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Judicial Navigation of Drug Name Regulation in India

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Almost two decades back the Supreme Court of India while deciding the trademark disputes related to pharmaceutical products raised serious concerns towards the medicines sold under unregulated similar proprietary names. Thereby the judiciary issued directions to the drug regulatory authority for drug name regulation. However, since then in the absence of a definite regulatory structure, the judiciary has continued navigating the scope of India's drug name regulation. In this context, the article reflects upon the judicial attempts for integrating drug-name regulations in the current regulatory structure, while critically analyzing the judiciary-backed recent amendments in the Drugs and Cosmetics Rule, 1945.

Keywords: Drug Name Regulation, Pharmaceutical regulation, Trademarks, Drugs and Cosmetics Act, Drug Regulatory Authority, Central Drug Standard Control Organization

Pharmaceuticals are the foundation of the health care industry with an intricate nomenclature system. A pharmaceutical can be identified by a brand or a generic name. Generally, a brand name is selected by the proprietor or the /manufacture to designate the source of origin along with marketing and advertising. The generic name is formally placed by the World Health Organization (WHO) with an objective of universal and uniform identification of drugs in prescribing, dispensing and controlling the drugs.[1,2]

India is one of the largest providers of generic drugs in the global pharmaceutical market.[3] It categorically holds a dominant position for the branded generics.[4]The term 'branded generics' is referred to the medicines which are now off-patent and sold under a brand name by companies. These brand names are different from the innovator brand names.[5]Though both, the non-branded and branded generics go through the same drug approval procedure. Branded-generics are identified by their proprietary name in the form of trademarks that let the manufacturers advertise their products and intend to aid consumers towards making the informed decisions. Amidst the circulation of different branded generics, Table 1 represents the list of branded generics ranked as per its moving annual turnover.[6]

It can be observed from the table that the drug market is engulfed with the branded generics, resulting in the availability of bioequivalent products marketed under different brand names. While the drug regulatory authority ensures the marketable drugs' quality, the brand names are regulated by two different authorities under entirely two distinct laws.[7] The drug regulatory authority regulates the quality; safety and efficacy of the marketable drugs, and the drug regulatory law plays a vital role in securing

Table 1 — Top-five branded generic drugs in India

S. No.	Branded generics	Other brands	Indications
1	Mixtard*Novo Nordisk, India*	Humulin M3 *Eli Lilly* NovoMix *Novo Nordisk, India*	Diabetes Mellitus
2	Glycomet *U.S.V.*	Okamet 500 Tablet *Cipla Ltd* Metatime*Mankind Pharma Ltd*	Type2 Diabetes mellitus
3	Spasmo Proxvyon Plus *Wockhardt*	Spaspokran Capsule *Noel Pharma India Pvt Ltd*	Treatment of acute pain
4	Lantus *Sanofi India*	Glaritus *Wockhardt* Basugine *Lupin Ltd.*	Insulin glargine injection
5	Galvus Met *Novartis India*	Gliptagreat *Mankind Pharma Ltd* Vilnip*Lupin Ltd*	Anti-diabetic drug

Source: Business Standard, https://www.business-standard.com/article/companies/here-are-top-20-generic-drugs-in-india-anti-diabetic-medicines-top-list-117051300977_1.html

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public health.[8] On the other hand, the trademark office grants exclusive rights to the proprietor over the trademark/proprietary name of a pharmaceutical drug registered under Class 5, with an objective to protect the registered mark against deception, infringement and thereby avoid consumer confusion,[9]as enshrined under the trademark statute.[9]The Trademark Law also extends its protection to the unregistered trademarks under the common law principle of passing off.

Such parallel administration of drug name regulation by two independent authorities on different standards often results in licensing similar formularies under identical or similar brand names, marketed by different manufacturers. In extreme cases, such similar named medicines treat entirely different medical conditions, which escalate the chances of drug name errors imperiling patients' lives. As an illustration, the proprietary name 'Benzol' used for regulating certain hormones in the body marketed by the company -Solitaire, is similar to the brand name used for the treatment of disease caused by an infestation of parasitic worms. In another example, an anti-diabetic drug marketed as 'Glucar' by *Glenmark Pharmaceuticals Limited* has aural similarity with 'Glucart', a drug used to treat osteoarthritis marketed by the *Juggat Pharma*. This may lead to drug name errors[7] raising doubts about the role of relevant authorities responsible for drug name approval under applicable laws of India. In the prevalent condition, the Indian judiciary has issued the requisite guidelines for drug name regulation while deciding the cases related to pharmaceutical trademarks. The compliance of such guidelines seems exasperated in the prevalent drug regulatory structure.

In this regard, the established legislative and administrative structure for India's drug name regulation is examined in the paper to make a critical analysis of the existing regulating policies for the drug name regulation.

Administrative and Statutory Arrangements for Drug Name Regulation in India

Pharmaceutical regulations have been a combination of legal, technical and administrative guidelines to ensure the safety, efficacy, and quality of medicines, with relevant and accurate product information. Consequently, every marketable drug in India has to go through a regulatory approval process,that assures its quality, safety and efficacy as per the Drug and Cosmetics Act, 1940 (DCA), supplemented with a large body of rules, the Drugs and Cosmetics Rules 1945 (DCR). The process is enforced by a dual administrative, regulatory system consisting of a Central Drug Standard Control Organization (CDSCO) at the Centre and State Drug Regulatory Authorities for each state. The Drug Controller General of India (DCGI) being the head of CDSCO is responsible for the approval of new drugs, clinical trials, standard-setting, import licensing, and licensing to manufacture specific categories of drugs at the central level.[10] The state regulatory authorities are individually responsible for issuing licences for the manufacture, distribution and sale of drugs and monitoring these activities.[11]In the absence of a definite structure for the drug name regulation, trademark protection plays a crucial role in preventing drug name errors by granting an exclusive right to the registered proprietor of the brand names in the form of trademarks.

In practice, the pharmaceutical companies prefer to file a bona fide 'proposed to be used' trademark application,[11]before the formal authorization from the drug regulatory authority. A uniform standard is followed for examining the trademark applications, irrespective of the class of goods. Hence, no separate criteria is followed for the pharmaceutical products, except prohibiting the registration of generic and chemical names, compounds and International Non-Proprietary Names (INNs), or names that are deceptively similar to such names.[12]

Specific provisions of the DCA can be interpreted to include drug name regulation in the purview of the provisions that prohibit the manufacture and sale of any misbranded, adulterated or spurious drugs.[12] However, the restrictive definition of 'misbranded drug' as defined under Section 17 of the Act merely considers the labeling and colour of the product itself without comparing or cross-checking other aspects related to the effect of the drug name.[13]Similarly, the definition of 'spurious drugs' under Section17 B (e) can be interpreted to include the drugs' proprietary name.[14] However, it lacks the structure for controlling the look-alike and sound-alike proprietary names of drugs against confusion, there being chances of gross medication errors due to similarity in brand name with similar or different formulations altogether. It raises apprehensions about the availability of safe and genuine medicines in India, affecting India's credibility of drug products. Therefore, in the absence of specific statutory and regulatory arrangements for

drug name regulation, the Indian judiciary has been playing an active role in regulating drug name errors and has issued guidelines to the responsible authorities

In this context, the following section describes and critically analyses the judicial decisions that pointed out the shortcomings, including the lack of regulatory structure for drug name regulations and accordingly laid the directions for drug name regulation.

Judicial Cognizance of Regulatory Challenges in Drug Name Regulation

The disputes arising from similar proprietary or brand names of the pharmaceutical products are predominantly settled through the civil suits for trademark infringement, restoring the rightful owner's exclusive rights, including the claims of passing off. However, in some instances, Therefore, the judiciary has made attempts by issuing directions for the drug name regulation to prevent the occurrence of drug name errors. In this reference, a judicial analysis of relevant cases is chronologically conducted in two sections. The first part highlights the principles laid by the Supreme Court (SC) of India in the landmark decision of *Cadila Health Care Ltd*. v *Cadila Pharmaceuticals Ltd*[15] (Cadila Case), followed by the guidelines and directions issued by the higher judiciary, emphasizing the guidelines issued by the High Court of Delhi in the case of M/S. *Curewell Drugs & Pharmaceuticals, Pvt. Ltd.* v *Ridley Life Sciences Pvt. Ltd.*[16](Curewell case). This section elaborates the judicial journey of the framework that began with the Cadila case in the year 2000 and ended with the Curewell decision in the year 2019.

The issue of the lack of an efficient regulatory mechanism for drug name evaluation was first addressed in the SC's decision in the Cadila case.[16]While contemplating the drug regulatory authority's responsibility, the SC laid the guidelines for drug name regulations in India. Through these guidelines the High Court of Delhi, almost two decades later, in the case of Curewelldrugs, get the framework devised by the responsible authorities and secured its enforcement through the Drugs and Cosmetics (Thirteenth Amendment) Rule, 2019.

The SC's Decision in the *Cadila Health Care Ltd.* v *Cadila Pharmaceuticals Ltd.*: Drugs are poisons, not sweets

The decision has set a precedent for the trademark infringement and passing off cases, primarily associated with medicinal products and prompted the need for drug name regulation in India.The cause of action arose when both the parties after the restructuring of the erstwhile Cadila group were using 'Cadila' as a Corporate name. Yet, both the companies were manufacturing Schedule L drug,[15] for the treatment of cerebral malaria, also known as 'Falcipharm' in medical terms. The parties respectively marketed the drugs as 'Falcigo' and 'Falcitab'. It is essential to observe that both the parties received authorization for the drugs from the DCGI to manufacture and market the drug under the respective brand names without trademark registration. Nevertheless, the appellant filed a suit of passing-off and pleaded an injunction against the respondent for using the trademark 'Falcitab'. The trial court refused to grant an interim injunction, and the High Court upheld the order and SC while refusing to interfere with the orders, set-out the principles, reasoned as:

> *Drugs are poisons, not sweets. Confusion between medicinal products may, therefore, be life-threatening, not merely inconvenient. Noting the... pressures placed by society on doctors, there should be as many clear indicators to distinguish two medicinal products foreach other.*

The Court acknowledged the situations with high chances of drug name errors. For instance, as part of the general practice, the drugs can be requested verbally under critical situations. Many patients who may be elderly, uninformed or illiterate may not be able to differentiate between the medicine prescribed and bought, which is ultimately handed over to them.[15] Thereby, the Court emphasized that India has a variable infrastructure established on diverse linguistic, urban, semi-urban and rural divide across the country, due to which, despite the specialized supervision of physicians and pharmacists of a medical professional, the consumers run at a high degree of possibility of accidental negligence.

To resolve the issue, the court relied on the definition of the 'spurious drug',[14] under Section 17-B of DCA[14] and emphasized the responsibility of the drug regulatory authority towards conducting a prior assessment of proposed proprietary names of the drugs. The Court thereby directed the concerned authority to ask the applicants to submit an Official Search Report, pertaining to trademark in question, to

be collected from the Trade Mark Office, to enable the Drug Authority to arrive at a correct conclusion.

This decision marked the beginning of the judicial inclination to implement an effective drug name regulatory mechanism for the pharmaceutical trademarks. As it is visibly evident in the post-Cadila decisions. An analysis of such judicial opinions is elaborated in the following part.

_Cadila_Judgment - Implementation of Drug nd Cosmetics (Thirteenth Amendment) Rule, 2019

Where a Court makes a decision that contains in itself a principle, it creates a judicial precedent.[17]The guidelines laid by the SC in the *Cadila* case became a source of law for drug name regulation in India. However, in the absence of an efficient mechanism in place, the courts continued to reflect upon the public health concerns through the cases of the pharmaceutical trademark-related disputes from laying the principles for drug name regulations.

***Bio-Chem Pharmaceutical Industries* v *Astron Pharmaceuticals and Assistant Registrar of Trade Marks*[18]**

The High Court of Delhi in 2003, reiterated the SC's directions and elaborated it further. The trademarks involved in the case were, 'Biocilin' and 'Bicillin'. The Court found it to be driven from the two drug components, namely, 'Bi' means two, 'Ceillin' standing a mixture of Ampicillin and Cloxacillin.

After examining the facts, the Court reprimanded the non-fulfillment of the guidelines issued by the SC in the Cadila decision.[19] Further, it identified the two significant barriers in implementing the SC's directions and proposed solutions. The primary identified barrier is the applicability of multiple statutes, enforced through different authorities acting differently, creating more confusion. The second barrier was recognized as the absence of a centralized drug authority office system for allotting names, as Central and State Regulatory Authorities work independently of one another. These barriers result in an irregular and non-uniform compliance of the directions issued by the relevant authorities. As the Court marked, "*some drug controllers may respond while others may sleep over the matter*".

Therefore, to avoid the confusion caused due to multiple statutes and authorities, the Court opined that any direction issued to the Drug Regulatory Authority must also be issued to the Registrar of Trademarks, *so that the right-hand knows what the left hand is doing*. There is no conflict, and any problem of this kind is sorted at the very initial stage. Also, to avoid overlapping, the Court proposed a standard system for sharing the requisite information involving the Drug Controllers; the Registrar of Trademarks and similar other authorities through the online medium. In furtherance, to make it a cost and time-efficient process, the Court recommended cross-checking of the data received from the respective authorities. This will also enable the drug controllers to differentiate between spurious drugs and genuine drugs. For its effective implementation, the Court urged the Law Commission and the Ministry of Law for making necessary amendments for furnishing information on the internet in various Acts and Rules for the aforesaid purpose.[19]

Despite the directions issued by the court in these cases, the implementation on the part of the concerned authorities was missing. Hence, it was treated as a matter of concern by the judiciary, as reflected in the following decisions.

***Milmentofth*ov *Allergan Inc.*[19]**

The SC discovered that an identical trademark-'Ocuflox' used for eye care products containing the chemical composition Ofloxacin was already approved and registered with the drug regulatory authority as a Schedule 'H' drug. In this reference, the court expressly referred to the Cadila decision and observed that amidst lack of competence, Schedule 'H' drugs may still be sold across the counter and confusion and mistakes could arise. Thereby, it held that exacting judicial scrutiny is required when a court is dealing with medicinal products.

Similarly, recently in the case of *Grandcure Healthcare Pvt Ltd* v *M/s Finex Healthcare Pvt Ltd,*[20] the Court followed the SC's dictum in the Cadila decision and injuncted the defendants from using the trademark 'Fravia' after finding it similar to the plaintiff's mark 'Bravia'. To ensure its implementation, the copy of the order issued in the case was sent to the DCGI and to the Controller General of Trade Marks, with the purpose to ensure that the drug licence issued to the*Finex Healthcare Pvt. Ltd.* and *Elfin Drug Pvt. Ltd*. for the mark 'Fravia' is cancelled within eight weeks. In this context the DCGI and Controller General of Trade Marks were also directed to file an affidavit stating the steps taken in compliance with the directions contained in the SC's judgment in *Cadila Case*.

Based on these decisions, it is evident that each court while following the dictum laid in the Cadila case, persuaded the regulatory authority to place a

mechanism for drug name regulation, to avoid unnecessary disputes and to secure the public from medication errors. Finally, as elaborated,in the case of *Curewell Drugs Pharmaceuticals Pvt. Ltd* v *Ridley Life Sciences Pvt. Ltd.*[17](Curewell case) the HC of Delhi mandated the DCGI to regulate the use of similar marks in pharmaceuticals.

The Curewell Case

This decision has fundamental role informing the drug name regulation in India. The court, while pointing out the non-compliance of the SC's directions by the drug regulatory authority, given in the Cadila case, granted the DCGI three months to draft the rules regulating identical brand names in pharmaceuticals. Consequently, the final rules were notified as law through publication in the official gazette on 31 December 2019. Along with this, the Court issued supplementary guidelines for the creation of a secured platform and electronic database to monitor infringing brand names and sharing a list of the trademarks registered in International Class5(pharmaceuticals and medicinal preparations) with State FDAs and Drug Controllers.

Similar to the previous judgments, in this case, the defendant was injucted to use the identical trademarks and packaging-'Bevital' in relation to a multivitamin supplement. Besides the disputes related to trademark rights between the parties, the court also noticed that the Drug Authorities overlooked and approved two identical trademarks submitted by two different applicants. In this relation, the court reiterated the SC's Cadila guideline that the authorities must demand a search report issued by the trademark authorities from the applicants, before drug approval. Recurrence of the same issue reflected the need for a required mechanism for the drug name regulation. Consequently, in reply to the notice, served to the DCGI, it was informed that as per the practice, the drug licences are granted only under the generic name and that there is no mechanism in place to implement the decision of the SC

In this context, the court highlighted that the drug regulatory law's objective is to ensure the quality, safety, and efficacy of the medicines. So, if products are sold with identical brand names, that primary purpose stands defeated. Accordingly, with an objective to frame the required mechanism the court directed the Secretary- Ministry of Health along with the DCGI and state drug regulatory authorities to hold an inter-se consultation amongst themselves and also take suggestions from other stakeholders. Subsequently, after consultation and recommendations, the rules were drafted and published as the Drugs and Cosmetics (Amendment) Rules, 2019.

For its efficient enforcement and regulation, the court also issued supplementary, non-exhaustive directions for the authorities, mentioned as follows:

Creation of a secured platform; under the supervision of the DCGI, which is accessible to all State FDAs, both for access to data and for uploading of data;

Creation of a 'master electronic database' of all the approved brand names for manufacture and sale of drugs issued by the DCGI and the State FDAs and making the same available to all states FDAs and Drug controllers through a secured platform. The list to be maintained and made available both brand wise and manufacturer wise, on the secured platform;

List of registered trademarks under Class 5 for pharmaceutical and medicinal preparations be obtained from the Controller General of Patents, Trademarks and designs and made available to the approving authorities at the Central and State levels. The said list ought to be updated bi-annually, i.e., on 1st January and 1st July every calendar year;

(i) Access to the data be given to Drug Inspectors/Drug Controllers across the country;
(ii) Drug Inspectors/Drug Controllers conduct regular and periodic inspections as per the Act and the Rules to ensure that the drugs manufactured in a particular unit are duly licenced. The reports of the said inspections are to be submitted through the secured platform;
(iii) Periodic and regular reports of drug inspectors should be compulsorily submitted to the respective licensing authorities on the secured platform, and a mechanism be set up for the review of the said reports at the State level;
(iv) Periodic meetings ought to be held at the central level, to review the status of manufacture and sale of drugs across the country, under the aegis of the DCGI;
(v) Strict action according to law ought to be taken against manufacturers who manufacture drugs without licences, indulge in adulteration or contamination of drugs, etc. A periodic report as to the number of actions taken, ought to be uploaded on the secured platform of the DCGI.

With this decision, the awaited mechanism for drug name regulation came into existence. However, its efficiency in resolving the issue is still debatable because of the existing government directions to promote generic drugs and the standard practices adopted for years. With this view, the pre and post amendment condition is analyzed in the next section.

Pre and Post Drugs & Cosmetics (Thirteenth Amendment) Rules, 2019 and its Supplementary Directions Issued By The Court

Prior to the enactment of the Drugs and Cosmetics (Thirteenth Amendment) Rules, 2019, the drug licences were granted by the competent licensing authorities on proprietary and generic names as applied by the applicants, without inspecting the proprietary names on the grounds of similarity or confusion arising out of the look-alike or sound-alike drugs. However,it prohibited the manufacture and sale of 'Spurious'[15] and 'Misbranded' drugs,[14]contraventions of which will invite the criminal sanctions.[21]Similarly, the labeling provisions mentioned under the Rules[22]also direct the applicants to adopt labeling practices of enhancing the proper name's visibility (generic name) besides the proprietary name of the medicinal product.

Interestingly, in the year 2012, the Central Government issued directions[23]under Section 33(P) of DCA to the licensing authorities to grant or renew manufacturing licences of drug formulations in proper or generic name only. The direction was backed by the reason that generally while granting the license to manufacture a drug formulation, the trade name/brand name applied by the manufacturer is also endorsed by the licensing authority that gives the legitimacy to market the drug under the brand or the trade name,[24]which ultimately adds to the reason for the availability of medications at an unreasonable hiked priced. Though the objective of the direction was to promote generic drugs, instead, it created more confusion among manufacturers that lead to many criticisms. Nevertheless, the direction nowhere seems to have conveyed the elimination of trade or brand name but instead directed the grant of the licence only under the generic name. Hence, after obtaining the licence in the generic name, the manufacturers are free to accord any trade or brand name to the formulation. With its effect, the applicable provisions that were interpreted for regulating drugs' proprietary names also went redundant.

Finally, the High Court of Delhi instructed the competent authorities to come with the legislative measures for regulating brand names, resulting in the enforcement of the Drugs and Cosmetics (Thirteenth Amendment) Rules, 2019. However, its effectiveness is still questionable on certain grounds. The Rule merely introduced an undertaking through Form No. 51, to be filed by the applicants seeking a licence for manufacture to sale or distribution of the drug. But, it is silent about the role and mechanisms for examining a brand name or to keep this undertaking in records and how the regulatory authority shall endure the correctness of undertaking given by the applicants. Consequently, the mechanism may fall short on the ground of imposition of liability in case of default approval of a similar mark. Also, due to the lack of effective centre-state coordination, the implementation of the Rule would not be uniform across the country. In short, the Rule has merely articulated a pressure on the applicants without any administrative mechanism or standards in place.

Suggestions and Recommendations

Based on the analysis drawn from the *dicta* articulated by the Indian judiciary, the interpretations constructed to the prevalent provisions of the legislative instruments along with the approaches employed by the administrative authorities, an efficient mechanism in following steps can be suggested for the drug name approval that can be devised under the aegis of the CDSCO.

The regulation can begin with implementing an online repository in the form of a 'master electronic database' comprising relevant data submitted by all the state licensing authorities. The database will comprise a list of manufacturer-approved brand names issued by the DCGI and the State FDAs. The data submitted will be accessible to all state drug regulators, drug controllers and drug inspectors through this secured platform. All manufacturing licence holders are also instructed to register with Portal SUGAM[25]and upload the information in the said portal, pertaining to licences granted for manufacture for sale and distribution of the drug.[26]Thus, information uploaded in the SUGAM portal may be utilized by CDSCO to create a master electronic database. The SUGAM portal can be utilised to make a database of all available brand names/trade names of drug formulations, across the country. The database of already existing brand

names can also be prepared based on the information augmented with the list of registered trademarks under Class 5 for pharmaceutical and medicinal preparations, obtained from the trademark registry.

As per the powers vested under the DCA, the Drug Inspector will ensure regular and periodic inspections of the drugs that are being manufactured in a particular unit are duly licenced. The periodic and regular reports of the said inspections are to be submitted to the respective licensing authorities through the secured platform. Finally, to review the status of the manufacture and sale of drugs across the country, the court directed to convene periodic meetings at the central level, under the aegis of DCGI. After the review, strict action according to law ought to be taken against those manufacturers who manufacture drugs without licences, who indulge in adulteration or contamination of drugs and its periodic report as to the number of actions taken uploaded on the secured platform of the DCGI.

Conclusion

Based on the analysis drawn from the decisions, it can be deduced that a pharmaceutical trademark infringement dispute attracts two significant issues. First is the fact-based issue, whether an infringement is there or not. Secondly, a principle-based issue that calls for a systematic regulatory mechanism for drug name regulation. Thereby, the issue raised due to the absence of a regulatory mechanism for preventing the marketing of pharmaceutical products under identical or similar brand names has been dealt differently in different cases following the principles laid in the Cadila case. Hence, this amendment supplemented by the court's directions can be seen as a positive step towards overcoming the drug name errors. But the prevalent gaps in the substantive law raise doubts about its enforceability. To clarify further, the DCA has not defined either the term 'brand' or 'trademark' or 'proprietary name' so far. However, the Drugs and Cosmetics (Amendment) Bill, 2017 proposed to define the term 'brand' under Section 2(aai) as "*a name, term, design, symbol, trademark or any other feature that identifies one seller's drug as distinct from those of other sellers*". This gap reflects a coherence between the practice originating from rules and the parent Act.

Moreover, in the absence of a validated central database of brand names, it would be difficult and arbitrary to reach uniform conclusions by the different State licensing authorities. Consequently, disharmony can be witnessed throughout the process. First is administrative disharmony between Trademark Registry and Drug Regulatory authority; and between states and central drug regulatory bodies, as pointed out in the BioChemCase.[19]Second there is an evident disharmony between the government policy for promoting generic drug names over the proprietary name, distressing the emerging regulations and judicial efforts towards placing a standard mechanism for drug name regulation. Amidst all these obstructions, the Drug and Cosmetics (Thirteenth) Amendment Rule, 2019 has laid the basis of a regulatory framework. However, the outcome of the Rule, in the absence of authorities' accountability is still doubtful. Nonetheless, the courts' guidelines to form a transparent online master database may bring efficiency in the drug name regulation which will be reflected in the days to come.

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(a) if it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is;

(b) if it is not labelled in a prescribed manner; or

(c) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.

14 Section 17 B (e) of The Drugs And Cosmetics Act, 1940, 'Spurious drugs';—For the purposes of this Chapter, a drug shall be deemed to be spurious,—(a) if it is manufactured under a name which belongs to another drug; or(b) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or (c) if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug,which individual or company is fictitious ordoes not exist, or (d) if it has been substituted wholly or in part by another drug or substance; or (e) if it purports to be the product of a manufacturer of whom it is not truly a product.

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