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Review Article

A REVIEW OF INFLUENCE OF THE GENERIC DRUG USER FEES ACT UPON THE EXPORT FROM THE INDIAN PHARMACEUTICAL INDUSTRY

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ABSTRACT

The review article evaluates the influence of the Generic Drug User Fee Act (GDUFA) on the Indian pharmaceutical industry. The GDUFA come into existence in Oct 2012. The GDUFA enables the US citizen to access safe, effective, and cost-effective generic drugs. Due to the GDUFA fees structure and other significant modifications, it is vital to understand its imprint on the various facets of Indian generic business. On the inception of the GDUFA, the Indian generic market has increased significantly in terms of both value and volume. It was observed that during the Post-GDUFA epoch, the pharmaceutical export was not influenced. The overall US Pharmaceuticals export contribution in the total revenue has illustrated an upward trend. Also, the % market share (value) of the domestic generic performers in the US generic marketplace indicates the positive growth. Bulk drug export shows a sliding trend, whereas the formulation export demonstrates in a growing manner. Hence, in summary, it can be concluded that the GDUFA has not squeezed the overall revenue growth of Indian Pharma business. The Indian pharmaceutical industry has played an enormous role to boost the Country's economy, moreover, it has also created the employment opportunities.

Keywords: GDUFA, USFDA, Generic drugs, Indian Pharmaceutical Industry, ANDA, DMF

INTRODUCTION

Overview of Indian Pharmaceutical Industry

Indian pharmaceutical industry is one of the largest industry and manufacturing hubs for the generic drugs. The various reasons such as the availability of the strong domestic manufacturing sector, labor abundance and low R&D expenditures are the contributing factors.

According to the PHARMEXCIL (Pharmaceuticals Export Promotion Council of India), pharmaceutical exports of India stood at 16.8 billion USD in 2016-17 and are anticipated to grow by 30% over in the next 3 years to reach 20 billion USD by the year 2020.

The numerous Indian companies are looking at the high-value products which are having limited competition in the market such as complex generic products. This move would assist in the future growth of the extremely competitive global pharmaceutical market.

Overview of the GDUFA

The GDUFA was implemented as agreed between the FDA and the pharmaceutical industry in the year 2012, it was further reauthorized w.e.f 1st Oct. 2017 and will be effective till September 2022. The GDUFA is based on an agreement negotiated by FDA and representatives from the Pharma industry to address an increasing number of regulatory issues[1].

The purpose of the GDUFA is to put Food and Drug Administration's generic drug program on a stable financial footing and to ensure timely access to high-quality, safe, and affordable generic drugs to the general public. This act allows the FDA to evaluate the user fees to fund critical and quantifiable development of the FDA's generic drugs program, bringing enhanced predictability, and relevance to the review process of the generic drug applications[2].

GDUFA and Indian Pharmaceutical Industry

The slower approval of ANDA has obstructed the several Pharmaceutical firm's performances. There has been a slowdown in the USFDA approval process of an ANDA which has squeezed the revenue growth from the US region for many Indian companies. Post-implementation of the GDUFA, the approval process of ANDA was still slower in its early two years. However, later the approval process has picked up and for some Indian companies, ANDA approvals have improved by over 50% between the periods Apr-Sept 2015. The cost of quality and the regulatory factors due to the GDUFA has increased in the various Pharmaceutical companies all over the world[3].

In view of Glessner[4] while the notable APIs portion in the market of the United States continues to arrive from Spain and Italy with sizable increases in the shares held by the industry of India. Nevertheless, the small firms who produce only the handful API will identify it as more complex to recoup the yearly facility fees than the huge firms who may spread price across the several products. Moreover, after the GDUFA implantation, the FDA inspection in India and China have doubled which is nearly 20 % of the total inspection which eventually resulted in a rise in the warning letters[5]. "Since the GDUFA, about 55 percent of the GMP (good manufacturing practices)-related warning letters were issued by the CDER division of the FDA to facilities in India/China. However, just one out of the total nine resolutions during the period was from India/China," wrote Deepak Malik, an analyst at Edelweiss Securities, in his current report[6].

Therefore, it is vital to understand the footprints of the GDUFA over the Indian Pharma industry in terms of export to the US and thereby to study the revenue growth, which is deliberated by covering the aspects discussed in the forthcoming sections.

AN ECONOMIC BEARING OF THE GDUFA ON THE INDIAN GENERIC PHARMACEUTICAL INDUSTRY

Export Rate and Revenues Post-Implementation of the GDUFA (API and Generic Drug Products)

The Pharmaceutical Industry of India has accomplished a considerable growth between the years 2008 to 2017. Table 1 indicates that the value of Pharmaceutical export in the year 2008 was 4.1 USD billion which amplified to 16.4 USD billion by the year 2017 with CAGR 16.65 %.

The Pre-GDUFA era is considered from 2008 to 2012 and the Post-GDUFA period from 2013 onwards, based on the GDUFA enactment. The CAGR for the Pre-GDUFA period is found 25.28% and after the GDUFA execution is recorded at CAGR 6.19%. Whereas, the % US export contribution in the total revenue in the Pre-GDUFA period has indicated % CAGR at -0.1 %, Post-GDUFA at 7.62% CAGR and for the entire period it is found at 3.36%.

In the year 2017, the export revenue was decline marginally to the US $16.4 bn from the previous year which was $16.89 bn. However, there was a gradual rise is seen by Pharma Industry of India in the export revenue for the year 2006 to 2017. Indian Pharma enterprises are benefited from the export prospects from both the regulated and the semi-regulated markets. The locally manufactured generic drugs contribute to around 20% of generic drug exports (in terms of volumes) in the entire globe[7]. The export to the US constitute more than 30% share in India's total export revenue in the year 2016-17, other contributors include; Europe with 19.7 percent,19.1 percent to Africa, and Asian countries contribute 18.8 percent of the total export revenue of India[8].

Table 1: India's pharmaceutical export in terms of value

Year	The total Pharmaceuticals Export from India in Billion USD	% US export contribution in the total revenue
Pre-GDUFA period		
FY 2008	4.1	24.5%
FY 2009	3.9	23.92%
FY 2010	5.1	21.67 %
FY 2011	6.1	22.92 %
FY 2012	10.1	24.6%
%CAGR*	**25.28 %**	**-0.1 %**
Post-GDUFA Period		
Year	**The total Pharmaceuticals Export from India Billion USD**	**% US export contribution in the total revenue**
FY 2013	12.9	24.6%
FY 2014	14.5	26.73 %
FY 2015	14.9	23%
FY 2016	16.89	32 %
FY 2017	16.4	33%
% CARG*	**6.19 %**	**7.62%**
For Entire Period*	**16.65 %**	**3.36%**

* Self Calculated

Source: Kulkarni 2015; IBEF 2017; Pharmexcil Annual Reports

It is evident from the previous results that the growth of Pharmaceutical Industry exports experienced an upward trend in the Post-GDUFA age. Overall the US export contribution to the aggregate revenues of Indian Pharma Industry does not present the significant fluctuations from the year 2008 to 2017. Hence it can be concluded that pharmaceutical export was not influenced by the GDUFA putting into practice.

Export Share of API and Formulation during the Pre- and Post-Implementation of the GDUFA

Table no 2 shows that between the years 2007-08 to 2011-12 API share was found greater as compared to the period between the years 2013 to 2017. Nonetheless, during the primary years of the GDUFA API export share was comparatively higher than the recent years of the GDUFA.

Table 2: Export share of API and formulation

Year	The total API export share in terms of the value	The total Formulation export share in terms of the value	Other Pharmaceuticals
Pre-GDUFA period			
2007-08	44%	55%	1%
2008-09	46.9%	52%	1.1%
2009-10	41 %	58%	1%
2010-11	37 %	62%	1%
2011-12	35.3 %	63.5 %	1.2%
Post-GDUFA period			
2012-13	34.8 %	64.0 %	1.2%
2013-14	24 %	74%	2.0%
2014-15	23 %	72.6%	3.0%
2015-16	21.22 %	74.87 %	3.91%
2016-17	20.19 %	75.42 %	4.39%

Source: Pharmexcil Annual Reports as on 31st March of each Year.

An aggregate API export share by worth before the GDUFA was found higher, which afterward declined after the GDUFA authorization it moreover sinks further in ascending orders of the GDUFA years. In summary, API export share declined during the Post-GDUFA period whereas formulation share has indicated skyward drift.

The Export of Pharmaceuticals to the US Market during the Pre- and Post-Implementation of the GDUFA

The Pharmaceuticals export scenario to the US is shown in table 3, in the Pre-GDUFA period from 2007-08 to 2011-12 the % CAGR was found 28.47 which was decreased to 10.63% during the year 2012-13 to 2016-17. For the entire period, the export value to the US market has grown at CAGR of 20.25% with the total revenue contribution at CAGR of 3.36%.

Nevertheless, after execution of the GDUFA the % US export contribution in the combined revenue has been grown at % CAGR 0.1 to 7.62. It shows that there was a gradual rise in the US export during the years 2007 to 2015 with minimal fluctuation in the US export share in the aggregate revenue. The US export share augmented further in the year 2016 and 2017.

Table 3: The export of pharmaceuticals to the US market

Year	Export revenue from the US, the value in (USD million)	% US export contribution to the total revenue
Pre-GDUFA period		
2007-08	1,061	24.5%
2008-09	1,562.95	23.92%
2009-10	1954.22	21.67%
2010-11	2,882.27	22.92%
2011-12	2,890	24.6%
CAGR*	**28.47%**	**-0.1%**
Post-GDUFA period		
2012-13	3,725	24.6%
2013-14	4,021	26.73%
2014-15	4,309.72	27.9%
2015-16	5,514	32%
2016-17	5,580	33%
%CAGR*	**10.63%**	**7.62%**
% CAGR entire period*	**20.25%**	**3.36%**

* Self-Calculated

Source: Pharmexcil Annual Reports

The % US export contribution in the total revenue has improved subsequent to the GDUFA commencement. The overall US Pharmaceuticals export contribution in the total revenue has also revealed an increasing trend after the GDUFA became operational.

The Market Share of Indian Pharma Firms in the US Generics Market before and after Implementation of the GDUFA

Indian firms are proficient in producing the variety of generic drugs which offer an excessive prospect for Indian firms. By way of, many drugs going off-patent in the US market in addition to other countries. The generic drug market will continue to rise in the next few years.

Table 4: Market share of Indian pharma firms in the US generics market

Year	% market share (value) of Indian players in the US generic market	The US generic market size (USD bn)
Pre-GDUFA period		
2005	1.92	49.4
2006	3.84	55.2
2007	5.94	59.2
2008	7.45	64.5
2009	7.43	67.4
2010	10.51	71.2
2011	11.3	85.5
2012	12.6	90.6
Post-GDUFA period		
2013	15.1	95.5
2014	18.1	106.3
2015	16.5	115.2
2016	16	116.1
2017	24	120

Source: IBEF 2008; Pharmexcil 2014; Dirnagl & Cocoli 2016; IBEF 2018 ; Kasera 2016

The % market share in terms of the value of the domestic establishments in the US generic market implies the upward trend. There was a steady growth of % market share in the US as assessed from the trend of the share valuations which compliments to the rise in the US generic market size. Whereby in the corresponding years of the GDUFA India's market share in the US generic market rose meaningfully. On the other hand, the US generic market had a steady growth over the years with miniature fluctuations in the trend line. This corresponds to the steady acceptance of the generic drugs in the United States. It may also be implicated that a rise in the US generic market is not solely responsible for the growth of Indian generic market share in the US. This is from the assessment that there is disregard between the rate of growth in the US market and Indian shares in the US Pharma Industry. Nevertheless, since the enactment of GDUFA the % market share (value) of the domestic generic performers in the US generic marketplace indicates the positive growth.

Bulk Drugs and Formulation Export by Indian Pharma Firms before and after the Implementation of the GDUFA

The bulk drugs export between the year 2007-08 to 2011-12 has grown at CAGR 1.19 % whereas for the formulations at 33.03% CAGR as depicted in Table 5.

Alternatively, during the Post-GDUFA stage, the export of bulk drugs have shown the negative trends i.e. -5.60 growth rate due to the constant drop in the prices after the patent expiration, a bigger competition from the Chinese market, and a burden of the GDUFA fees. Correspondingly, the formulation of export has displayed at CAGR of 5.08%.

The export to the US market collapsed for the first time in the year 2015-16 due to the patent cliff. Indian Pharma Industry is budding in terms of volumes but not in terms of worth extraordinarily. The formulation exports matured at around 17% CAGR in the year 2013-14 from 2009-10. This was due to the 22% growth in the exports to the regulated markets. The exports to other countries, which have grown up to 13% over the same duration, also reinforced the development of the combined exports[9].

The negative export trend was attributed to the import alert on the native organizations. The regulated markets exports were dominated by that of off-patent drugs with a sustained growth rate of 15% through the former 5 years up to 2013-14

Table 5: Bulk drugs and formulation export by Indian pharma firms

Year	Bulk drugs export in USD million	Formulation export in USD million
Pre-GDUFA		
2007-08	4,486	2,760
2008-09	4,800	4,100
2009-10	3,650	5,183
2010-11	3,972	6,612
2011-12	4,704	8,388
% CAGR*	**1.19%**	**33.03%**
Post-GDUFA		
2012-13	4,536	9,912
2013-14	3,900	10,800
2014-15	3,564.57	11,214.16
2015-16	3,585.05	12,645.51
2016-17	3,401	12,701
% CAGR*	**- 5.60**	**5.08%**

* self-calculated

Source: Appaji 2014, Pharmexcil AR 2015-16; IBEF 2014

Bulk drug export after the GDUFA introduction shows a sliding trend, whereas the formulation export demonstrates in a growing manner which indicates no noteworthy control of the GDUFA on the formulation export from India.

Indian Pharma Segment Revenues Trend before and after the Implementation of GDUFA

It is evident from table no 6 that the revenue growth for Indian Pharma companies were not taken fast pace after the foundation of the GDUFA which grew at CAGR of 4.83% between the years 2013 to 2017. Whereas before the introduction of GDUFA the revenue growth was fast paced with %CAGR of 23.36. Conversely, % CAGR for the revenue growth for the period, 2008 to 2017 was found at 13.2%.

The US generic trade has contributed to the growth and the revenue generation for the local generic enterprises through the former decade. Although, it realized a significant rise in the revenue from the US market over the latest few years. The erosion of generic prices is attributed to quicker an ANDA appreciation marching to the greater competitive force[8].

Table 6: Indian pharma segment revenues trend

Year	Revenue in USD billion
Pre-GDUFA Period	
2008	9.7
2009	11.2
2010	13.8
2011	20.95
2012	22.46
% CAGR*	**23.36**
Post-GDUFA Period	
2013	24.52
2014	28.53
2015	29.77
2016	27.57
2017 (Estimated)	29.61
% CAGR*	**4.83**
% CAGR* for the entire period	**13.2**

*self-calculated
Source: IBEF (2013, 2014, 2017)

The overall revenue growth experienced by the Indian Pharmaceutical Industry was gradual for the period 2008 to 2017. Even though the revenue growth not booked the fast pace after the GDUFA launch, it witnesses the rising growth. Hence, in summary, it can be concluded that the GDUFA has not squeezed the overall revenue growth of Indian Pharma business.

FUTURE PROSPECT OF INDIAN GENERICS DRUG MARKET

The future of Indian generics drug market globally looks promising at the present, the pharmaceutical industry in India is estimated to account for 3.1% – 3.6% of the worldwide pharmaceutical industry in terms of value and 10% in terms of volume. By 2025 it is expected to rise to 100 billion USD. Also, by the year 2020, the Indian market is expected to grow to 55 billion USD. Thus, emerging as the sixth leading pharmaceutical market worldwide by absolute size. Due to the increasing market size and scope of this sector is expected to generate 58,000 additional jobs by the year 2025[7].

DISCUSSION

In India, the effect of the GDUFA is very significant. The growth of Pharmaceutical Industry export experienced upward trends in the Post-GDUFA period except for the minor concavity in the year 2015 and 2017. The % US export contribution in the total revenue has enriched succeeding to the GDUFA commencement. The overall US export contribution of Pharmaceuticals in the combined revenue has found growing after the GDUFA became effective. After the inception of the GDUFA, the % market share of the domestic generic firms in the US generic marketplace designates the encouraging growth.

The bulk drug export has displayed growth the descending movement, whereas, the formulation export validates rise which specifies no

notable influence of the GDUFA on the formulation export from India. The overall revenue growth of Indian Pharma commerce was not pressed by the GDUFA.

CONCLUSION

From the concise analysis, it was found that API and generic drug export on the implementation of the GDUFA had ignited the export rate making India the largest producer of bulk drugs in the world. The market share of both APIs and generic drug globally has increased by 30% and 20% respectively and revenues had also increased by approx. 20% and 25% respectively. However, in 2012 there was a drop-in exports with the implementation of the GDUFA, but gradually there was exponential growth. Thus, with respect to the economic impact of GDUFA, it can be assessed that pre-GDUFA the generic drug market and its other components were very juvenile but the post-GDUFA era has provided an extended opportunity and positively impacted the Indian Pharmaceutical industry.

Strong portfolio with a presence in differentiated generic products like injectable segment, binary opportunities in biologics, inhalers, ophthalmic, transmucosal, topicals, intranasal, transdermal, etc. paves the way for the future growth. Government's streamlined policies for a single window clearance on the regulatory fronts, shared infrastructure through a cluster-based development approach like Pharma Parks, availability of API, creating availability of trained manpower, planned expenditure on R&D, etc. are some key steps to produce an impact within the country and stay ahead of the competition in the global Pharma market.

Therefore, it can be implicated that the GDUFA has a significant beneficial effect on Indian Pharmaceutical Industry and the country's economy. All these factors are interrelated to each other starting with generic drug and API exports which are controlled by the number of ANDA approvals. Therefore, the approvals elevated the number of drug manufacturers and facilities and consequently cause the USFDA to look into the compliance issues more rigorously and frequently.

Lastly, it can also be concluded that either the GDUFA proved positive for the growth and the export of the generic drugs to the US or Indian firms are determined to utilize its resources to stay ahead in the global market. It can also be concluded that the GDUFA implementation has brought all the Pharmaceutical companies in compliance with the USFDA regulations and to practice good manufacturing practices all the time, therefore the increased performance is witnessed.

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