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PHARMACEUTICAL SECTOR AND COMPETITION COMMISSION OF INDIA: AN ANALYSIS OF JUDICIAL PRONOUNCEMENTS OF COMPETITION COMMISSION OF INDIA

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Abstract

Indian Pharmaceutical Industry is one of the major contributors in the nation's GDP leading to the prosperous growth of the economy. The practices followed in the pharma industry have a major impact both from the consumer and the market perspective. It is also very important to understand that pharmaceutical industry is an industry which works towards human welfare as the main purpose that is carried out in the industry is to manufacture lifesaving drugs and ensure the supply of those drugs in the form of medicines across the markets. In the present paper the researchers have focused upon the causes and possible reasons of monopolistic trade practices in the medical and pharmaceutical sector and the Role of CCI to overcome the same and have suggested methods by which the said practices can be eliminated to maintain a healthy competitive market environment.

Keywords: Anti-competitive, Regulations, Drug Control, Transparency, Health Care, Competition, Monopoly.

1. INTRODUCTION

Life is the very subject matter of all debates in relating to policy implementations and public health - whether in terms of access to medicines, sovereignty over living and genetic material, privacy and integrity in the individual body[1]. Healthcare is one of the most basic needs and an inviolable right of every human being. Health and human development are interdepended and both contribute towards each other to build the other strong. Various International as well as

[1] JOHANNA GIBSON, INTELLECTUAL PROPERTY, MEDICINE AND HEALTH: CURRENT DEBATES, 7 (1st ed. Routledge 2009).

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national forums have recognized the right to access highest standards of health including India[2]. Right to access to quality and affordable medicines is an important component of right to health. However, at times, this right to access to medicines gets violated in the midst of many anticompetitive practices.[3]

Until 2002, India did not have a competition law regime. The earlier regime consisted of the Monopolies and Restrictive Trade Practices Act, 1969. MRTP was later on substituted by the Competition Act in 2002 and amended in 2007.[4] The Competition legislation of India came into full force after notification of major provisions i.e. the provisions relating to anti-competitive practice and abuse of dominance were brought into force in May 2009 during the second phase of implementations and provisions relating to combination to be brought into force in during third phase of implementations in June 2011.

The Competition law is essentially a legal framework to ensure curbing of monopolistic measures in commerce and industry. It is an instrument to intervene in markets in the situations of market dominance, monopoly and correct market failures. It is concerned with the promotion and maintenance of competition for the benefit of society.[5] It is founded on the elementary postulates that market forces and their contracts need to be structured in a competitive fashion. Such laws primarily seek to encourage competitors to compete against each other and thereby create an economically efficient free market system. Thus, competition law and authorities intercede whenever commercial contracts are found to be obstructive in nature.

Since its inception, CCI has dealt with around sixty cases related to pharmaceutical and the healthcare sector. While dealing with the cases CCI perceived that the pharmaceutical sector is induced information asymmetry (uneven or disproportionate) and demands influenced by the suppliers that ultimately influences the choice of the consumers. As a result in such a scenario various kinds of practices occur which limits the markets from working effectively and efficiently. Moreover, CCI has also depicted its concern regarding the need of regulation in the sector. Also identification of regulatory gaps and overreach and the need of requisite reforms are

[2] India has recognized Right to health as a part of right to Life in N D Jayal v. Union of India 2004 (9) SCC 362.
[3] Centre for Trade and Development (Centad), Competition Law and Indian Pharmaceutical Industry.
[4] The provisions of the Competition Act have been notified by the Government in a phased manner and the whole Act is expected to come into force in the near future. Services were also included under the new regime.
[5] K.D. RAJU, THE INTELLECTUAL PROPERTY RIGHTS & COMPETITION LAW: A COMPARATIVE ANALYSIS, 27 (Eastern Law House, 2015).

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other critical factors which need to be assessed for determining affordable and quality healthcare through proper functioning of the markets.

2. OBJECTIVE OF RESEARCH

In the famous case of *East Line Projects Pvt. Ltd.* v. *Dr. B. Borooah Cancer Institute Guwahati*[6]one of the conditions in a tender to establish a pharmacy was challenged. The challenge was on the ground that "the stockiest enjoy a dominant position and if he is allowed to compete with the distributor or the retailer, it will amount to abuse of dominant position which will be in violation of the provisions of Section 4 of the Competition Act, 2002". However, the Court found that "considering the avowed object for which the pharmacy is going to be established, the Competition Act, 2002 does not apply in the matter." Therefore, through this study, the researcher aims to make an analysis of such kind of cases relating too the pharma industry, and wants to determine the causes as a result of which anti-competitive and monopolistic trade practices are existing in the pharmaceutical sector.

3. ANALYSIS OF COMPETITION COMMISSION OF INDIA'S INTROSPECTION IN PHARMACEUTICAL AND HEALTHCARE SECTOR

Since its commencement, the Competition Commission of India has received approximately Sixty cases pertaining to the pharmaceutical and healthcare sector. While adjudicating the matters, the Commission has observed that the pharmaceutical sector is characterised by information asymmetry and supplier-induced demand that significantly circumscribes consumer choice, a condition necessary for well-functioning markets[7]. The Commission has also expressed the need for optimal regulation in the pharmaceutical sector. The Commission is of the opinion that identification of the regulatory gaps/overreach and necessary regulatory reforms is another area of critical importance in the quest of ensuring affordable and quality healthcare through well-functioning markets.

In order to meet the requirements of quality healthcare services and to find out solution, The Commission undertook a series of initiatives focused on the Pharmaceutical and healthcare

[6] AIR 2005 Gau 5
[7] Annual Report on Competition Policy Developments in India, Organisation for Economic Co-operation and Development, DAF/COMP/AR(2019)45.

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sector. The Commission collaborated with IIM, Ahmedabad and carried out Competition Assessment of Drug Price Control Order, 2013. It also conducted an internal review of the regulatory architecture governing the Pharmaceutical sector in India; and conducted a Technical Workshop on "Competition Issues in the Healthcare and Pharmaceutical Sector". The present study discusses the key issues and recommendations for policy/regulatory reform suggested by CCI in Pharma Industry in India.

1). Role of Intermediaries in Determining Drug Prices

India produces drugs of worth US $ 33 billion amongst which forty percent of the drugs are exported to other countries. Interestingly even after such a massive production about 50-65% people in India does not have a consistent access to the crucial and essential medicines as a result of which most of the expenses out of pocket expenses are spent on medicines or for healthcare aspects. Further, high trade margins is one of the major reasons as a result of which the drug prices in India are considerably high, The same is evident from the huge disparity in the drug prices existing and varying from state to state. For instance there is a high disparity in the market prices and the prices at which the same drugs are purchased by the states like Rajasthan and Tamil Nadu are under the public procurement and distribution systems.

Moreover, high margins influences that which drug is to be sold or distributed by the traders and are used as a bonus/incentive by the drug companies to market their products. Also the self-regulation by various trade associations to control the entire mechanism of drug distribution are responsible for such high prices of drugs and in the in a way completely disables the competition in the country.

Suggestions

1. The essential drugs can be availed by the consumers at a standard price by introducing the system of public procurement widely, which can also help in curbing the problems of high pricing due to long distribution chain.
2. Supplying the medicines through online medium by various platforms with certain regulations will not only be transparent but also will end the monopoly and will build a healthy competition among various retailers as it is seen in other kind of products.

In view of the same the Ministry of Health and Family Welfare, Government of India had released draft rules on Drugs (Sale and Distribution) Rules 2017 which aimed at removing ambiguity

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regarding the regulations on sale of drugs through online platforms.

2). Perceptions of the buyers about the quality of Branded Generics

Throughout the world, low cost generic drugs are seen as a tough competition against the branded drugs with expired patent which are marketed at monopolistic prices but on the contrary in India the pharmaceutical market is captured by the branded generics. Interestingly the competition between these branded generic version of drugs are largely based on brand and not on prices. Though the difference in quality b/w the branded and unbranded generics is not much provided same regulations are applied on both the categories but still the branded generics are marketed more as the people have a perception that the branded ones are more effective and have more therapeutic value as a result the doctors as well as the pharmacists prescribe the same in order to earn maximum profits. This in turn helps the companies to earn maximum revenue even though there is no difference at all between both the varieties.

Suggestions

The regulatory authorities while granting license to any brand for launching a drug should do a thorough study about the drug its composition and should see that the clinical trial of the said drug is done properly or not. Also adding to it the regulatory authorities should confirm that the qualities of the said drug are actually the same which the manufacturer claims it to be before granting the license and the permission to launch the drug.

3). Lack of Transparency and Alternate Arrangements in Healthcare Services

The lack of availability of information in the public domain about where the consumers can get the best treatment or proper healthcare services does not permit the consumers to make informed choices about the various services. As a result it can be seen that at many instances the various healthcare providers in the private sectors cheat the consumers by charging hefty sum of money from them for medicines and various other services which are otherwise available in the market at reasonable prices. These private health care services force the people to obtain the services and purchase of medicines from their intra service providers by making it compulsory.

Suggestions

Strict Regulations and framework should be there for ensuring that transparency is there in determining the prices for various services and medicines provided by the in house pharmacy and

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the hospitals.

4). Competition Commission and Regulation of Pharmaceutical Sector

As it is a well-known fact that regulations are important to ensure safety, smooth and effective functioning, quality control etc. In a sector like healthcare regulations are really necessary on manufacturing, import and purchase and sell of drugs.

But while imposing regulations it should be kept in mind that the regulations imposed are neither too strict nor too simple as both have their own implications. As to maintain the spirit of competitiveness in the market no strict regulations can be imposed on entry and distribution of the drugs. On the other hand to ensure that the drugs which are produced and are supplied in the market are not of inferior quality the regulations imposed can be too simple. As a result there should be a correct balance between the two and the regulations imposed should be clear transparent and not arbitrary.

In India the *Drugs and Cosmetics Act, 1940* (DCA) and the Drugs and Cosmetics Rules 1945 are enacted for maintaining the quality, safety and efficacy of the drugs manufactured, supplied or imported to India. Moreover, drug controlling authorities like CDSCO are also responsible for approving and licensing the production, imports and clinical testing of the new drugs. Also the officials at the state level are responsible for providing licenses for producing, supplying and selling of drugs and for monitoring these activities.

But however due to the presence of two different regulatory authorities at the State as well as the National Level there arises the following problems:-

i. ***Lack of uniformity*:-** As there are two different regulators at state and National level this creates a problem in applying the Drugs and Cosmetics Rules uniformly and effectively throughout the country as at various instances it has been seen that the Central and the State Authority fails to have a smooth coordination amongst themselves and as a result of which currently stringent and even multiple regulations are prevailing on the production, sale and import of drugs which varies from state to state and this in turn are creating a lot of trouble for the drug companies to carry out their operations and businesses resulting in unequal playing field for the companies into this business.

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ii. ***Inconsistency in approval and testing*:-** There is no definite process or rules for obtaining the approval for new drugs. There is a lot of disparity for granting approval to a new drug mostly depending upon who has applied for the approval. Moreover even for the clinical testing there are no prescribed rules and may vary in each case and depends on the contentment of the licensing authority pertaining to its safety and efficiency. As a result all this leads to unnecessary delay in launching of the new drugs causing a lot of loss to the manufacturers as well as a threat to the public health.[8]

iii. ***Difficulty in access to the biological drugs*: -** In the past ten years the drug manufacturers in India have made steady progress in the manufacturing of generic drugs and registering the biological medicines by increasing the competition and thus in turn to reduce the cost of expensive treatments in the world. [9] But access to these biological drugs is difficult due to the stringent regulation process as a result of which the national regulators asks most of the manufacturers to not only conduct the Phase-1 & Phase-2 Trials but also to do a comparative trial before receiving the final approval. As a result of conducting multiple trials for each biological medicine leads to exhausting a lot of time and money as there a very few companies who would enter into a competition with the large pharmaceutical companies thus in turn it leads to monopoly and killing the competition.[10]

Suggestions/Recommendations

1. A framework should be designed under the supervision of CDSCO that ensures coherence for basis adhered by the state licensing authorities and a centralized mechanism for the training of inspectors to ensure uniformity in the interpretation and implementation.
2. There should be a centralized data base where all the data related to issuance and cancellation of licenses, list of sub-standard drugs, prosecutions etc should be made and the same should be linked to all the state authorities to maintain a better coordination between the CDSCO and the State Drug Authorities.
3. The Drug Approval Process should be more transparent and should be completed within a limited time period. In order to do the same there should be definite set of rules determining the time period within which the same should be completed. Other than that

[8] Prajapati Vishal et al, A Review on Drug Approval Process for US, Europe and India, International Journal of Drug Regulatory Affairs, 2014
[9] Leena Menghaney, Competition is the key to making drugs affordable, Hindu Business Line, May 12, 2017
[10] Ibid

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there should be strict rules for each step involved in the approval of new drug inclusive of the time required for clinical trials, deliberation by the experts etc.

4. There should be a common database available in the public domain containing information related to the number of new applications for new drug, number of drugs for which clinical trials were required/waived, number of approvals/rejections, time taken for approval/rejection etc. This will make the process more clear and accountable.

5). Anti-Competitive Practices and the Role of CCI:-

In order to prevent monopolistic trade practices and allow fair playing field for various companies and manufacturers in the pharmaceutical sector Competition Commission of India will have to carry on applying anti-trust laws in the pharmaceutical sector. Also CCI through a variety of judgements has also helped to address the various underlying reasons responsible for non-competitive market conditions. The major areas which will be focused upon will include acts of the trade associations in the pharmaceutical distribution chain to limit competition and also the malpractices involved in the development of generic medicines.

i. Malpractices by Trade Associations in distribution of drugs:-

To establish a equal level playing field and avoid anti-competitive trade practices it is important to ensure that at each level of the supply chain whether it is manufacturing, wholesale or retail is working smoothly and there are no monopolistic trade practices involved. But however by looking at the existing high trade margins in India it is clear that there is a monopoly involved in the distribution of drugs.

By looking at the previous judgments passed by the commission such as the BCDA case, Arora Medical Hall Case or the JDMDA case it is clear that the entire supply-chain management in the drug distribution sector is regulated by the trade associations themselves.

The malpractices into which the trade associations are involved are as follows: -

1. Collecting Product Information Service (PIS) Charges from the manufacturers: -

It has been found in a variety of cases that the trade associations in various districts are involved in collecting money illegally from the manufacturers in the name of PIS charges. The same has been noted by the commission and as a result heavy penalties were imposed on such associations and the President and Secretary of such trade associations are also made liable for the same.

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In the instant case of ***Nadi Jauhri* v. *Jalgaon District Medicine Dealers Association (JDMDA)***[11] the said trade association in the name of Product Information Service Charges was collecting a hefty sum of money from the product manufacturers. The said act of the association was reported by the informant to the commission wherein it was found that on the pretext of publishing the details of the new drug launched in the market the association used to charge a fee of INR 500/- from each manufacturer. But when an enquiry was conducted by the Director General in respect of the same it was found that the said charges though were not compulsory to be paid but if any manufacturer refuses to pay the said charges then the product launched by their company will be boycotted and no retailer of that district will sell that products.

Here the JDMDA has violated S.3(3)(b) r/w S.3(1) of the *Competition Act 2002* as the said act by the association has imposed a limitation on the free flow of supply of new products by various pharmaceutical companies in the market. Moreover the said act of the association has made it clear that the companies which will not pay the said fee will have no chance to market their products in the district and on the other hand the people who will pay the said charges will have a monopoly over the market.

The opposite party had tried to oppose the above said allegations leveled against them by the informant and the investigation report of the DG by saying that the commission is not empowered to take cognizance in the said matter as vide the order dated 2.12.2015 the Delhi High Court by which the commission and the DG were directed not to take any coercive steps and hence it was expected from the commission to wait for further orders of the superior court before enabling any kind of proceedings. Also the OP had denied the allegations leveled by the informant that the payment of PIS charges are voluntary and not compulsory to which they had relied on the statements of Mankind Pharma Limited, Koye Pharmaceutical Private Limited, Unichem Laboratories Limited to prove that the payment of PIS charges was not mandatory. Also the opposite party had refused to accept that they were failing to advertise about the concerned products on time even after receiving the PIS charges which was not correct though.

After hearing to the contentions of both the parties and the witnesses the CCI had held that the collections of PIS charges were neither for the purpose of advertisement nor for the compliance with DPCO. Accordingly the CCI had imposed fine with interest for three financial years. Further,

[11] 2019 SCC OnLine CCI 12

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penalties were imposed on both the President and Secretary of the JDMDA. Hence, this case is a clear example of the CCI's concerns for the pharmaceutical sectors and against the unfair practices.

2. Paying of charges for obtaining NOC is compulsory: -

Another kind of malpractices into which the trade associations are involved into is the collection of the No Objection Certificate Letter and Letter of Credit by paying the fees as ascertained by the association. The said had declared that the said acts are violative of the provisions of the Competition Act 2000 and held the same in the following case.

In the instant case of ***M/s Arora Medical Hall, Ferozpur v. Chemists and Druggists Association Ferozpur, (CDAF)***[12] the association had violated S.19(1)(a) of the *Competition Act, 2002*. The informant alleged that the said association was imposing a sum of Rs.2100/- for obtaining a NOC certificate and a letter of credit on all the chemists/druggists who wanted the distributorship for medicines in Ferozpur. The informant/petitioner disagreed to pay the said charges and as a result the association not only boycotted the informant but also defamed them and passed a resolution in the general body meeting to boycott the petitioner from the pharmaceutical business.

After the investigation of the DG it was found that the above said allegations leveled against the association are true and as a result the said act have violated the freedom of trade of the plaintiff and was an attempt to limit and control the supply of drugs in the market.

The association in its submissions stated that all the allegations leveled against them by the informant is false and malicious and it has not committed any of the said acts and alleged that the general body meeting was called on receiving a lot of complaints from various retailers against the informant and said that the investigation of DG had missed out on the fact that the informant being the sole stockiest in the city to some of the drug manufacturing companies was misusing its power and the same was brought to the notice of the said companies by the association through a letter. Moreover the association also contended that FIR's were registered against the informant by various retailers u/s 420 of IPC and u/s 66(1) of the *IT Act 2000* alleging that the informant had generated computerized bills to some retailers without excluding the amount of the expired drugs.

[12] 2014 SCC OnLine CCI 18 : [2014] CCI 38

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After hearing both the parties the CCI contended that the opposite party or the association CDAF is liable for indulging into anti-competitive practices under Section 3 and 4 of the Competition Act 2002 and were involved in collecting fees from the distributors in the name of NOC Certificates and Consent Letters, fixing trade margins at different levels, issuing instructions to chemists/druggists/manufacturers to sell the drugs at a certain rate by fixing the rate of discount they can give and the issuance of boycott notice against the informants.

The CCI issued directions to associations by listing out the anti-competitive practices and if at all these activities are still carried out then they will be violating the provisions of the Competition Act, 2000. The CCI found the defendants liable for the alleged charges and imposed penalties on them regarding the same.

3. Associations are involved in price fixing, limiting supply and fixing the selling price of the drugs: -

The various trade association involved in supplying of drugs are involved into acts such as fixing, limiting supply and fixing the selling price of the drugs to earn more profits and setup a monopoly in the pharmaceutical sector.

In the case of ***Re: Bengal Chemists and Druggist Association and Others*** [13]the CCI had received information via e-mail that BCDA was involved in the acts like price fixing, limiting supply and fixing the selling price of the drugs. CCI took suo-motto cognizance and an investigation was by the Director General (DG) was ordered in the said matter.

After the investigation was concluded by the DG it was found that the BCDA had instructed the retailers to not to offer any discount and have also have also directed them to sell the drugs at the MRP determined by them thus this act of the association had caused an adverse effect on the competition and will lead to limiting the supply of the medicine and will be in violation of Section-3 of the Competition Act 2000.

Therefore BCDA submitted that BCDA is a non-profit association as per the Companies Act and therefore cannot be treated as an enterprise. It further added that the association had voluntarily complied with S.27 of the Competition Act 2000 hence it is not liable to pay the penalty. Lastly

[13] 2014 SCC OnLine CCI 38

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BCDA had concluded that their office bearers cannot be held liable as their liability is limited to the MOA as the same is a non-profit entity.

CCI observed that firstly the BCDA will be covered under the category of 'entities' and the decisions taken by the association of behalf of its member will fall under the ambit of section 3 of the Act. In the said case CCI penalized BCDA for practicing anti-competitive practices and also held 78 of the senior office bearers personally liable for endorsing anti-competitive conduct and further went on imposing a penalty of Rs. 18.38 Crores (fine imposed on BCDA was only Rs. 13.24 Lakh).

4. Manufacturing Companies involved in restrictive trade practices: -

Apart from associations it has been seen that the manufacturing companies by colluding with other organizations are involved in anti-competitive practices thus creating trouble for the retailers and in such a case associations comes as a survivor for such retailers.

In the instant case of ***Re: Belgaum District Chemists and Druggists Association (BCDA) v. Abbott India Ltd. & Ors.*** [14]filed a complaint before the Director General of Investigation and Registration (DGIR) against Abbott India Ltd. and Geno Pharmaceuticals as the said companies had stooped stopped the supply of the essential medicines to some of its members on the ground that they did not fulfill the pre-requisite of obtaining the *"No Objection Certificate"* from All India Organisation of Chemists and Druggists (OP-4) and Karnataka Chemists and Druggists Association (OP-2). The DGIR transferred the complaint to the Commission under Section 66(6) of the Competition Act, 2002 with an observation that the alleged practice opted by the Original Petitioner-1 and OP-3 appeared to be a restrictive trade practice of refusal to deal. The Commission further passed an order on 29th June, 2010 under Section 26(1) and directed the Director General to organize/conduct an investigation/examination in the present matter.

The Director General in his investigation observed that Original Petitioner-2 and Original Petitioner-4 have indulged into anti-competitive practices by contravening the provisions under Section 3 (3) (a) & Section 3 (3) (b) of the Act.

The Competition Commission has stated that in the absence of any evidence to show that Original

[14] 2017 SCC OnLine CCI 20

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Petitioner-4 cannot be found guilty of contravention of the said provision. The Competition Commission has held that the Original Petitioner-2 has acted in contravention to the provisions of the Act. The Commission directed Original Petitioner-2 to cease the requisite of the mandating NOC and have also advised not to indulge in such practice in future. The Commission has held that the appointment of the stockiest and the fixing of trade margins for retailers and wholesalers are considered to be anti-competitive under the provisions of Section 3 (1) read with Section 3 (3) of the Act. The Commission has stated that as a penalty of Rs. 860321 has been imposed upon OP-2 in similar matter of mandating the NOC for the appointment of stockiest, therefore the Commission refrained from imposing any monetary penalty.

Conclusion

The Indian pharmaceutical industry is one of the major pharmaceutical industries in the world, both in terms of volume of consumption and value of production. Further, given its critical importance, this industry has attracted significant policy attention. Given the ever changing policy environment, it is only appropriate to assume that the firms also adapt their strategies as per the policy environment, thereby altering the industry dynamics itself. In short, the competition law of India has a crucial role to play in the pharmaceutical sector. In India the consumers suffer direct and immediate harms, as they frequently are not able to afford the drugs prescribed to them.[15] Anti-competitive behavior often is not justified based on innovation or patents and the complexity of the conduct does not diminish and in fact necessitates careful competition law scrutiny of the pharmaceutical industry. The CCI had played a vital role in maintaining anti-competitive environment and has established a equal playing arena for all the manufacturers in the pharmaceutical industry/sector. Also the CCI had played a vital role in keeping the various trade associations under a strict check and thus ensuring that the freedom of trade prevails and delimiting the control on manufacturing and supply of drugs by the various companies. In the end, we can conclude that the CCI has ensured that the customers are protected against duplicate products and have made efforts to ensure that the prices of essential drugs remain reasonable.

[15] C. S. Hemphill and B. N. Sampat, "*When Do Generics Challenge Drug Patents*?" Journal of Empirical Legal Studies, 8 (4): (2011) 613 – 649.