CLINICAL TEST DATA AND MARKET APPROVAL OF DRUGS: UNDERSTANDING INDIAN LAW VIS-À-VIS TRIPS AGREEMENT

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Abstract

Marketing of pharmaceuticals requires approval from the drug regulatory authorities of countries to ensure that the drugs satisfy the requirements of quality, safety and efficacy. Drug originators are required to submit data to the authority in this regard. Generation of such data generally involves elaborate experimentation, chemical analysis, trials in various phases and estimation of the impact on environment. These are time-consuming and expensive processes. These tests generate valuable data regarding a particular drug. For granting market approval to pharmaceutical products, a country's drug regulatory authority requires the drug registrants to submit clinical test data proving the drugs' safety, efficacy and quality. Whether the generic drug manufacturers can rely on the data submitted by the drug innovator, or they have to generate the data by undertaken clinical trials on their own has been debatable. Article 39.3 of the TRIPS Agreement provides that "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use." Some member states are of the opinion that it provides for 'data exclusivity' that is, exclusive rights of the originators over the test data submitted by them, thereby excluding its reliance by any subsequent generic manufacturer seeking market approval, as according to them such reliance would result in 'unfair commercial use.' The other set of argument is that data exclusivity delays the entry of generics in the market and leads to increase in price of drug. This article aims to clarify the relevant provisions of TRIPS Agreement regarding submission of test data for market approval of drugs. The author has also discussed the Indian law in this regard to clarify the position of India.

Introduction

Pharmaceutical products are required to seek approval from the drug regulatory authorities of the country before they could be marketed. The drug registrants are required to submit data proving drug's efficacy, safety and quality. This requires the drug originator to undertake several tests. The data thus generated is valuable as it undertaking such tests demands time as well as investment. Whether the data submitted to drug regulatory authorities can be relied upon to grant market approval to subsequent generic drug[1] manufacturers is an issue which has conflicting opinions. On one hand it is argued that the information about quality, safety and efficacy of the drug should not be kept disclosed. As the national authorities already have knowledge of the characteristics and effects of the original drug, it is not rational to require a generic manufacturer to carry out the same tests all over again. Proving similarity to the authorities is sufficient.[2] On the other hand it is argued that manufacturer of an original drug invests heavily in conducting the required tests and thus, he deserves to get adequate returns. Thus, generic drug manufacturers should not be allowed to rely on the data submitted by the original manufacturer. The subsequent manufacturers would get an unfair advantage as they would not be required to investment in conducting the required tests. This would discourage the developers of new pharmaceutical products.[3] Thus, manufacturer of the original drug should have exclusive right over this data, at least for a limited time period, called data exclusivity.

Article 39.3 of the TRIPS Agreement provides "*Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair*

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[1]Rafael Alfonso-Cristancho, *Definition and Classification of Generic Drugs Across the World,* 13 APPL. HEALTH ECON. HEALTH POLICY. 5, 6-7 (2015).
[2]Animesh Sharma, *Data Exclusivity with Regard to Clinical Data*, 3 INDIAN J. L. & TECH. 82, 83-86 (2007).
[3]Carlos María Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement*, ESSENTIAL MEDICINES AND HEALTH PRODUCTS INFORMATION PORTAL A WORLD HEALTH ORGANIZATION RESOURCE (Oct. 10, 2019, 12:30 PM), http://www.southcentre.org/publications/protection/protection.pdf.

commercial use." Data or information falls under the purview of Article 39.3 only when the following conditions are fulfilled:

i) Data Necessary to Obtain Marketing Approval

The very condition of the said provision is that member country through its national regulations requires submission of test data for providing market approval to pharmaceutical or agricultural products. Thus, if a member country does not stipulate the requirement of submitting such data, Article 39.3 is not applicable. Such data contains results of safety and quality testing of agrochemicals and drugs. The data is to be submitted only to the extent it is necessary for obtaining marketing approval. Excess data submitted voluntarily by the applicant is not protected under this provision.[4]

ii) Undisclosed Data

Data or information already in public sphere is not covered under Article 39.3. Information relating to drugs made available by the health authority, or published in scientific journals falls into public domain. Thus, disclosed and undisclosed nature of information is an objective attribute. Applicant's declaration of undisclosed information is verified.[5]

iii) New Chemical Entity

The expression "new" is not defined in the TRIPS Agreement. Though the requirement of "new" in Article 39.3 does not presumably entail a patent standard of novelty, member states still have the option to do so. Even if a chemical entity is considered new under Article 39.3, it will not imply that it is necessarily patentable because either it might possibly not fulfil the standards of novelty or inventiveness for the purpose of patent. Interpretation of "new" has been left to the member countries. "New" can refer to the date of application for approval of the drug. Newness could be either absolute or relative, i.e., new can mean first application anywhere in the world or in the member country where it was filed, depending upon the approach adopted by the member state.[6]

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[4] *id* at 17.
[5] *id* at 15.
[6] TREVOR COOK, SPECIAL REPORT: THE PROTECTION OF REGULATORY DATA IN THE PHARMACEUTICAL AND OTHER SECTORS 10 (Sweet & Maxwell, London 2000).

A product recognized and used in a field could find a new application in the pharmaceutical sector. It might not be deemed to be a new chemical entity as the chemical was already known. Alternatively, newness can be determined within a particular regulatory framework, regardless of the fact that the same chemical could have been used in the context of a different regulatory framework.[7] It can also be construed that protection may not be provided when the test data is developed for a *new use* of a pharmaceutical product (known as a "second indication").[8] In such case, the method or application of use of a known chemical entity is new, however the entity is not new as such.[9]

Article 39.3 would not be applicable when approval is required for new indications, dosage forms, crystalline forms, combinations, etc. of existing drugs, because no new chemical entity would be involved.[10] The issue was addressed in the *"Squibb"* case[11] where it was held that a (subsequent) product is "essentially similar" to an earlier approved product if the subsequent product possesses "the same qualitative and quantitative composition regarding active principles" and it is bio-equivalent of the first product, "unless it is different from the original product regarding efficacy or safety". In such cases, the original applicant is not granted new periods of "marketing exclusivity" for every new indication.[12]

iv) Considerable Effort

Article 39.3 deals with information pertaining to test data about clinical trials for pharmaceuticals and field trials for agrochemicals. There is no aspect of creation or invention in this information. Under the TRIPS Agreement, any substantive standard for granting protection to data under Article 39.3 is not defined. The only stipulation is that there should be a "considerable effort" in obtaining the data. However, what will amount to "considerable effort" is not mentioned in the agreement. It can signify special or concentrated activities, mental or physical, which are extensive in duration or scope.[13] It can also mean the extent of investment

[7] *Id* at 6.
[8] Correa, *supra* note 3, at 17.
[9] Correa, *supra* note 3, at 18.
[10] Correa, *supra* note 3, at 17.
[11] Bristol – Myers Squibb Company v. Royce Laboratory Inc., 69 F.3d 1130 (Fed. Cir.1995).
[12] *Ibid.*
[13] G. Lee Skillington, *The Protection of Test and Other Data Required by Article 39(3) of TRIPS*, 24 NW. J. INT'L L. & BUS. 1, 28 (2003).

made by the applicant in coming up with the pharmaceutical or agrochemical product. [14] This requirement can be established in proportion with the significance of efforts made, on a case to case basis. When the above conditions are fulfilled, an obligation is casted on the member countries to provide protection to undisclosed data submitted to government authority from disclosure.

Exceptions to the Obligation of Non-Disclosure

Under Article 39.3, national authorities have to ensure that the data submitted is not disclosed, unless:

i) it is necessary to protect the public; or

ii) steps are taken to ensure that the data protected against unfair commercial use.

i) Necessity to Protect the Public

For determination of necessity, WTO/GATT rules and jurisprudence may provide guidance to the member states. However, at the same time member countries have to bear a heavy burden of proof to invoke it.[15]

ii) Ensuring protection of data against Unfair Commercial Use

Information may be disclosed, if its unfair commercial use is prevented. Unfair commercial use would pertain to an act contrary to honest practices in commercial or industrial matters.[16] Yet again what will be "unfair" depends from country to country. It is not defined in the TRIPS Agreement. Countries have been provided with enough room of maneuver to determine what will amount to unfair commercial use.

1. Unfair Commercial Use and Unfair Competition regarding Article 39.3

"Unfair" means "not honest or equitable or impartial or according to rules".[17] The idea of "unfair" is relative to the values of a particular society at a given point in time. Hence, what amounts to "unfair" varies from country to country.[18] The Vienna Convention on Law of Treaties, 1969 provides that a treaty shall be interpreted in good faith according to the ordinary

[14] *Id.*
[15] TREBILCOCK ET.AL., THE REGULATION OF INTERNATIONAL TRADE 40 (Routledge, London & New York 1999).
[16] Paris Convention for the Protection of Industrial Property, art.10 bis, Mar. 20, 1883 21 U.S.T. 1583; 828 U.N.T.S. 305.
[17] Correa, *supra* note 3, at 25.
[18] TREBILCOCK ET.AL., *supra* note 15, at 50.

meaning to be given to the terms of the treaty in their context and in the light of its purpose and object.[19] Article 39.1 of the TRIPS Agreement mandates protection of "undisclosed information" in the framework of "unfair competition". It requires that to ensure effective protection against unfair competition as under Article 10bis of the Paris Convention (1967) members shall protect the data submitted to governments or governmental agencies according to paragraph 3. Thus, Article 39.3 should be interpreted in the light of Article 39.1, that is, in the context of "unfair competition."[20] Article 10bis of the Paris Convention for the Protection of Industrial Property, 1883 provides that an act of unfair competition would mean any act of competition contrary to honest practices in industrial or commercial matters. Yet again what will be "unfair" varies from country to country.

Regarding data protection, the WIPO Model Provisions on Protection against Unfair Competition suggests that "any act or practice, in the course of industrial or commercial activities, shall be considered an act of unfair competition if it consists or results in an unfair commercial use of secret test or other data, the origination of which have been submitted to a competent authority for the purposes of obtaining approval of the marketing of pharmaceutical or agricultural chemical products which utilize new chemical entities."[21] Thus, an act which constitutes unfair commercial use of the submitted data will also result in an act of unfair competition. Article 39.1 and Article 39.3 thus cast an obligation on member countries that, for ensuring effective protection against unfair competition, the data submitted for market approval should not be disclosed by the national (government) authorities, unless steps have been taken to prevent its unfair commercial use.

2. Whether data exclusivity is mandated under Article 39.3 of TRIPS Agreement?

Article 39.3 of TRIPS directs protection against "unfair commercial practices" however it allows countries to determine practices which can be considered as commercially unfair. Thus, different approaches may be adopted by member states, consistent with Article 10bis of the Paris Convention. Countries may:

a) permit the second-entrant to rely upon "originator's" data in lieu of compensation, or

[19] Vienna Convention on the Law of Treaties art. 31(1), May 23, 1969, 1155 U.N.T.S. 331.
[20] General Agreement on Trade-Related Aspects of Intellectual Property art. 39(1), Jan. 1, 1995, U.N.T.S. 299.
[21] WIPO Model Provisions on Protection against Unfair Competition art. 6(3), 1996 no. 832(E).

b) grant approval to market approval application of generic manufacturer without examining or relying upon confidential data submitted by originator, or

c) require the second-entrant to generate test data on its own for obtaining authorization of use from the "originator" of data, or

d) Undertake examination and may rely upon the data submitted by the "originator" for evaluation of application of second-entrant.

However, developed nations (like U.S.) argue that Article 39.3 mandates that data submitted by drug originator can't be relied upon by the national authority to award market approval to second entrant, or the generic drug producer.[22] Thus, the provision mandates data exclusivity, that is, originator of a drug has exclusive right over the test data submitted by it to the national authority for market approval. U.S. & EU argue that allowing national authorities to rely on the data submitted by originators to grant market approval to generics would provide a commercial benefit or advantage to them as they will not have to invest in conducting the clinical trial. Thus, it would amount to unfair commercial use of the submitted data, which is not permitted under the provision.[23] The pharmaceutical industry and some developed countries strongly argue that Article 39.3 requires granting of exclusive rights to the drug originator. Granting commercial advantage to a generic manufacturer amounts to "unfair commercial use" of the data, irrespective of the fact that actual use may not occur and the practice as such might not be "dishonest." As per them, the only way to ensure effective protection to test data against unfair commercial use is by providing a period of exclusivity to use the data.[24] Similar argument was given by U.S. in its complaint against Australia. Australia did not have the provision of exclusivity. The generic companies were required only to demonstrate bio-equivalence to get market approval of a similar product. Besides, Australian authorities gave certificates of free sale, permitting generic companies to export to other countries, where market approval was granted automatically based on Australian certificates. It was argued by U.S. that this was in violation of Article 39.3. The U.S. pressure ultimately resulted in an amendment to the Australian law.

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[22] Manthan D. Janodia et al., *Data Exclusivity Provisions in India: Impact on Public Health,* 13 J. INTELLEC. PROP RIGHTS. 442, 444 (2008).

[23] *Id.*

[24] Priapantja, *Trade Secret: How does this apply to drug registration data*?, ASEAN WORKSHOP ON THE TRIPS AGREEMENT AND ITS IMPACT ON PHARMACEUTICAL, DEPARTMENT OF HEALTH AND WORLD HEALTH ORGANIZATION (2000).

Under the Therapeutic Goods Legislation Amendment Act, 1998 Australia introduced five years of test data exclusivity. Similarly the U.S. pressure led to incorporation of exclusivity provision in the USA-Jordan Agreement on the Establishment of a Free Trade Area, 2000. Similarly, it is also argued by EU that Article 39.3 provides for an exclusivity obligation. Member countries only have the liberty to determine the duration thereof.[25] On the contrary, the other group (mainly developing countries) argues that data exclusivity is not mandated under Article 39.3. Reliance on data by national authorities for granting market approval to generic manufacturers does not result in 'unfair commercial use.' Thus, data exclusivity is a TRIPS-Plus provision. This, brings us to a major interpretational issue- *whether reliance on originator's test data by drug regulatory authorities to grant market approval to subsequent generic drug manufacturers amounts to 'unfair commercial use' (thereby resulting in unfair competition)?* In other words, *whether data exclusivity is mandated under Article 39.3 of TRIPS?*

2.1. Negotiating History of Article 39.3

TRIPS Agreement's requirements regarding trademarks, copyrights, industrial designs, patents and integrated circuits, all explicitly provide for exclusivity. The negotiating history of Article 39.3 clarifies that though members had discussed data exclusivity, but ultimately they did not adopt text that mandated test data exclusivity.[26] U.S. had proposed that TRIPS should prevent use of test data, without consent of right holder or on payment of "reasonable value of the use" if that use amounted to "commercial or competitive benefit of any person or of the government." But it was not included in Article. Instead the term "unfair commercial practices" was included. And, what will amount to unfair commercial use was left to members' discretion.

Article 39.3 provides for protection of test data however use of data by governments is not prevented under it. It rather aims to protect its use by competitors. It does not provide for implementation of protection only in the form of data exclusivity. The same is confirmed by the negotiation history of TRIPS Agreement. If the negotiating parties had agreed to provide for exclusivity, it could have been provided explicitly.

2.2. **Reliance on Data by the Government is not an Unfair Commercial Use**

[25] Correa, *supra* note 3, at 49.
[26] Correa, *supra* note 3, at 50.

Article 39.3 seeks to provide protection against "unfair commercial" uses. An act of competitor deriving benefit from his act of competition or causing monetary loss to another is not, in itself, unlawful. An "unfair commercial use" can be said to exist, for illustration, in cases where a competitor obtains the results of testing data, through dishonest practices such as breach of confidence or fraud and uses them for applying for market approval for its own benefit. It can also be applicable in situations where government provides access to undisclosed test data to provide advantage to a firm which did not produce it or share its cost. It would correspond to contravention of the non-disclosure obligation and an "unfair commercial use."[27] Despite the desire of some TRIPS negotiating parties, the phrase "unfair commercial use", reasonably interpreted, does not mean that Article 39.3 necessitates the provision of exclusivity, or of compensation. It has provided wide room of maneuver for member countries for determining the existence of such a use and the means of protection thereby. Only covers "commercial" uses are covered under Article 39.3. It excludes use by the national health authority for assessing efficacy and toxicity of agrochemical or pharmaceutical products.[28] Article 39.3 does not add to Article 10bis of the Paris Convention. It only incorporates examples of general principles contained in Article 10bis paragraph (2).[29]

2.3. Judicial Interpretation

Ruckelshaus v. Monsanto Co.[30] is related with protection of data submitted for registration of an agrochemical product. Monsanto argued that the opportunity given to a competitor to use Monsanto's original data on payment of compensation denied its "reasonable investment-backed expectation." Rejecting Monsanto's complaint, the Supreme Court held that when Monsanto provided data to the Environmental Protection Agent (EPA), then under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 1910, EPA had freedom to use the submitted data not being trade secrets while determining the application of another, provided that EPA required the subsequent applicant to pay "reasonable compensation" to the original submitter.[31] In absence of any specific provision granting a period of exclusivity, relying on data to approve subsequent

[27] Correa, *supra* note 3, at 40.
[28] STEPHEN LADAS, PATENTS, TRADEMARKS AND RELATED RIGHTS: NATIONAL AND INTERNATIONAL PROTECTION 1676-1677 (3 Harvard University Press, 1975).
[29] Correa, *supra* note 3, at 29.
[30] Ruckelshaus v. Monsanto Co., 467 U.S. 986 (1984).
[31]The Federal Insecticide, Fungicide and Rodenticide Act., 7 U.S.C. § 3(C)(1)(D) (1910).

applications does not result in illegitimate misappropriation of trade secrets. In *Bayer's case*[32] the Court concluded that, provisions of the North American Free Trade Agreement (NAFTA)[33] are meant for protection of trade secrets. If the health authority actually relies on the data submitted by the drug originator to assess generic manufacturer's application, then minimum five years of protection from competition is provided to the innovator. However, if the authority neither examines nor relies on that confidential information for approving the generic, the data is not used and thus, provision of exclusivity does not apply. The issue that whenever Abbreviated New Drug Submission (ANDS) is filed, the applicant must be given five years of exclusivity, was rejected.

4.4. Doha Declaration – TRIPS Flexibilities and Healthcare

Health problems affecting various developing and under-developed nations were recognized at the Doha World Trade Organization Ministerial Conference, 2001.[34] It was realized that WTO TRIPS Agreement should be a part of the broader national and international action for addressing healthcare issues.[35] While it was recognized that intellectual property rights are necessary for development of new pharmaceuticals, however, its effects on prices of medicines was also recognized.[36] During the Doha Declaration, an important step was taken by agreeing that TRIPS does not and should not be a barrier for member states in taking measures to protect public health.[37] TRIPS Agreement ought to be construed and implemented in support of WTO Members' right to protection of public health and promotion of medicines. Thus, member states affirmed that TRIPS provisions provide flexibility in this regard and they can be utilized.[38]

Article 39.3 of TRIPS provides flexibility in defining what would amount to "unfair commercial use" of test data. Thus, taking into account the Doha Declaration on public health, it can be said that data exclusivity is not mandated under Article 39.3. Member states have sufficient flexibility

[32] Bayer Inc. v. The General Attorney of Canada, The Minister of Health, Apotex Inc. and Novopharm Ltd., 1 S.C.R. 533 (2015).
[33] The North American Free Trade Agreement, 1994 art. 1711 (6) 32 ILM 289, 605 (1993).
[34] World Trade Organization, Ministerial Declaration, Nov.14, 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 Para 1 (2002).
[35] *Id*, at 2.
[36] *Id*, at 3.
[37]. *Id*, at 4.
[38] *Id.*

regarding interpretation and application of Article 39.3. They are free to interpret and apply provisions for test data protection keeping in mind their public healthcare needs.

4.5. Test data is not a separate IP

In many jurisdictions, the unfair competition law regulates the misappropriation of trade secrets. Under the discipline of unfair competition, existence of "property" rights is not necessary for protection. The TRIPS Agreement also takes an unfair competition approach for undisclosed information. It neither treats undisclosed information as property nor obligates countries to confer exclusive rights. Article 39.3 refers to undisclosed information "under the control" of a person. This is different from the concept pertaining to provisions concerning other categories of intellectual property rights. During the TRIPS negotiations, U.S. suggested that undisclosed information can be considered as "property."However, it was not adopted.[39]

Conclusion - Data exclusivity is not mandated under TRIPS. It is a TRIPS- Plus provision and member states are not mandatorily required to provide for it. It gives sufficient flexibility to the member states to decide the provisions to govern protection of undisclosed information.

5. Legal Framework in India regarding submission of Clinical Test Data

In India, the Drug and Cosmetic Act, 1940 provides for the requirements for importing, manufacturing, distributing and marketing a drug. The central regulatory authority, Central Drug Standard Control Organization (CDSCO) also called the Drug Controller General of India (DCGI) is responsible for providing authorization to new drugs.[40] As per the Drug and Cosmetic Rules, 1945, second entrants with new dosage forms, new fixed dose combination, new indication, etc. are considered as new drugs which require approval of DCGI.[41] For obtaining market authorization for new drugs, Form 44 is to be submitted to the CDSCO. After getting marketing authorization by CDSCO, an application is made to the State Drug Control Authority for permission for manufacturing the drug through Form 29. The guidelines and requirements for authorizations are incorporated in Schedule Y of the 1945 Rules. For new drugs to get market approval, data has to be submitted proving safety, quality and efficacy of the drug, proven by conducting clinical trials.[42] However, for seeking permission for manufacture of a new drug

[39] Correa, *supra* note 3, at 54.
[40] The Drug and Cosmetics Rules, 1945 Rule 122-E.
[41] The Drug and Cosmetics Rules, 1945 Rule 122-E (b).
[42]The Drug and Cosmetics Rules, 1945, Sch. Y, Appen. I.

already approved in the country, data pertaining to bioequivalence or bioavailability and comparative dissolution studies for oral dosage forms are to be submitted along with the application.[43] Generic drugs fall under this category. A new drug is regarded as "new" up to a period of four years from the date of its first approval.[44] This implies that a generic drug seeking authorization within four years of first authorization is regarded as a new drug and thus, requires approval of DCGI. Once a period of four years from the first authorization expires, the State Drug Control Authority can be approached for market approval of a generic version of the already approved pharmaceutical.[45] To obtain market approval within four years of the first authorization, generic manufacturers have to produce data proving bioavailability or bioequivalence of the drug for approval by DCGI. After a period of four years the innovator's drug is not new. Thus, generic drug manufacturer need not submit bioequivalence tests to the central authorities. It can directly be granted by application to the state FDA authorities.

The Dr. Ranjit Roy Choudhary Committee in 2013 made recommendation that bioequivalence studies should be made mandatory for all generics regardless of the time of their approval.[46] The Drug Consultative Committee did not accept the recommendations of Choudhary Committee on the ground that "infrastructure for conducting such studies is not sufficiently and uniformly available in the country. Thus, it can't be implemented as a rule."[47] However, in 2017, notification was issued by the Ministry of Health and Family Welfare which incorporated the recommendation of Choudhary Committee making bioequivalence or bioavailability tests compulsory for generics.[48] Indian patent regime has not incorporated data exclusivity provision. Generic drug manufacturers are required only to submit data proving bioavailability of the drug. They don't have to conduct clinical trials all over again to seek market approval. The CDSCO will compare the bioequivalence data of generic drug with the clinical trial data already

[43]The Drug and Cosmetics Rules, 1945, Sch. Y, Appen. I-A.
[44] The Drug and Cosmetics Rules, 1945, Rule 122-E Expn. (ii).
[45] Mathew Joe C, *Roche's cancer remedy loses new drug status,* BUSINESS STANDARD (Nov. 15, 2019, 12:30 PM), https://www.business-standard.com/article/companies/pharma-tops-in-patent-suits-110011600017_1.html.
[46] Prof. Ranjit Roy Chaudhary, *Expert Committee to Formulate Policy Guidelines for Approval of New Drugs*, CLINICAL TRIALS AND BARGAINING OF DRUGS (Oct. 12, 2019, 12:30 PM), http://www.indiaenvironmentportal.org.in/files/file/clinical%20trials1.pdf.
[47]Prashant Reddy, *India makes a long overdue move to ensure better drug safety,* SCROLL (Oct. 15, 2019, 10:30 PM), https://scroll.in/pulse/834356/india-makes-a-long-overdue-move-to-ensure-better-drug-safety.
[48] *Ministry of Health and Family Welfare (Department of Health and Family Welfare) Notification (3rd April, 2017)* CENTRAL DRUGS STANDARD CONTROL ORGANIZATION (Oct. 17, 2019, 10:3 PM), https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTgy.

submitted by the innovator drug manufacturer. Thus, Indian patent regime does not follow the TRIPS-Plus standard of data exclusivity.

Conclusion

The TRIPS Agreement gives enough room of manoeuvre to the member states to determine steps for protection of clinical trial data. Data exclusivity is not a TRIPS mandate, rather a TRIPS Plus provision. The Indian Drug and Cosmetic Act, 1940 and the Drug and Cosmetic Rules, 1945 do not provide for data exclusivity. The innovator drug manufacturers have to undertake clinical trials to prove safety, efficacy and quality of the drug, while the generic drug manufacturers have to submit data to establish bioavailability or bioequivalence of the drug. The DCGI is not prohibited from relying on the clinical trial data submitted by the drug originator to grant market approval to the generic manufacturers.