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An Incursion into Certain Legal Aspects of Patient Safety

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I. Introduction

A patient seeks either alone or with one's guardian or attendant a medical professional for prognosis, diagnosis and treatment. It may or may not involve hospitalisation, but treatment may stretch over a period of time. Depending on the jurisdiction one belongs to there may be a variation in the process of consultation and treatment. During the course of treatment the patient is entitled to certain information and consent is an important requisite in proceeding with treatment. Such treatment is with a view to obtain relief from the sickness or illness, as the case may be. It involves aspects of quality health care and appurtenant issues.

The quality and safety aspect of healthcare is of utmost importance in health delivery. One of the cornerstone principles here is that there should be no further harm to the already sick people. Quality healthcare, besides involving a quality of medical equipment in healthcare, also includes quality handling of apparatus and quality handling of processes and medical interventions.

Patient safety is a discipline that emphasizes safety in healthcare through the prevention, reduction, reporting and analysis of medical error that often leads to adverse effect. Many aspects or elements are involved.

For a person or any living being to function effectively with fully-abled potential, or otherwise to be able to execute desires and potential and explore the more of it, health is the foremost constituent. In common parlance, an enquiry as to one's health may refer to one's physical health. However, the meaning of it and the facets that health is inclusive of both mental and physical is recognized globally by medical field as well as law. Medical errors, besides resulting in additional costs for hospitalization, litigation, hospital acquired infections, loss of income and disability etcetera also cause erosion of trust, confidence and satisfaction among the public and health care providers.

II. Definition and Meaning of the Concept of Patient Safety

Patient safety is a serious global public health issue. Patient Safety means prevention of harm to patients during hospital care and/or health care. It is about eliminating preventable medical mistakes by care givers, guarding against the impact of human error and establishing system safeguard patient's health and well being. In recent years, countries have increasingly recognised the importance of improving

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patient safety. It demands a complex systematic effort, involving a wide range of actions on a collective basis in performance improvement, environmental safety, safe clinical practice and safe environment of care (World Health Organisation,2002).[1]

In 2002, World Health Organisation member states agreed on a World Health Assembly resolution on patient safety. In fact, though the terminology "patient safety" was formed in 2004, momentum to this movement arose only after initiative was taken to include patients for Patient Safety in March 2006 in London Declaration.[2] Further action on "Patients for Patient Safety" was evident in Jakarta Declaration, July 2007.[3]

III. Patient Safety in India

India has taken up patient safety issues on a priority basis in the form of a new initiative, namely "Hospital Patient Safety Initiative" post the signing of India Pledge on Patient Safety by Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India in July 2006. The aims of this initiative include a successful and healthy outcome of patient care, safe and error free care, making available the most expert and advanced medical care for patients, comfort and peace of mind for patients and healthcare providers.[4]Some of the activities started under this initiative include constitution of patient safety committees in centrally administered tertiary care hospitals in Delhi, namely Ram Manohar Lohia Hospital, Safdarjung Hospital and Lady Harding Medical College along with the inclusion of representative of a non-governmental organization, a journalist and one patient or his or her attendant apart from other members of the hospital. Further, the initiative has been mandated to develop a training module on patient safety for the hospital staff, introduction of check list for safety of surgical patients of ward and operation theatre, introduction of auto disabled syringes, introduction of adverse reaction reporting cell, processing correction studies to improve processes like time taken to attend a newly arrived patient in a trauma centre. The tasks further involve introduction of trainings in infection control and biomedical waste management for different levels of health workers, regular monitoring of quality of water supplied in the hospital, devising safety norms for patients in vital areas of hospital, conducting regular death review meetings, training of senior resident doctors in giving Direct Shock, obtaining feedback from Grievance Cell, implementation of patient safety measures in Out Patient Departments in the

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[1] http://www.who.int/patientsafety/en/brochure_final.pdf (accessed on 15th November 2017)

[2]http://www.who.int/patientsafety/patients_for_patient/London_Declaration_EN.pdf (accessed on 17th November 2017)

[3] http://www.who.int/patientsafety/patients_for_patient/jakarta_declaration.pdf (accessed on 19th November 2017)

[4]supra,note2

form of single window approach, 'May I Help you Counter' and proper signage system etcetera[5].

IV. Provisioning and Regional Strategies

Patient Safety also finds place in the draft National Patient Safety Implementation Framework (NPSIF) which states that Patient Safety is a fundamental element of healthcare.[6] In 2015, during the 68th World Health Organisation Regional Committee for South-East Asia, all Member States of the region including India endorsed the "Regional Strategy for Patient Safety in the World Health Organisation South-East Asia Region (2016-2025)" aiming to support the development of national quality of care and patient safety strategies, policies and plans and committed to translate six objectives of the Regional Strategy into actionable strategies at country level.[7]In this context, Ministry of Health and Family Welfare, Government of India has constituted a multi stakeholder Patient Safety Expert Group in August 2016 that was given a task to operationalize patient safety agenda at country level and develop a National Patient Safety Implementation Framework, which was finally released by the Ministry of Health and Family Welfare identifying some challenges in patient safety. These challenges include unsafe injections, biological waste management, medication and medical device safety and high rates of health care associated infections.[8]

One of the key provisions of the Draft Framework is that it shall be applicable to both public and private sectors across different elements of health care provision, including prevention, diagnosis, treatment and follow up. Patient safety is said to be all about safe drugs dispensing, surgical care, safe childbirth, injection safety, blood safety, medication safety, medical device safety, safe organ, tissue and cell transportation and donation etc. Some of the parameters to ensure it are physical safety which include safety of health care infrastructure including designing, planning and maintenance of hospital infrastructure, safety of electrical installation which involves secured wiring, adequate earthing, availability of standard and adequate power outlets, display of danger signs and a system of periodic check up, power audit of electrical installations in the hospital, special areas requiring high power load(Intensive Care Unit, Cardiac Care Unit, Sick Newborn Care Unit). These are few areas needing special attention for the safety, safety of engineering and support services, fire safety which includes availability of fire extinguisher ,fire exit plan, training and mock drill of staff for using firefighting equipment and evacuation too have been provided for under the Rules. Besides,

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[5] id

[6] http://rstv.nic.in/patients-safety-fundamental-element-healthcare-ministrys-draft-framework.html (accessed on 20th November 2017)

[7] http://www.searo.who.int/entity/patientsafety/documents/en/ (accessed on 20th November 2017)

[8] http://www.livemint.com/Politics/6FxVaaDcbgfXRvWwCiIqtI/Centre-proposes-law-to-protect-hospital-patients-personal-i.html (accessed on 20th November 2017)

safe environment in hospital in the form of proper cleaning and decontamination of patient care and procedure areas like labour table, Operation Theatre, wards, injection rooms, dressing room etc. proper segregation, storage and disposal of biomedical waste as per the guidelines(Biomedical Waste Rules 1998),ensuring adequate air exchanges especially in high risk areas(Intensive Care Unit, Sick Newborn Care Unit, Operation Theatre etc.) have also been provided for. In addition, proper sewage disposal and prevention of water logging in healthcare facility, safety of clinical care like ensuring proper hand washing practices among the care providers, proper disinfection/sterilization of surgical instruments and surfaces, use of personal protection equipments like gloves, masks, apron and periodic immunization and medical checkup of the care providers are required to be taken care since they are taken for granted but not effectively supervised. These apart, other areas include medication safety, monitoring and reporting of adverse events like hospital acquired infections and adverse drug reaction.[9]

The aim of patient safety is not to play a blame game but successful, healthy outcome with safe, error free care, resulting into comfort and peace of mind for patients and care providers.

V. Medication Safety

Patient safety issues and concerns very much involve proper medication. Though people may take it very simply as taking of the prescribed medicines, there is much more to it. Medication use in fact is a complex process that comprises the sub-processes of medication prescribing, order processing, dispensing, administration and effective monitoring on which lie the recovery process of the patient. If medication safety is compromised, the result would be occurrence of medication error which is any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care professional, patient or consumer.[10] Such events may have relation either to professional practice, health care products, procedures and systems including prescribing, order communication, product labeling, packaging, nomenclature, compounding, dispensing, distribution, administration, education or monitoring and use[11].

Some key elements that affect the medication-use process are patient information, drug information, communication of drug information, drug labeling, packaging and nomenclature, drug storage, stock, standardization and distribution, drug device acquisition, use and monitoring, Environmental factors, staff

[9] https://www.health-e.org.za/wp-content/uploads/2016/01/Final-Draft-National-Policy-to-manage-Patient-Safety-Incidents-in-South-Africa-18-Dec-2015.pdf (accessed on 24th November 2017)

[10] http://www.who.int/patientsafety/medication-safety/en/ (accessed on 25th November 2017)

[11] https://www.ncbi.nlm.nih.gov/books/NBK2656/9(accessed on 21st November 2017)

competency and education, patient education, quality processes and risk management.[12]

VI. Pharmacovigilance

Medical safety begins from the stage of discovery of a drug to its dispensation out in the market. Once it is out for customers to be able to access it in pharmacies post prescription by a doctor, the branch which governs the safety of these drugs/ medicines /medications are Pharmacovigilance. Speaking of safety of medicines/ drugs, once they are in the market, the source of knowing whether they are safe or not lies in the consequences it offers or leads to. If the medicines result in undesirable effects further resulting to a large scale morbidity and mortality, the medicines /drugs are said to have resulted in what is termed as 'Adverse Drug Reactions'. Hence, what is necessary is a collective monitoring system right from the stage of discovery of a drug to its release in the market, and the process whereby adverse effects are detected through regular monitoring after the release of a drug in the market is called Pharmacovigilance.

In India, The Central Drugs Control Organisation is the apex regulatory authority for the purpose of approval of drugs efficacy and quality of drugs and medical devices. Pharmacovigilance is important as many a time, only after a drug is dispensed to the market outside and only after it is available to and have been taken by patients, are its adverse effects known. In this regard, one of the things holding importance is the fact that the process of Pharmacovigilance involves stages of detection, assessment understanding and prevention of adverse events. The rules and responsibilities of the Central Drugs Control Organization are as per the Drugs and Cosmetics Act.

The Pharmacopoeia Commission formed in terms with the above Act functions as the National Coordination Centre for the Pharmacovigilance Programme of India (PvPI) and the Adverse Drug Reactions Monitoring Centres reports Adverse Drug Reactions to the National Coordination Centre, which is the Indian Pharmacopoeia Commission.[13]

The Central Drugs Control Organisation notified important safety label changes on drugs such as carbamazepine and piperacillin+tazobactum in the year 2015 and other drugs are under monitoring for regulatory interventions.[14] *Hospitalisation due to adverse drug reactions are evident in places like England, United States of America too, meaning instances of*

[12] http://ismp.org/communityRx/aroc/files/Key_Elements.pdf (accessed on 26th November 2017)

[13] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5155460(accessed on 25th June,2019)*

[14] id

adverse drug reactions occur there too. However, the issue with India is lack of monitoring and reporting.[15]

Indian Pharmacopoeia Commission is that autonomous body under the Ministry of Health and Family Welfare, Government of India which is tasked with formulating/setting standards of drugs in the country, keeping up with the Drugs and Cosmetics Act. Apart from the task of updating regularly the standards of drugs, it publishes official documents for improving quality of medicines in the form of Indian Pharmacoepoeia which has the recognisation of the official book of standards for drugs manufactured and/or marketed in India. The Indian Pharmacopoeia standards are authoritative to the extent that in cases of disputes in the court of law, the IP standards are legally acceptable.[16]

The Drug Controller General of India(DCGI) recently wrote to all state drug regulators directing manufacturers of certain antibiotics and anti psychiatric drugs to include their new recorded adverse effects in the leaflets inside the package with a view to promote patient safety.[17] According to the letters sent by the DCGI following a report of the Indian Phatrmacopoeia Commission, post collection and analysis of reports of adverse effects associated with the use of certain drugs and scientific findings sent to the Central Drugs Standard Control Organization, commonly used antibiotic like Cefotaxime was found to be causing angioedema-rapid edema, or swelling of the area beneath the skin or mucosa. Similarly, the use of Cefixime leads to rapid development of sterile pustular lesions, fever and leucocytosis. Another antibiotic, named Ofloxacin which is useful in the treatment of certain bacterial infections was found to be developing Stevens-Johnson Syndrome, a rare and life threatening skin reaction. Yet another drug named Quetiapine, an antipsychotic drug used for the treatment of schizophrenia, bipolar disorder and major depressive disorder was stated to cause urinary incontinence[18]. One more similar instance is alert being issued by the Indian Pharmacopoeia Commission (IPC) regarding two drugs named Dabigartan and Sertraine that were reported to having led to severe adverse events in the vision and neuro system. Dabigartan, which is recommended for prevention of stroke ,systemic embolism and reduction of vascular mortality in adult patients with cardiovascular diseases and Sertraline which is prescribed for major depressive disorders, obsessive compulsive disorders and panic disorders were found to cause unpredictable hair loss and damage to the part of the eye which is responsible for the central vision[19].

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[15] id

[16] https://www.ipc.gov.in/#sskltbsResponsive2(accessed on 25th June,2019)

[17] https://www.livemint.com/companies/news/dcgi-directs-manufacturers-to-incorporate-adverse-effects-in-leaflets-1555589048342.html(accessed on 25th June 2019)

[18] Supra, no.16

[19] https://www.deccanchronicle.com/nation/current-affairs/180419/vision-blurring-drugs-put-on-alert.html(accessed on 25th June 2019)

The World Health Organization defined Adverse Drug Reaction as a response which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function. In fact, the IPC directs healthcare professionals to report adverse events to the website in the format available.

Bodies that play a role in medicine safety include pharmaceutical companies that develop, test and produce medicines, regulatory agencies that approve the use of medicines, doctors who prescribe medicines, pharmacists and nurses who dispense and provide counseling relating to medicine and medication, and patients who take medicines and relatives who give medicines to those they care for.[20]

Hence, a number of stakeholders are involved, though much is not being thought of. The lack of a proper system of pharmacovigilance is one of the factors posing hurdle in medication safety. Proper use of medicines requires proper standard treatment guidelines, therapeutic intervention and other medical intervention. Basically, the major function of the IPC, which functions as the National Coordination Centre is to collect, collate and analyse Adverse Drug Reactions and report it to the NPC. Some of the reasons of Adverse Drug Reactions may be prescription of high number of drugs, lack of formal system for monitoring adverse drug reactions, ever increasing number of drugs in the market etc.

Adverse Drug reactions can either be augmented (meaning it is dose dependant and that severity increases with dose), bizarre, continuous drug use, (meaning it occurs as a result of continuous drug use), delayed (meaning, it occurs after the cessation of treatment), end of dose (meaning, withdrawal reactions), failure of therapy(meaning, it results from ineffective treatment).[21]

VII. Legislative Endeavour

One of the legislative endeavours by the Government of India occasioned when it took a landmark decision to introduce the National Health Bill, 2009. The bill recognises health as a fundamental human right and states that every citizen has a right to the highest attainable standard of health and well-being.[22] The National Health Bill of 2009 also presents a policy window for the government to overhaul medical education and truly integrate all systems of medicine, as envisaged in the National Health Policy of 2015.[23]

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[20] http://cdn.intechopen.com/pdfs/31746/InTechEthics_in_pharmaceutical_issues.pdf (accessed on 1st December 2017)

[21] jact04i1p27)(Vikas Dhikav,Sindhu Singh,KS Anand, Clinical Pharmacology, Adverse Drug Reaction Monitoring in India (accessed on 27th June 2019)

[22] http://www.prsindia.org/uploads/media/Draft_National_Bill.pdf (accessed on 5th December 2017)

[23] https://thewire.in/99213/health-commission-bill/ (accessed on 7th January 2018)

VIII. Blood Transfusion-Another Vital Count for Patient Safety

One of the vital aspects of patient safety is that of safe, proper and prompt blood transfusion in case of need. Many patients need to be provided blood transfusion on a very urgent basis and their plight depends much on the timely supply of blood and its quality as well. Blood Transfusion should be savior of life and not a danger to life. In a country where nearly two-thirds of injections are administered in unsafe manner (62.9%) (India CLEN Study 2002-04) [24] one has be to particularly vigilant to ensure that contaminated blood in any manner is not transmitted to a patient.

The acute medical services could not be envisaged to exist without blood banks or any such facilities providing for transfusions, as it is life-saving treatment in many situations. Transfusions can also be a quick and easy route for the transmission of infectious agents such as Human Immunodeficiency Virus, Hepatitis B Virus, Hepatitis C Virus and malaria. Hence, safe blood transfusion has been mandated by law and related policies. Laws related to blood transfusion services exist in India as a part of the Drugs and Cosmetics Law under the Drugs and Cosmetics Act, 1940.

In the developed world, most blood donors are unpaid volunteers who give blood for a community supply. But the country with such a gigantic populations suffers woefully for want of awareness on this count, leading to grave scarcity of blood that should be available and in adequate quantity. In order to augment safe blood transfusion services in India there is a need to develop operational legal guidelines on recruitment and retention of voluntary blood donors to direct related organizations for this imperative activity.

At the international level, the World Health Organization has identified blood safety as one of the priority areas. The theme of the World Health Day for 2000 was 'Blood Saves Life: Safe Blood Starts with Me.' But the campaign or its mandate is yet to achieve the desired objective. It is one of the chosen areas where World Health Organisation has been requested to accelerate technical cooperation.[25]

Blood transfusion services is an integral and indispensable part of the National Health Service. Without blood transfusion, effective management of severe trauma, major elective surgery, and serious obstetric complications is not possible as it is an essential part of the infrastructure.[26]Before donation, the prospective donors should be screened with the medical history and a short physical examination conducted to make sure that donation is not hazardous to donor's own health and testing for transfusion transmitted infections in the donated blood.

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[24] http://www.indianpediatrics.net/feb2005/feb-155-161.htm(accessed on 10th January 2018)
[25] http://www.who.int/mediacentre/factsheets/fs279/en/9(accessed on 10th January 2018)
[26] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC315
9250/%20-%20ref6(accessed on 11th January 2018)

In order to improve the standards of blood banks and the blood transfusion system in our country, the National Acquired Immune Deficiency System Control Organization through the Technical Resource Group on Blood Safety has formulated comprehensive standards to ensure better quality control in the collection, storage, testing, and distribution of blood and its components.[27] For quality, safety and efficacy of blood and blood products, well-equipped blood centers with adequate infrastructure and trained manpower is an essential requirement. For effective clinical use of blood, it is necessary to train clinical staff. To attain maximum safety, good laboratory practices to attain a total quality management is vital for organization and management of the blood transfusion system.

In India, an improved transfusion service is required since all donated blood units are not screened adequately for transfusion transmitted infections.[28]Testing for transfusion transmitted infections is unsatisfactory and poorly regulated in India. Reporting of adverse events after transfusion is poor and there exists no stringent donor deferral system.[29]

IX. Judicial Mandate

The Hon'ble Supreme Court of India had taken up the issue of blood safety by banning paid donations in 1997.On the 4th January, 1996 in Common *Cause v Union of India and Ors*,[30] it has ordered the establishment of an autonomous National Blood Transfusion Council and State Transfusion Councils. A major problem plaguing blood banks[31] in India is poor monitoring and control because of the multiplicity of agencies involved. Blood and blood products are under the regulatory control of the Drug Controller (General) of India, the central licensing authority is assisted by the State Drug Controllers. What still remains as a need are a truly autonomous agency manned by competent people from the blood transfusion sector. This agency should have branches in all the States. The Supreme Court in the very same (1996) case [32]had asked the government to consider the advisability of enacting legislation to regulate the collection, processing, storage, distribution of blood and the operation of blood banks.[33] This is yet to happen, though, as directed by the Court, the government has set up a National Blood Transfusion Council as the apex policy-making body for Blood Transfusion System.

Subsequently, State Blood Transfusion Councils were also set up, but these bodies have an advisory role only and exercise no control over the blood banks. These

[27] http://naco.gov.in/blood-transfusion-services(accessed on 11th January 2018)
[28] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3159250/#ref119(accessed on 11th January 2018)
[29] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3159250/(accessed on 12th January 2018)
[30] 1996/Case No.: Writ Petition(civil) 91 of 1992
[32] Id
[33] Supra, note 19

various bodies are in addition to the Drug Controller General of India and this multiplicity of authority has resulted in poor monitoring of blood banks which are proposed under draft rules of 2018 to be renamed as blood centres. More than any legal or bureaucratic measure, what is really necessary is achieving 100% voluntary donation which happens to be a goal highlighted by the government's plan of action in pursuance of the national policy on blood transfusion to improve the blood safety in clinical practice. [34]Earlier, the Apex Court on November 13, 1995 upheld the National Consumer Commission's judgment of April 1992, whereby patients who receive deficient services from medical profession and hospitals are entitled to claim damages under the Consumer Protection for safe donor selection and safe blood processing. Yet, there are no transfusion triggers or national guidelines for safe transfusion. According to the Central Drug Standard Control Organisation, India had 2,760 licensed blood banks as on 2015. This perhaps can also be attributed to the shortfall in the required blood supply. A 2012 World Health Organisation report stated that only nine million of twelve million blood units needed annually in India were collected through voluntary donation.[35]

X. Progression Awaiting Legislative Formulation

The National Blood Transfusion Council is the policy formulating apex body in relation to all matters pertaining to operation of blood centres. The National Blood Transfusion Council is the central body that coordinates the State Blood Transfusion Councils and also ensures involvement of other Ministries and other health programmes for various activities related to Blood Transfusion Services. Presently, the National Blood Transfusion Council is housed within National AIDS Control Organisation and functions through resources available with the Blood Transfusion Services Division. Blood Transfusion Services have to ensure that Blood/ Components (Whole Blood/ Packed Red Cells/ Plasma/ Platelets) are available, accessible, affordable, safe and of standard quality. This is in tune with the World Health Organisation recommendation that National Blood System should be governed by National Blood Policy and legislative framework to promote uniform implementation of standards and consistency in the quality and safety of blood and blood products. Towards this end the Health policy has been adopted by the government.[36]

Though healthcare has emerged as one of the most powerful industries, yet, affording it has become difficult. The possible reasons that can be attributed to it

[34] https:///www.ncbi.nlm.nih.gov/pmc/articles/PMC3159250, Ranabir Panabir Pal at.all(accessed on 10th June 2018)

[35]http://www.thehindu.com/news/national/now-blood-banks-can-borrow-from-oneanother/article7775269.ece (accessed on 20th January 2018)

[36] http://naco.gov.in/national-blood-transfusion-council-nbtc-0 (accessed on 9th March 2018)

include factors such as the global economy, governmental and inter-governmental policies and change of lifestyles of people.[37]

XI. Generic Medicines and Drugs

Patient care involves availability of medical supplies over and above medical services. These include among others availability of medicines at affordable price which can be facilitated through generic medicines. Generic medicines, to mean simply and clearly are basically the chemical equivalents yet cost effective versions of brand name drugs, with the same active ingredient, dosage, safety , strength, quality, performance and intended use.[38] According to World Health Oganization, a generic drug is a pharmaceutical product, usually intended to be interchangeable with an innovator product that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights.

People residing and working in India commonly have the experience of buying drugs for friends and family back home.[39] Though available, these more often are not used to the required degree for want of being prescribed. The common tendency of doctors has been to prescribe company brands that often are found to be expansive. Their availability in the Indian market or production by the pharmaceutical companies can be vouched through the following illustration.

A recent Chinese film 'Dying to Survive' busted and presented a picture of China's import of cheap(affordable) Indian generic drugs for fighting cancer (particularly for patients suffering from chronic myeloid leukemia) and the big generic drug industry along with the country's generic drug industry.[40]

According to the guidelines from the United States Food and Drug Administration (FDA), the generic drug must have the same active ingredient as the brand name drug as well as the same dosage, strength, safety, conditions of use and route of administration[41]. It further mandates that the generic drug must have the same active ingredient as the brand name drug as well as the same dosage, strength, safety, conditions of use and route of administration[42] .

Therefore, manufacturers must conduct studies to determine whether their version is bioequivalent to the original drug, which demands that the generic version

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[37] https://health.economictimes.indiatimes.com/news/pharma/how-are-generic-medicines-unleashing-a-revolution-in-pharmaceutical-industry-across-the-world/65006841, Sujit Paul,Managing Director,Stay Happi(accessed on 11th March 2018)

[38] ibid

[39] www.globaltimes.cn/content/1111174.shtml),Bai Yunyi),published 2018/7/17

[40]ibid

[41] https://www.news-medical.net/health/What-are-Generic-Dr ugs.aspx) (Author-Dr Ananya Mandal, MD(accessed on February 3rd 2018))

[42]id

releases its active ingredient(the drug) into the bloodstream at virtually the same speed and in virtually the same amount as the original drug. Since the active ingredient in the generic drug has already been shown in testing of the brand name drug to be safe and effective, bioequivalence studies only have to show that the generic version produces virtually the same levels of drug in the blood over time.[43]

In July 2013,an expert committee headed by Prof. Dr Ranjeet Roy Choudhary recommended vide a report on formulating policy and guidelines for approval of new drugs, clinical trials and banning of drugs.[44].Among other things, it recommended making bioequivalence studies compulsory for all generics irrespective of when they were approved. In India, the Drugs and Cosmetics Act, and Rules1945 provides for conducting bioequivalence studies which are studies meant to establish that the original patented drug and a generic version of it have the same purpose.[45]

Recently the Medical Council of India through a 2016 notification amended clause 1.5 of the Medical Council(Professional Conduct, Etiquette and Ethics) Regulations 2002 making it mandatory for doctors to prescribe medicines by generic names in place of brand names.[46] This seem to be breached more often than not and attributed to the fact that patients are yet to be aware of the existence of any such provision. Hence, it is essential that wide publicity should be given to the guidelines.

According to the guidelines on manufacture of Generic Pharmaceutical Drugs, a Drug can be manufactured as a generic drug when generic pharmaceutical manufacturers can prove to the Food and Drug Agency that their version of a brand name drug contains the same active ingredient, is identical in strength, has the same dosage form and route of administration, has the same indications, dosing and labeling and provides the same efficacy and safety profile to patients(bioequivalent) and have been prepared following appropriate good manufacturing practices.[47]

XII. Conclusion

A comprehensive legal regime is a desideratum, which at present calls for exploration. The extent laws related to patient safety should aim at facilitating the

[43] https://www.msdmanuals.com/home/drugds/brand-name-and-generic-drugs/bioequivalence-and interchangeability-of-generic-drugs((accessed on 3rd March 2018)
[44] www.indiaenvironmentportal.org.in/files/file/clinical%20trials1.pdf(Accessed on 15th March 2018)
[45] https://www.google.com/amp.scroll.in/article/834356/india-makes-a-long-overdue-move-to-ensure-better-drug-safety (accessed on 15th March 2018)
[46] https://www,google.com/amp/s/www.deccanchronicle.com/amp/lifestyle/health-and-wellbeing/111117/welcome-curb-on-branded-meds.html(accessed on 11th March 2018)
[47] https://www...accessiblemeds.org(accessed on 2nd March 2018)

right to health in a meaningful manner. Within the confines of patient safety, parameters like accessibility to safe and effective generic medicines ,availability of blood in blood banks ,safe blood transfusion , medication safety, maintenance of proper hospital infrastructure, rights and duties of doctors and patients respectively, medical and pharmaceutical interventions , pharmacovigilance ,adverse drug events should be clearly laid down imposing accountability for deviations or violations. It should address the needs of the very people for whom these health services exist, taking into account aspects of medical errors, adverse drug reactions, among others.

This would lead to reduction in the discrepancies resulting from overlapping and conflicting rules that exist. International developments that have taken place over the years indicate the paramount significance attached by the international community for safe treatment extending from initiation of treatment till it leads to its logical conclusion. Therefore, such an approach calls for being adopted by the government. This however depends on very many factors that include medical treatment as well as legal and ethical attributes. In the absence of any holistic policy backed up by a comprehensive and effective legal regime, reliance has to be by way of exploration of the international developments. Incorporating patient views into quality assessment offers one way of making health services more responsive to people's needs

Considered the geographical spread and the health needs of patients that constitute a sizable number much remain to be done in terms of facilities and services in the arena of patient safety. Concerted efforts will result in creating awareness in the related field of patient safety and ensure fulfillment of legal obligations of stakeholders as well.