

## Authorized Generics: Effect on Pharmaceutical Market

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### Abstract

The study addresses the effect of authorized generics practice in pharmaceutical market. The practice of marketing an “authorized generic” has been growing in the pharmaceutical industry. An “authorized generic”—sometimes termed a “branded,” or “pseudo” generic—is a pharmaceutical that is marketed by or on behalf of a brand name drug company, but is sold under a generic name. The brand drug companies employ a generic company or its own generic subsidiary to market their drug product; under their own new drug application (NDA). Authorized Generics compete on price, quality and availability basis with generic products approved by the FDA as substitutable for specific brand products. Over the past couple of years, innovator drug companies have been launching authorized generics simultaneously with the first Abbreviated New Drug Applications (ANDA) filer’s launch of its generic drug product. The study analyzed the current prospects of authorized generics practice, examines the effect of authorized generics practice on consumers affordability to medicines, effects on the generic companies to file paragraph IV certifications to challenge patented drugs, study also observed the effect of authorized generics practice on Indian pharma companies. The questionnaire were prepared relevant to study and distributed to the Indian pharma regulatory personnel, and their responses were analyzed.

### INTRODUCTION

Authorized generics (AG) are brand name drugs packaged and sold by an innovator drug company as generics, under its own New Drug Approvals (NDA), through either the innovator’s generic subsidiary or an independent generic drug company.<sup>[1]</sup> The US Food and Drug Administration (FDA) has described an authorized generic as “any marketing by an New Drug Application holder or authorized by an NDA holder, including through a third-party distributor, of the drug product approved under the NDA in a manner equivalent to the marketing practices of holders of an approved Abbreviated New Drug Application (ANDA) for that drug.”<sup>[2]</sup> Authorized Generics compete on price, quality and availability basis with generic products approved by the FDA as substitutable for specific brand products. Over the past couple of years, innovator drug companies have been launching authorized generics simultaneously with the first Abbreviated New Drug Applications filer’s launch of its generic drug product. Although authorized generics are fully substitutable for the brand name drug, they are not listed in FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).

### Difference between Generics and Authorized Generics

According to the US FDA, “A generic drug is a copy that is the same as a brand-name drug in dosage, safety, strength, how it is taken, quality, performance and intended use.”<sup>[4]</sup> Generics are produced and marketed under an Abbreviated New Drug Application. An Authorized Generic is a brand-name prescription drug marketed by innovator Drug Company as a generic, under its own NDA. Authorized generics produced from the same manufacturing line of Brand Name Company but marketed by generic drug company under separate label.

### How Authorized Generics are brought to market?<sup>[3]</sup>

Authorized Generics can be brought to the marketplace in a number of ways: Three of the most common are identified below-

1. Brand pharmaceutical companies can establish subsidiaries to market Authorized Generics of their own brands. Several companies have launched

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Authorized Generics this way, but some have abandoned this approach for other options.

2. Brand companies establish agreements (oftentimes a result of a patent challenge settlement) with generic drug manufacturers to produce the Authorized Generic products.
3. Brand companies establish agreements with private label marketing and distribution companies to market and distribute Authorized Generic products. The benefit of aligning themselves with a major generic company brings a unique set of marketing skills and focus to ensure a maximum marketplace penetration.

The practice of authorized generics has recently been the subject of considerable attention by the pharmaceutical industry & regulatory body. The brand-name manufacturer either sales the authorized generics itself through a subsidiary or licenses a generic firm to sell the authorized generics. The label typically differs for the brand-name drug and it's authorized generics equivalent, but the drug product is exactly the same. Issues have been raised regarding the impact of authorized generics and the 180-day exclusivity period. The first generic applicant to file an application with a Paragraph IV certification (claiming that patent protecting the brand drug is either invalid or not infringed) receives 180 days of market exclusivity, which means the FDA cannot approve any additional ANDA filers until 180 days after the first-filer begins marketing its product. The 180-day marketing exclusivity period does not prevent competition from NDA-approved authorized generics. In recent years and with increasing frequency, brand name drug manufacturers have begun to market authorized generics at precisely the same time that a paragraph IV generic is beginning its period of 180-day marketing exclusivity. The likely effects of this practice on generic competition have been subject to some debate. In the short run, the entry of an authorized generic drug may benefit consumers by creating additional competition that lowers generic prices further than if only the paragraph IV generic were marketed. Many generic manufacturers assert, however, that in the long run consumers will be harmed because an expectation of competition from authorized generics will significantly decrease the incentives of generic manufacturers to pursue entry prior to patent expiration, especially for "non-blockbuster" drugs. For a generic manufacturer, the additional competition from an authorized generic may result in significantly less profit during the period of 180-day exclusivity than if the generic manufacturer had no authorized-generic competition during that time. Another concern is that, in the context of settlement, the brand-name manufacturer will promise to forego introducing an authorized generic in exchange for

the first-filer agreeing to push back its entry date. This study focused on the present prospects of authorized generics practice, impact of authorized generics entry on consumers and ANDA with Paragraph IV certifications and also identifies the benefits of authorized generics practice on both innovator (Brand) companies and generic drug companies. Study also analyzed whether the authorized generics practice benefits the consumers. This study has taken into account the responses from Indian pharma company professionals at managerial level who are involved in the process of filing ANDA for these companies, as authorized generics pose a challenge to Indian pharma companies who are striving to increase their presence in the US market through launch of generics.

## RESEARCH METHODOLOGY

Data sources: The first step in any research activity is the identification of data sources

The two types of data sources are

- a) Primary data sources.
- b) Secondary data sources.

a) *Primary data sources:* Primary data was collected through structured, non-disguised questionnaire, which was circulated to pharmaceutical regulatory personnel through e-mails and personal visits. The questionnaire aims to analyze the current prospects of authorized generics practice, the impact of authorized on pharmaceutical market. The opinions of regulatory personnel were analyzed and data presented in the form of charts, bar diagrams and pie charts etc.

b) *Secondary Data Sources:* The relevant information about authorized generic was collected through latest national and international periodical journals like Pharma biz, Express Pharma pulse, Med Ad news, Regulatory Affairs focus, and most of the data collected from internet source.

Sample size: 120-Drug regulatory personnel

Sampling unit: Drug regulatory professionals working in various companies

Sample procedure: Non probability sampling by convenience method due to non-availability of data pertained to total size.

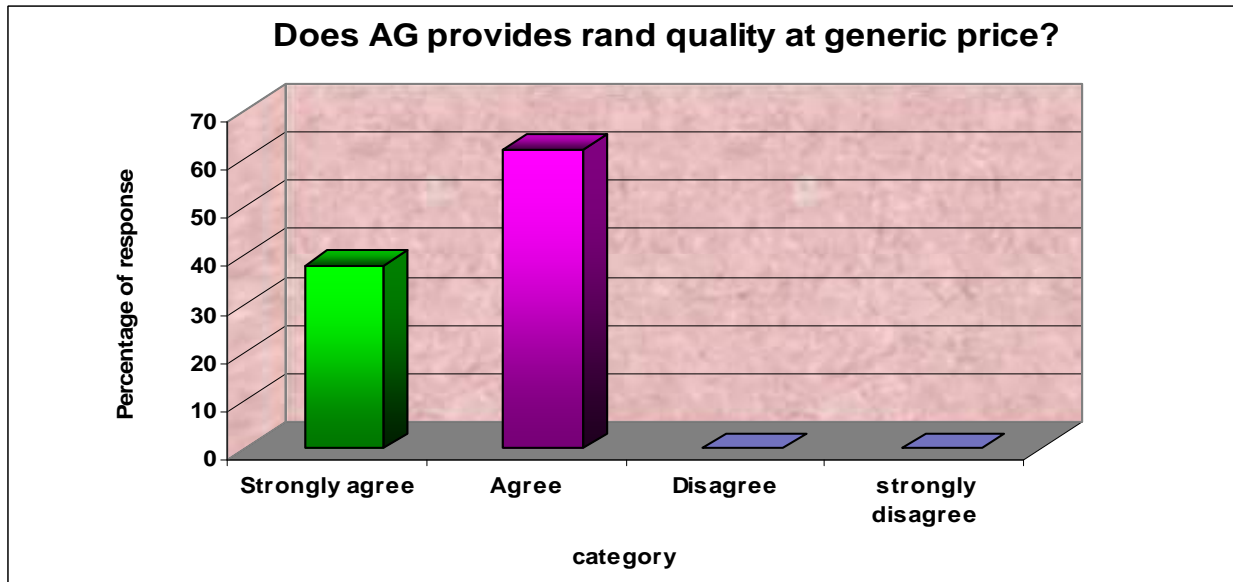
Data collection: Through the self administered questionnaire. Pharmaceutical regulatory personnel were requested to give their opinion on the questionnaire.

Nature of Questionnaire: The questions in questionnaire were structured, non-disguised type. All the questions are prepared based on the available secondary data.

Following questionnaires were asked to drug regulatory professionals and their opinions and views are depicted in graphs and pie diagrams.

**Q1 “Authorized Generics provide consumers quality product at a lower price.” Do you agree?**

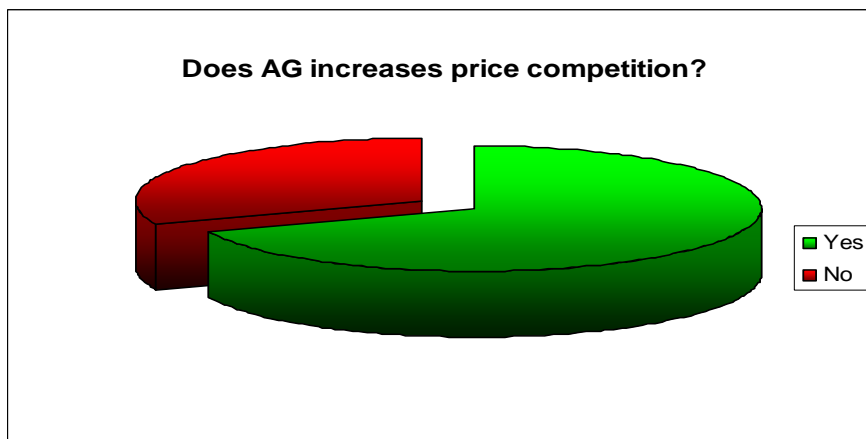
**Interpretation:**



The above question tries to identify whether the authorized generics are providing quality product at lower price (i.e. generic price)? Among the chosen pharma regulatory personnel, 38% pharma regulatory personnel strongly agreed and 62% agreed that the authorized generics provide quality products at lower price. Overall the result satisfactorily says that authorized generics provide consumers with the product of same quality as that of brand manufacturer but at a lower price.

**Q2 Does Authorized Generics increase price competition?**

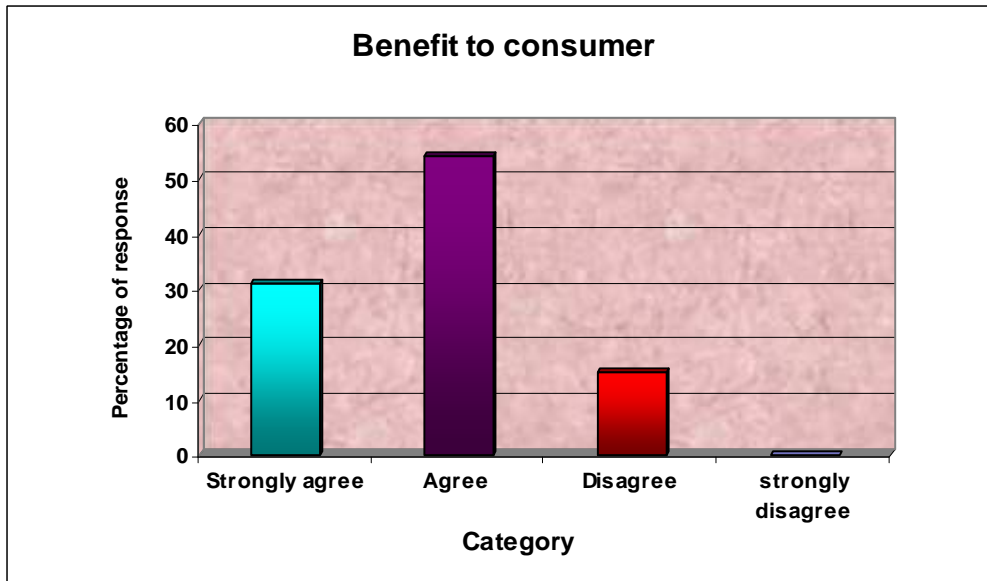
**Interpretation:**



This question tries to analyze whether the authorized generics affects price factor by increasing competition into market. The above diagram reveals that the 69% of pharma regulatory personnel agreed that authorized generics increases price competition and remaining 31% disagreed. Thus majority of respondents believe that, entry of authorized generics create price competition in the market.

**Q3. “Authorized Generics give benefit to consumers by offering a lower-priced alternative.” Do you agree?**

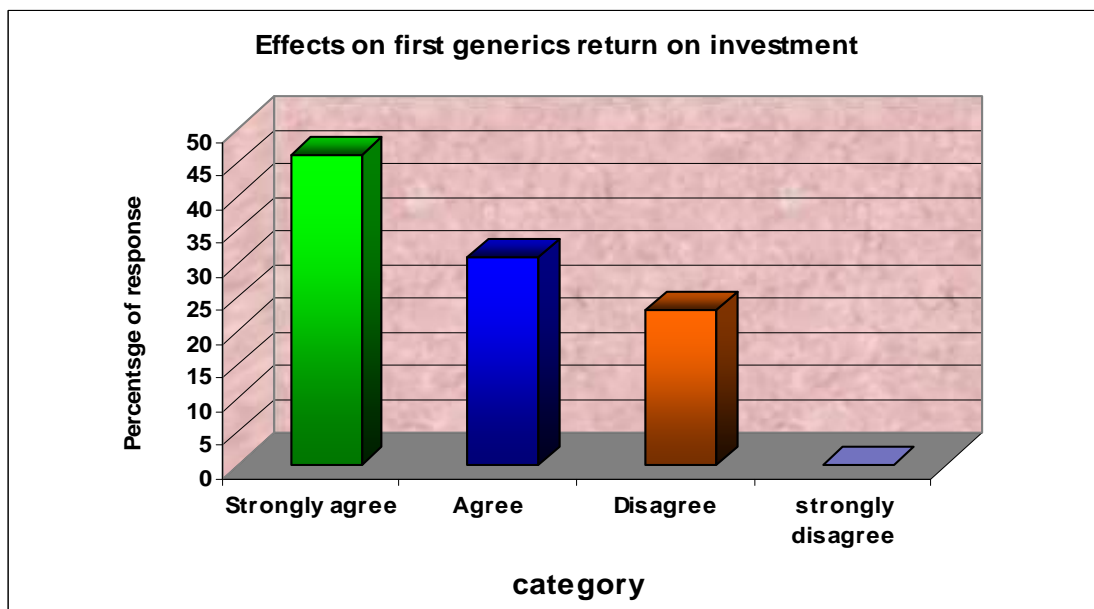
**Interpretation:**



The above graph shows that 31% pharma regulatory persons strongly agreed and 54% agreed that authorized generics give benefit to consumers by providing lower price alternative, but 15% regulatory personnel disagreed with the statement. A comment made by regulatory personnel tells what actually the beneficial effects of authorized generics are? He stated “actually authorized generics do not provide benefits to consumers but because of the competition between generic drug companies keep their drugs price low”.

**Q4. Does authorized generics affect patent-challenging generic firm’s Returns on Investment during the 180-day exclusivity period?**

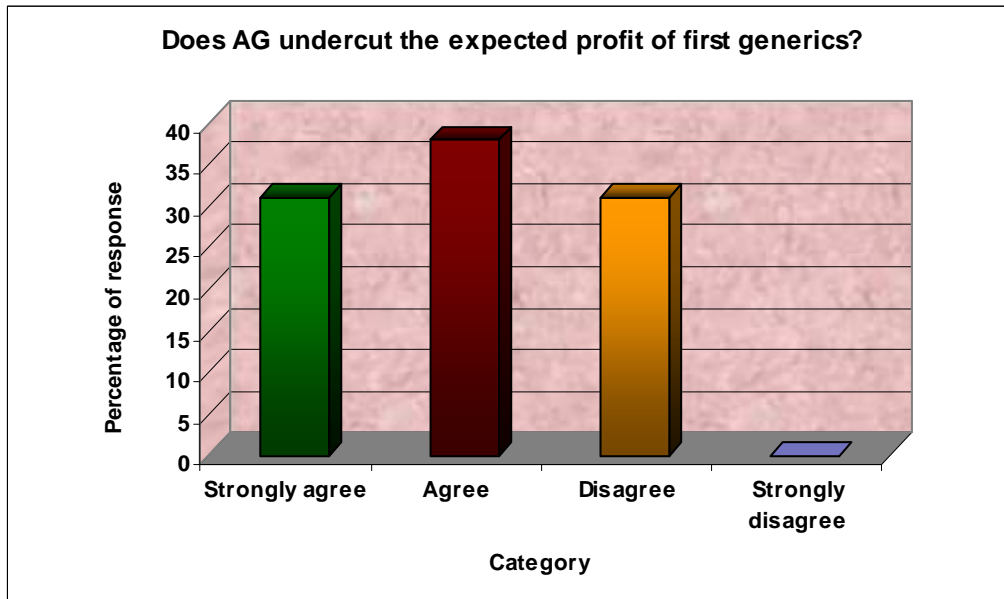
**Interpretation:**



The above graph depicts that, 46% pharma regulatory personnel strongly agreed and 31% agreed that authorized generics affects the patent challenging generic firms Return On Investment while 23% personnel disagreed with the above. This could attribute to lengthy and costly legal challenges that would require patent challenging firm to pump in lot of money without knowing the outcome of the case. On the other hand due to competition in the market the profit margin needs to be kept low, which would again dent the generic manufacturers ROI.

**Q5. Authorized Generics Players would eat away the expected profit of first ANDA filing company. Do you agree?**

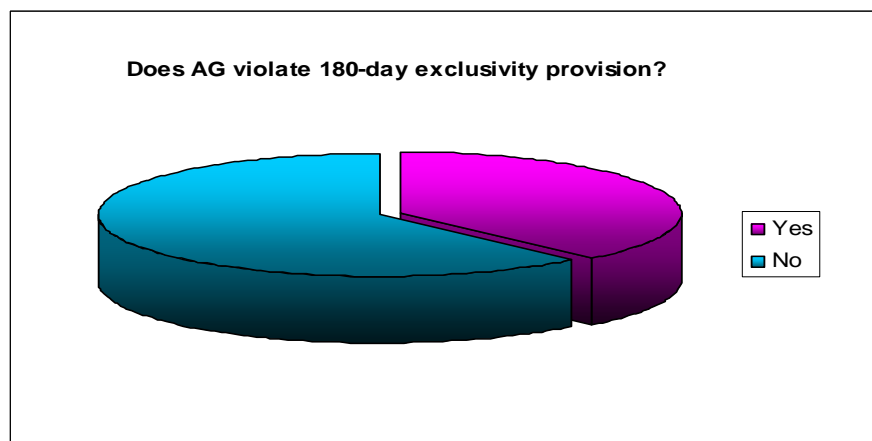
**Interpretation:**



Among the pharma regulatory personnel, 31% strongly agreed and 38% agreed that authorized generics launching companies undercut the expected profit of first ANDA with Para IV filers, while 31% pharma regulatory personnel disagreed. As authorized generics are from the brand manufacturer only which is sold either through its subsidiary or third party, the marketing strength and market functions are already known to the authorized generics marketer. This would help the company to better penetrate the market. This may not be the case with first ANDA filer.

**Q6. Does Authorized Generics violate the 180-days exclusivity period provision of Hatch Waxman Act?**

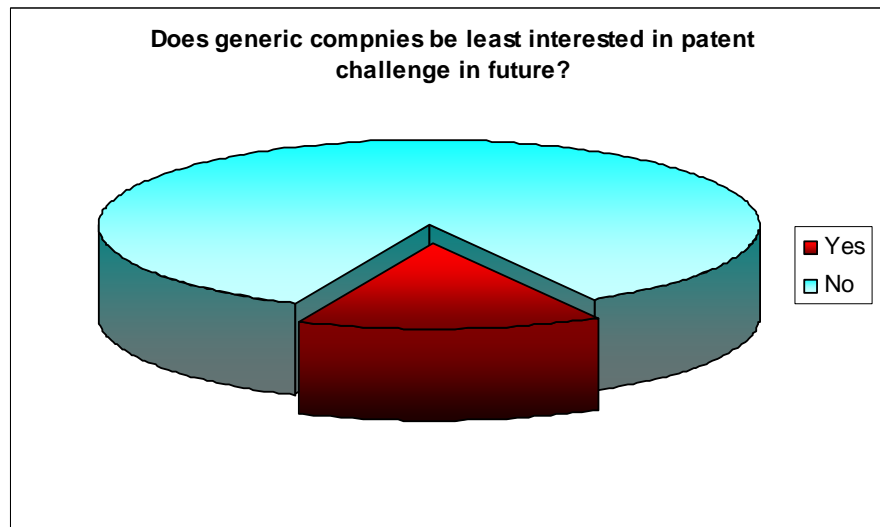
**Interpretation:**



From the above diagram it shows that, 62% pharma regulatory personnel agreed that authorized generics do not violate the 180-day exclusivity provision of Hatch Waxman Act but 38% pharma regulatory personnel said that authorized generics violate the 180-day exclusivity of generic company. As Hatch Waxman Act does not specify anything regarding authorized generics, nor are there any regulations specifying competition of authorized generics with other generics or ANDA filers, the provision of authorized generics is open to interpretation and has given differing opinions.

**Q7. Do you believe that generic companies would be least interested to challenge patents if Authorized Generics are allowed to continue?**

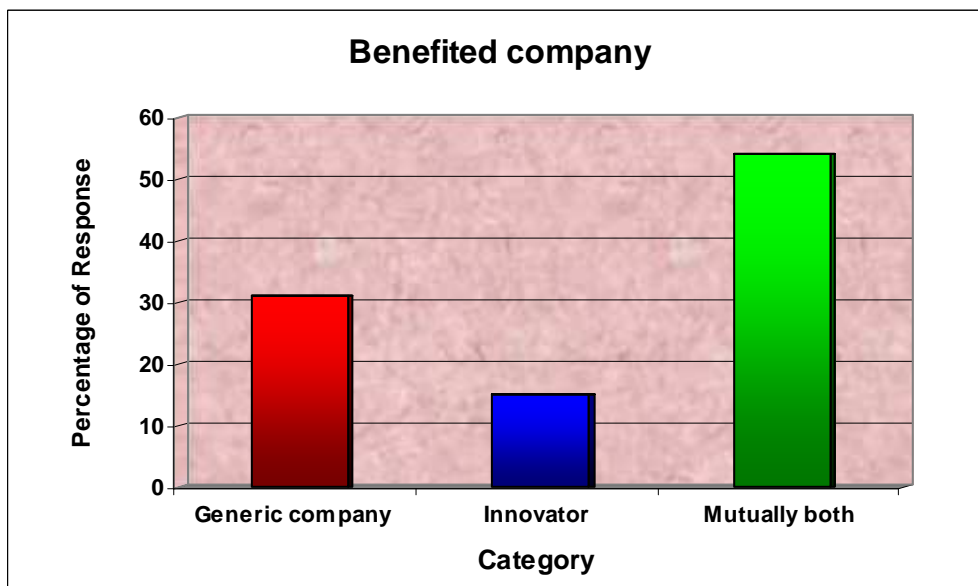
**Interpretation:**



From the above diagram it is clear that the generic companies will continue to challenge the innovators patented drugs even in the presence of authorized generics practice. 85% pharma regulatory personnel said that the generic companies wouldn't be least interested to challenge patented drugs if authorized generics allowed continue, but 15 % pharma regulatory personnel said that, generic companies would be least interested if authorized generics are allowed to continue.

**Q8. If a brand company provides license to a generic company to market authorized generics, which company you think would be more benefited by such licensing agreement?**

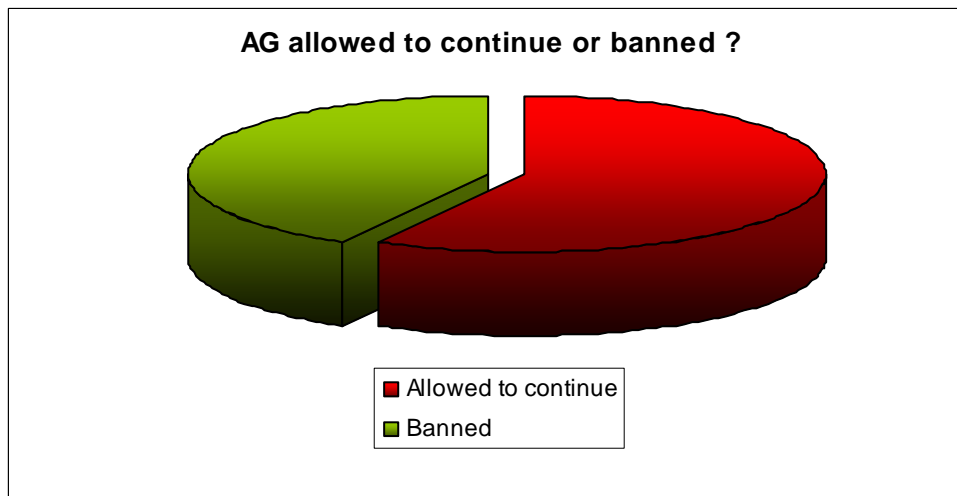
**Interpretation**



The above graph depicts that, 54% pharma regulatory personnel said that Innovator Company and generic company are mutually benefited with such authorized generics marketing agreement, while 31% pharma regulatory personnel said that generic company would be more benefited rather than innovator. But 15% pharma regulatory personnel said that Innovator Company would be more benefited.

**Q9. Authorized Generics practice should be “banned” or “Allowed to continue”?**

**Interpretation:**



**The above diagram shows that, 58% pharma regulatory personnel responded that authorized generics practice should be allowed to continue but 42% regulatory personnel are opposed to allow continuing the authorized generics practice they wish to ban on the authorized generics practice.**

Duration of Data Collection: Couple of months was required for literature survey, for secondary data development of questionnaire and its pre testing, making necessary changes, finalizing the question and sampling frame. Couple of months for field work, administering of the questionnaire to the respondents, collection of filled questionnaire. Couple of months for post survey work, interpretation of data collected its analysis and preparation of report.

Analysis and Interpretation: Analysis and interpretation of data were carried out to work out final conclusion with the aid of suitable statistical tools.

Following questionnaires were asked to drug regulatory professionals and their opinions and views are depicted in graphs and pie diagrams.

**RESULT AND CONCLUSION**

The authorized generics practice has recently been considerable issue in pharmaceutical industry; different views and different comments were obtained through experts from pharmaceutical industry. Some commentators and studies favor authorized generics practice and some opposes the authorized generics practice. The innovator companies are favoring the authorized generics practice because of many reason, they may discourage the generic companies to challenge patented drugs and keep in flow to generate revenue from patented drugs. While generic players are opposing the authorized generics practice; mainly Generic Pharmaceutical Association (GPhA) opposing the authorized generics

practice, because authorized generics practice hurts generic companies, due to presence of authorized generics in market, the expected profit of first generic companies are diminished.

The questionnaire was distributed among the Indian pharma regulatory personnel and their responses obtained were analyzed. The most Indian pharma companies are dealing with the generic drugs hence there might be chance of contradictory responses against the authorized generics practice.

In the analysis of effect of authorized generics practice on consumer affordability to medicine, from the primary and secondary data source it is found that authorized generics practice has been providing benefit to the consumers in short term, but in the long term effect of authorized generics practice on consumers is found to be unobvious.

From the secondary data source, it is clear that, despite increasing and relatively high rate of authorized generics entry, the rate of filing paragraph IV certifications is higher than it has ever been. Even when authorized generics entry reduces the expected gain from filing paragraph IV challenges, the recent evidence is clear that sufficient incentive remain so that in spite of recent increased authorized generics entry, the intensity of filing paragraph IV challenges remains high.

From the analysis of the questionnaire, it is found that the authorized generics providing brand quality product at lower price. Authorized generics are identical to brand products they go through the same brand manufacturing line. The brand name company markets and sold authorized

generics at generic price sometimes lower than that of first ANDA filer. Thus, authorized generics provide the identical experience that the patient receives from the brand drug but at lower price.

The entry of authorized generics increases price competition in market. Launching an authorized generics by innovator drug company on the first day of exclusivity period develops competition to the first generic drug companies. Because of entering additional generic drugs (authorized generics) in market the first ANDA filers get affected. To compete and capture the market share the first ANDA filer companies consider the price factor. As the number of drugs increases in the market, price competition also increases.

Different comments and different view are found about the effect of authorized generics practice on consumers. Some experts said that authorized generics give benefit to consumers for short terms but it will hurt the consumers in long term. Developing competition and lowering prices of drugs helps consumers in short term, but entering authorized generics during six month exclusivity, compete to first ANDA filer generics and deter the incentive of exclusivity period. This results generic companies would least interested to challenge patented drugs in future and consumers will strive to get cheaper generic drugs. Presently the authorized generics are providing benefits to consumers through providing brand product at lower price, but in future because of this brand firm strategy, the consumers may get affected. Generic companies would be less interested to challenge patented drugs mainly “non-block blaster” drugs, smaller generic companies may hesitate to develop generic copies if they believe that the authorized generics will have the effect of diminishing their initial profits and market share. Also another brand companies strategy, settlement of patent litigation with the patent challenging generic companies, brand companies avoid to create early generic competition and enjoy full patent exclusivity. This causes consumers would require to wait more for cheaper drugs.

In the aspect of first generic companies expected return on investment (ROI), different views were shown, the some experts are accept that the authorized generics affect the patent challenging generic firms return on investment, but some experts believed that, without an authorized generic, a first ANDA filer could gather 1000% return on investment, but with an authorized generic it declines to half. So, even with the authorized generics, the patent challenging company still makes five times their investment during six month exclusivity period.

It is found that during the exclusivity period the authorized generics undercut the expected profit of patent-challenging generic firms. According to research by Merrill Lynch analyst

Greg Gilbert, “An authorized generic during the exclusivity period can cut the generic maker’s sales profits by 59 percent.

The authorized generics do not violate the 180-day exclusivity period provision of Hatch Waxman Act. Authorized generics are launched through innovators NDA and can enter during the 180-day exclusivity. The intent of Hatch-Waxman Act to promote competition and allow low cost generic drugs to reach the marketplace, the 180-day period was designed to encourage generic companies to challenge patents in order to promote competition. Authorized Generics promote competition and bring lower prices to consumers faster.

It is found that, even in the presence of authorized generics practice, generic companies will not stop to challenge patented drugs. Indian pharmaceutical regulatory personnel strongly responded that, even in the presence authorized generics practice, generic companies will not stop file Para IV certification against patented drugs. Some commentators argued that, if authorized generics practice allowed to continue, generic companies would be least interested to challenge patented drugs, fewer paragraph IV certificates will seen and ultimately affect consumers. But from the last decade, it is found that the prevalence of authorized generics has been increasing year by year. It shows that even in the presence of authorized generics practice, ambitious generic companies are taking risk to challenge patented drugs.

Authorized generics agreements provide benefits to both brand-name Company and generic company. Authorized generics provide the brand-name firm an additional income source, such as a royalty on sales made by its generic subsidiary or contracting partner. Authorized generics may also facilitate settlement of patent infringement suits between brand-name and generic firms. The generic company making an authorized generic can also benefit by not having to expend funds on litigation with an uncertain outcome or pursue an ANDA at the FDA, while expanding its product line, acquiring manufacturing experience, and gaining the first mover advantage in the generic market.

In the last and most awaiting part of this debate of authorized generics practice, it is difficult to conclude that the authorized generics practice should be continued or banned. Though Indian pharmaceutical companies are dealing with generic drugs, among the respondents, 42% responses were in favor of authorized generics practice, but 58% respondents were opposing the authorized generics practice.

## REFERENCES

1. Sapana Dogra, “Drug on Hire”, Express Pharma, 2006,12.



2. Jeffrey N. Wasserstein and Kurt R. Karst, "New Law Reins in Authorized Generics Despite Generic Industry Court losses, But Leaves Several Ambiguities" 12 June 2006. [http://www.authorizedgenerics.com/index.cfm?fuseaction=home.viewPage&page\\_id=54B25D08-9C5C-7C39-7BE1E1D53E17724B](http://www.authorizedgenerics.com/index.cfm?fuseaction=home.viewPage&page_id=54B25D08-9C5C-7C39-7BE1E1D53E17724B)
3. <http://www.ftc.gov/opa/2006/03/authgenerics.htm>
4. Food and Drug Administration. Generic Drugs: Questions and Answers. [Online] 30 March 2006.
5. <http://www.gphaonline.org/AM/Template.cfm?Section=Home&TEMPLATE=/CM/HTMLDisplay.cfm&CONTENTID=1932>
6. John R. Thomas, Authorized Generic Pharmaceuticals: Effects on Innovation August 08, 2006.
7. Narinder S. Banait, Authorized Generics: Antitrust issue and the Hatch Waxman Act. 2.
8. Pharma's Cutting Edge Vol. 3 Number 3 - March 2005 Authorized Generics: Here to Stay?
9. Sanda Levy, "Why authorized generics are making a comeback," Drug Topics: The Online Newspaper for Pharmacists, Nov 3, 2003.
10. Andrew Humphries and Nick D'Amore, "Generic Deluge: As U.S. Regulators Receive a Record Number of Generic Drug Applications, Pharmaceutical Companies Continue to Align With or Combat Generic Competition," 24 Med Ad News no. 11 (Nov. 1, 2005).
11. Mylan Citizen Petition, Docket No. 2004P-0075 (7 February 2004), at 3.
12. Teva Citizen Petition, Docket No. 2004P-0261 (9 June 2004).
13. FDA Response, Docket Nos. 2004P-0075 & 2004P-0261, at 2 (2 July 2004).
14. Andrx Citizen Petition, Docket No. 2004P-0563 (23 December 2004).
15. Kurt R. Karst, Regulatory Affairs Focus Magazine, March 2005: Biogenerics Authorized Generics-Historical Overview and Current Issues.
16. Ernst R. Berndt, Richard Mortimer, Ashoke Bhattacharjya, Andrew Parcee, and Edward Tuttle, "Authorized Generic Drugs, Price Competition and Consumers' Welfare" (Oct. 26, 2005).
17. Sipkof, Martin, "Battle Over Authorized Generics Grows Increasingly Heated," Drug Topics, April 1, 2005 <http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?id=152726>
18. Federal Trade Commission, "Generic Drug Entry Prior to Patent Expiration: An FTC Study," July 2002, page 10.
19. Jeena Green, "Big Pharma's Big Leap", IP Law and Business /January 2006.
20. Ernst R. Berndt, Richard Mortimer, and Andrew Parcee, "Do Authorized Generic Drugs Deter Paragraph IV Certifications?" (April 17, 2007)
21. Stephen Barlas, "Authorized Generics may pose Unauthorized Problems: Government Worries about Potential Brand-Name Blocking Technique", Vol. 30 No. 8 • August 2005 • P&T, 435
22. Katya Naidu, "Striking the US Market" Pharmaexpress March 1-15 2007.
23. Peter Loftus, "Ranbaxy CEO open to authorized generic pacts", marketwatch.com news, Jan 24, 2007.
24. <http://patentbaristas.com/archives/2006/10/30/imitrex-authorized-generic-steps-in/>
25. "The Battle Between Generics and Brand Name Pharmaceuticals", Article available at <http://ipnewsblog.com/index.php/2007/03/04/>
26. Combating Generics: Pharmaceutical Brand Defense", Research Triangle Park, NC: January 2004;
27. Different views of Agencies and industry experts on Authorized Generics; [http://www.authorizedgenerics.com/index.cfm?fuseaction=home.viewPage&page\\_id=54B09ACA-F8B9-5558-D85D28BB32F19DA5](http://www.authorizedgenerics.com/index.cfm?fuseaction=home.viewPage&page_id=54B09ACA-F8B9-5558-D85D28BB32F19DA5)
29. <http://genericpharmaceuticals.blogspot.com/2007/04/authorizedgenericandgeneric.html>