benefit in two ways: either they partner with the multinationals and take part in the manufacturing process and benefit from technology transfers and the surge of R&D investment in the pharmaceutical industry (approximately 40 percent per year on average); and/or these dealers will benefit from increased imports and exports in the Lebanese pharmaceutical industry which is estimated to grow at an annual rate of 20 percent under a new interpretation of Article 47.

The extent to which these dealers benefit from stricter DE regulation is directly related to the degree with which innovative pharmaceutical companies are motivated by the incentives offered from article 47 and thus to the extent with which these companies introduce new products to the Lebanese market. Our research identified that after a country applies DE; its pharmaceutical industry is projected to grow at an average annual rate of 10 percent, indicative of the interest for partnership from innovative multinationals.

The Lebanese Government

The Lebanese government can expect to benefit from the positive global image it will secure through the implementation of DE. In general, global companies view economies that adhere to intellectual property protection more positively⁴².

A new interpretation of Article 47 is also projected to result in long-term reductions in healthcare expenditures.⁴³ The reduction in THE associated with the implementation of a new interpretation of article 47 is estimated at approximately \$74 million per year for the initial five years DE regulatory implementation.⁴⁴ Based on the share of costs subsidized by the Lebanese government

based on the percentage of total expenditures on healthcare that was associated strictly with the pharmaceutical sector.

⁴² Monitor Group, Developing a Common Understanding of the Impact of DE on Pharmaceutical Industry and Health Care Economics in Turkey, June 2003

⁴³ See section on “The Lebanese Public”, pg. 22.

⁴⁴ Projected to increase at a slower rate than GDP (Table 3), growth in THE is estimated at approximately 4.2% annually based on the relative increase in THE to GDP.



as outlined in Table 2, 40 percent of these savings will be foregone by the government and 60% by the private sector. For the government this could mean a significant reduction in projected annual deficits and long-term debt currently estimated at approximately 134% of GDP⁴⁵.

Resulting from increases in pharmaceutical production⁴⁶, the Lebanese Government is also expected to realize increases in tax revenue. Assuming a corporate tax rate of approximately 15%, and a conservative 15% profit on revenues for Lebanese pharmaceutical companies, this translates to tax revenue increases of approximately \$3 million on average annually over the first five years after the implementation of a new interpretation for Article 47.

Exporters and Importers

An environment that values the protection of data will boost Lebanon's stature in international trade, increasing exports by an average of 20%⁴⁷. This is driven by increases in original and generic pharmaceutical production, and overall industrial output associated with increases domestic FDI and R&D spending. The beneficiaries of such increases would be the Lebanese importers and exporters who profit from increases in trade throughput.

Health Authorities

Health Authorities are projected to benefit from an improvement in their oversight processes associated with public safety and health in the pharmaceutical sector. Under stricter guidelines for DE, multinational pharmaceutical companies are projected to increase their operations in Lebanon, also increasing the availability of new products and with that demand for regulatory oversight. Having to undergo similar regulatory requirements in Lebanon, pharmaceutical manufacturers approach the safety and effectiveness of their products with a sophisticated approach to QA that is not inherent within the domestic Lebanese pharmaceutical operations currently. Presenting the same level of data as required by international regulators from the US, EU, etc. will identify potential changes to HA's current processes for ensuring the safety and security of their public. By modifying their own requirements to align with international standards, HAs will also incentivize domestic producers to increase their own safety and QA requirements for distribution.

Besides aligning them with international standards, while making it easier for generic manufacturers to now sell their products in international markets, this will open opportunities for domestic manufacturers to partner with international companies looking to outsource portions of their operations to domestic firms. When these multinationals decide which local companies to

⁴⁵ World Bank Databank – Lebanon - <http://data.worldbank.org/country/lebanon>

⁴⁶ See section on “International and Lebanese companies”, pg. 25

⁴⁷ Atsuko Kamiike and Takahiro Sato, *The TRIPs agreement and the pharmaceutical industry: The Indian Experience*, 31 August 2011



partner with, they will choose those companies with the most existing potential to produce at international quality standards. As a result, the demand for domestic production capacities from multinationals will incentivize Lebanese companies to meet international quality standards and will motivate the Lebanese HAs to regulate the pharmaceutical industry with the objective of providing incentives for local producers to comply with international quality standards, a process that will ensure safer products will be offered on the Lebanese Market.

The quantitative impact of these benefits has already been accounted for through increases in FDI, R&D, and reductions in healthcare expenditures for consumers and the Lebanese government.

VII. Quantitative Summary of Costs and Benefits

The RIA identified that the benefits associated with implementing a new interpretation of Article 47 will outweigh the anticipated costs by a factor of approximately 2.8/1 (Table 5) over the initial five years. Based on similar examples of DE regulation recently implemented in India, Jordan, and Turkey, Lebanon is expected to see increases in pharmaceutical production, reductions in health care expenditures to both consumers and the government, and an enhanced business environment witnessed through increases in Foreign Direct Investment (FDI) and R&D expenditures for the pharmaceutical industries. The primary overall cost bearers of this regulation will be the manufacturers, importers, and exporters of illegally produced copycat drugs, which represent less than 10% of the pharmaceutical industry in Lebanon today. Any lost revenue by these companies is expected to be outweighed by increased investment and collaboration activities between legitimate domestic manufacturers, importers, exporters, and international manufacturers.

Table 5: Summary of Costs and Benefits

Anticipated Direct and Indirect Costs						
Cost Bearers	2012 \$M	Year 1	Year 2	Year 3	Year 4	Year 5
Lebanese Copy Cat Producers	Reduction in Annual Revenue	-\$72	-\$75	-\$79	-\$83	-\$87
Copy Cat Importers and Exporters	Reduction in Annual Revenue	-\$21	-\$22	-\$23	-\$25	-\$26
Health Authorities	Increases in Operations Costs	-\$4	-\$4	-\$4	-\$4	-\$4
Total Costs 2012 \$M		-\$97	-\$101	-\$107	-\$112	-\$117
Anticipated Direct and Indirect Benefits						
Beneficiaries	2012 \$M	Year 1	Year 2	Year 3	Year 4	Year 5



Lebanese Public	Cost Savings on Health Care Expenditures	\$40	\$43	\$46	\$49	\$52
Lebanese Government	Cost Savings on Health Care Expenditures	\$27	\$28	\$30	\$33	\$35
	Increases in Tax Revenues	\$3	\$3	\$3	\$3	\$3
International and Lebanese Pharmaceutical Companies	Increase Domestic Production	\$72	\$75	\$79	\$83	\$87
	Increases in Generic Drug Exports	\$42	\$45	\$47	\$49	\$52
	Increase in Pharmaceutical FDI	\$66	\$69	\$72	\$76	\$80
	R&D Increase	\$15	\$17	\$19	\$21	\$23
Total Benefits 2012 \$M		\$264	\$280	\$296	\$313	\$331
Benefit/Cost Ratio		2.7	2.8	2.8	2.8	2.8

VIII. Conclusion

A new interpretation of Article 47 is projected to show an overall benefit to the Lebanese economy. The RIA identified that the benefits associated with implementing a new interpretation of Article 47 will outweigh the anticipated costs by a factor of approximately 2.8/1 (Table 5) over the initial five years.

Beneficiaries:

- The analysis shows a projected financial benefit to domestic generic manufacturers and international innovative manufacturers. As seen from similar examples in India and Turkey, innovative manufacturers are also projected to appear in Lebanon’s domestic market resulting from projected increases in outsourcing partnerships between domestic and international manufacturers and increases in R&D related activities. The regulation is expected to enhance the business environment in Lebanon for these companies to invest, develop, market and sell their products without the risk of forfeiting their cost outlays over years of investment to copycat manufacturers. Although not witnessed in all example of DE regulatory reform (mainly Jordan), based on India and Turkey where DE regulation has been implemented, DE regulation is estimated to increase FDI for the Pharmaceutical sector by approximately 300% per year and R&D spending in the pharmaceutical industry by 67% per year.



- A change in this regulation is also expected to provide wider access to pharmaceutical products and improvements in public sector regulation of pharmaceutical manufacturers, importers, and retailers. This is expected to reduce health expenditures by 30% by increasing the availability and reducing the cost of drugs, minimizing the potential negative side effects of generic drug usage, and lowering the costs involved with their historically-noted side effects (higher hospitalization rate, longer hospital stays, etc.). Given the allocation of total healthcare expenditures, 60% of which is currently funded by the private sector, this change could result in wider-ranging economic benefits not accounted for in this analysis, resulting from reductions in the long-term debt, reductions in the cost of production for firms, and increases in personal disposable income for consumers.

Cost Bearers

The projected overall cost bearers will be the manufacturers, importers, and exporters of illegally traded copycat drugs that will likely be either converted into legitimate business operators or forced out of business due to improved regulation, but currently represent less than 10% of the Lebanese pharmaceutical industry. Any lost revenue by these companies is expected to be outweighed by increased investment and collaboration activities between legitimate domestic manufacturers, importers, exporters, and international manufacturers.

IX. Advocacy Recommendations

Based on the results of this analysis, the Working Group recommended that international pharmaceutical manufacturers develop a new engagement strategy with the Ministries of Economy and Health moving forward. This strategy should focus on engaging more closely with domestic generic and innovative pharmaceutical manufacturers currently operating in Lebanon. Based on similar examples from Turkey, Jordan, and India, the completed RIA can help shape the argument for these companies to support the revised interpretation of Article 47 as beneficial to their long-term financial growth.

Domestic manufacturers are regulated by these ministries and are more likely to be seen as reflecting the domestic private sectors interests versus those of the international community. Assuming successful engagement with domestic manufacturers, the most effective approach will be for these industries to directly engage with the Ministries of Economy and Health on their own behalf, reducing any predisposed bias about this regulation, and working to promote the results of this cost/benefit analysis within the necessary departments.