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Use of Nanomedicine and the Ethico-Legal Challenges for the Indian Healthcare System

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Abstract

Nanotechnology has made a tremendous impact across a wide range of scientific fields. In recent years, the application of nanotechnology has significantly expanded, with one of its most notable applications being in the field of medicine, known as nanomedicine. The use of nanomedicine has made a revolutionary change in the diagnostics and treatment of major diseases such as cancer and cardiovascular problems. But, like any other technological advancement, the field of nanomedicine also confronts various ethical dilemmas concerning safety and toxicity. This paper addresses the ethical concerns in the application of nanomedicine. However, the major challenge regarding nanomedicine is in terms of its governance, because of its rapid advancement and multidisciplinary nature. In India, there is a lack of specific legislation governing nanomedicine. Consequently, due to its therapeutic nature, the existing legislation concerning pharmaceuticals regulates the aspects of nanomedicine. This paper aims to explore the diverse applications of nanotechnology in the healthcare sector and critically evaluate the efficiency and adequacy of existing legislation in regulating this innovative field.

Keywords: Gene Therapy, Health risks, The Drugs and Cosmetics Act 1940, Therapeutic Goods Act 1989

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1. Introduction

Nanomedicine is a rapidly evolving field of new technology that has the potential to revolutionize the healthcare system. It offers great promise for the future of healthcare, with the capacity to diagnose and treat a wide range of diseases at the molecular level. Nanomedicine involves the application of nanotechnology in therapeutics to diagnose, monitor, prevent, and treat various medical conditions. It has advantages over conventional medicines in terms of its improved pharmacokinetics and enhanced efficacy.[1] It has made a substantial revolution in the treatment of some major cardiovascular diseases and cancer. However, the advancement of nanomedicine also raises many legal and ethical concerns regarding its toxicity and safety, which highlight the need for robust and specific regulation. The major challenge concerning nanomedicine is due to its multidisciplinary nature. Currently, there is no specific legislation pertaining to nanomedicine and due to its therapeutic nature, it is classified under the broad category of drugs. Therefore, in India, the legislation that regulates drugs, mainly the Drugs and Cosmetics Act 1940 [2]and its allied Rules, are also applicable to nanomedicines. However, as the field of nanomedicine is technologically advancing, it is necessary to critically analyse whether the existing legislations governing drugs are adequate in regulating nanomedicine. At the same time, the ethical considerations regarding the application of nanotechnology to medicine have not been seriously discussed. Therefore, it is crucial to address these concerns regarding the application of nanomedicine.

2. Application of Nanotechnology in the Therapeutic Field

Before considering the ethical and legal challenges associated with the use of nanomedicine, it is necessary to understand the concept and application of nanotechnology in the therapeutic field. This was put forward by Richard Feynman, an American physicist, during his lecture titled "There's Plenty of Room at the Bottom: An Invitation to

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[1] Weijia Lu et al., Nanomedicines: Redefining Traditional Medicine, 134 Biomedicine & Pharmacotherapy 111103 (2021), https://www.sciencedirect.com/sciences/article/pii/S07 53332220312968 (last visited Aug 15, 2024).

[2] The Drugs and Cosmetic Act, 1940, No. 23, Acts of Parliament, 1940 (India)

Enter a New Field of Physics" in 1959.[3] The term nanotechnology was first introduced by Norio Taniguchi, a Japanese Scientist, in 1974.[4] The word 'nano' is derived from the Greek word 'nanos', which means 'a dwarf', and it signifies 'one billionth'. Thus, nanotechnology can be considered as manipulating matter into nanoparticles, with size ranging between 1 and 100 nanometers, to produce new materials and devices. [5]In recent years, nanotechnology has become a crucial area of research and development and has been applied to various fields such as agriculture, the fertilizer industry, etc. One of the most significant applications of nanotechnology is in the medical field, known as nanomedicine. There is no commonly accepted definition of nanomedicine. However, in broad terms, nanomedicine refers to the application of nanomaterials in the field of medicine for the diagnosis, monitoring, control, prevention and treatment of diseases.[6] So it has a wide range of application and with impressive modifications makes a significant contribution to the healthcare sector. Due to their extremely small size, nanomedicines have a significant surface-area-to-volume ratio. This unique feature helps them to move more quickly through the blood and thus enabling the patient to take large doses of medicine. It also helps in faster drug release. The increased surface area of the nanomaterials also provides them with distinct capabilities. It enhances their mechanical, magnetic, and catalytic qualities.[7] As a result, nanotechnology has numerous uses in the healthcare sector. They are mainly used in three areas, namely, diagnosis, controlled drug delivery and regenerative medicine.[8]

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[3] Samer Bayda et al., The History of Nanoscience and Nanotechnology: From Chemical–Physical Applications to Nanomedicine, 25 Molecules 112 (2019), https://www.ncbi.nlm. nih.gov/pmc/articles/PMC6982820/ (last visited Apr 15, 2025).

[4] S Ganguly & S K Mukhopadhayay, *Nano Science and Nanotechnology: Journey from Past to Present and Prospect in Veterinary Science and Medicine*, 2 International Journal of NanoScience and Nanotechnology 79 (2011).

[5] Samer Bayda et al., *supra* note 3.

[6] Abid Haleem et al., *Applications of Nanotechnology in Medical Field: A Brief Review*, 7 Global Health Journal 70 (2023), https://www.sciencedirect.com/science/article/pii/S2414644 723000337 (last visited Feb 21, 2024).

[7] *Id*.

[8] Sara Soares et al., *Nanomedicine: Principles, Properties, and Regulatory Issues*, 6 Front. Chem. (2018), https://www.frontiersin.org/journals/chemistry/articles/10.3389/fchem.2018.003 60/full (last visited Feb 16, 2024).

Research is ongoing in the medical field related to neurology, nephrology, cardiovascular diseases, gene and cancer therapy, etc. The applications of nanotechnology are mainly used in:

2.1. Targeted drug delivery

The nanoparticles play a vital role in targeted drug delivery to treat various diseases. This is essential for effective treatment of diseases. If the drug is released in some parts other than the targeted cells, it may enter the bloodstream and pass to other parts of the body, which sometimes causes harm to the healthy cells. The drug delivery using nanomedicine technology ensures precise delivery of drugs to the target tissues or cells when compared to conventional medical techniques. One of the examples of the recently used targeted drug delivery is nano-liposomes, which are used to treat various types of cancer and cardiovascular diseases.[9] These nanocarriers have the ability to efficiently penetrate the cell membrane because of their small size, and thereby, they can ensure precise delivery of drugs to the targeted site.[10]

2.2. Cardio vascular Treatment

The use of nanotechnology in therapeutics aids in earlier detection of cardiovascular diseases ensuring effective treatment. Apart from the role of nanocarriers for the targeted delivery of drugs, nanotechnology also enhances the imaging of cardiovascular diseases through cardiovascular imaging probes. This can be done effectively because of the ability of the nanoparticles to cross the biological barriers and reach the target place more easily. The nano-imaging helps in diagnosing cardiovascular diseases and monitoring the patient, especially during surgery.[11]

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[9] Sumaira Anjum et al., *Emerging Applications of Nanotechnology in Healthcare Systems: Grand Challenges and Perspectives*, 14 PHARMACEUTICALS 707 (2021), https://pmc.ncbi.nlm.nih.gov/articles/PMC8401281/ (last visited Feb 26, 2024).

[10] Rajasekharreddy Pala et al., *Nanoparticle-Mediated Drug Delivery for the Treatment of Cardiovascular Diseases*, Volume 15 IJN 3741 (2020), https://www.dovepress.com/nanopart icle-mediated-drug-delivery-for-the-treatment-of-cardiovascula-peer-reviewed-article-IJN (last visited Apr 15, 2025).

[11] *Id.*

2.3. Cancer Treatment

The application of nanotechnology is mainly used in diagnosing and treating severe diseases like cancer. It helps in improving the pharmacokinetics and also reducing the toxicity of chemotherapy by selectively and specifically targeting the tumor cells and delivering the anticancer drugs only to the tumour tissues. With the development of various drugs for cancer treatment and the use of nano-based cancer biomarkers, early detection of cancer has been made possible. This may significantly impact controlling and treating cancer in its pre-invasive stage, thereby improving the chances of effective and successful treatment.[12] Another emerging technology in this field is the application of nanorobots, which perform certain specific biological tasks in collaboration with medicine. It helps to minimize the side effects, as it specifically targets cancer cells. They work on the target cells without causing any harm to the healthy cells.[13]

2.4. Treatment of ocular diseases.

The proper delivery of medicine to the eye poses a significant challenge, primarily because of the presence of intricate barriers such as the tear film and the ocular surface, epithelium, which is a thin outer layer that protects the eye.[14]The nanoparticles, because of their smaller size and variable surface properties, can overcome these barriers and can deliver the drug to the targeted area effectively. It also improves drug resistance time on the cornea surface and enhances the bioavailability of drugs.[15]

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[12] Fei Ye et al., *Advances in Nanotechnology for Cancer Biomarkers*, 18 NANO TODAY 103 (2018), https://www.sciencedirect.com/science/article/pii/S1748013217304486 (last visited Feb 14, 2024).

[13] Devasena Umai R, Brindha Devi P & Thiruchelvi R, *A Review On DNA Nanobots – A New Technique for Cancer Treatment*, 11 ASIAN J PHARM CLIN RES 61 (2018).

[14] Mohammad Mofidfar et al., *Drug Delivery to the Anterior Segment of the Eye: A Review of Current and Future Treatment Strategies*, 607 INT J PHARM 120924 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8579814/ (last visited Jul 13, 2024).

[15] Dawin Khiev et al., *Emerging Nano-Formulations and Nanomedicines Applications for Ocular Drug Delivery*, 11 NANOMATERIALS (BASEL) 173 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7828028/ (last visited Feb 21, 2024).

2.5. Gene therapy

Gene therapy is used to treat genetic disorders and various other diseases by introducing DNA molecules into the cell to replace the defective gene. It can be used to treat various hereditary and acquired diseases. With the help of nanotechnology, these genes are introduced into the cell by using nanoparticle-based delivery systems. It enhances the ability to enter into the cell, thereby increasing the efficacy of gene therapy. Another major application of nanotechnology in gene therapy is that it helps in modifying the DNA sequences and corrects genetic mutation with the use of nano-scale tools. [16]

Thus, the healthcare sector may enter a new era of growth with the potential benefits of nanomedicine. However, the application of nanotechnology in the healthcare sector is not without legal and ethical challenges. Issues that arise from the application of nanomedicine have a detrimental effect on human health, which highlights the need for specific and stringent regulation. In the absence of specific legislation governing nanomedicine in India, it is necessary to conduct a thorough analysis of various issues and critically analyse the adequacy of the existing legislation applicable to this innovative field.

3. Ethical Concerns

Inspite of significant development in the field of nanomedicine, the potential risks associated with the application of nanotechnology persist due to the ambiguity about its overall effectiveness and safety. The use of nanomaterials in the diagnosis, prevention, and treatment of various diseases poses certain threats, such as toxic effects on the human body. For example, exposure to nanomaterials used in various oral diseases, through inhalation and ingestion, has toxic effects on the lungs, kidneys, liver, etc.[17] Inhaled nanomaterials

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[16] Fernando Herranz et al., *The Application of Nanoparticles in Gene Therapy and Magnetic Resonance Imaging*, 74 Microsc Res Tech. 577 (2011), https://analyticalsciencejournals. onlinelibrary.wiley.com/doi/10.1002/jemt.20992 (last visited Apr 15, 2025).

[17] Harini Karunakaran, Jogikalmat Krithikadatta & Mukesh Doble, *Local and Systemic Adverse Effects of Nanoparticles Incorporated in Dental Materials- a Critical Review*, 36 The Saudi Dental Journal 158 (2024), https://www.sciencedirect.com/science/article/pii/S101390 5223001736 (last visited Dec 17, 2024).

tend to get deposited in the lungs, nasal and alveolar regions. Certain nanoparticles, such as titanium, cause pulmonary toxicity and broncoalveolar lavage inflammation.[18] In addition to this, there are certain categories of nanoparticles that are frequently reported as having toxic effects. For example, carbon nanotubes are shown to have toxic effects similar to the toxicity of asbestos and the use of these nanoparticles causes mesothelioma, a type of cancer that develops from the thin layer of tissues.[19] Furthermore, positively charged lipid nanomaterials are found to cause hepatotoxicity, a condition where the liver is damaged by exposure to harmful substances when they are injected into the blood.[20] However, it is challenging to assess the safety of nanomaterials because of the unique nature they possess. Each material should be assessed on its terms. Nanoparticles may exhibit distinct characteristics in an organism when compared to what they do in cell culture.[21] The physicochemical properties and the size and shape of nanomaterials have a great impact on their pharmacokinetics and the supply of nanomaterials in the body. For instance, nanoparticles measuring 10 nm are mainly located in the liver, spleen, kidney, thymus, heart, lung and brain. However, larger particles can only be identified in the blood spleen and liver.[22]

The size, shape and surface area of these particles also affects toxicity.[23] Nanoparticles having small size and larger surface area can enter biological membranes more easily, causing toxicity in various organs. For example, gold nanoparticles with a diameter of 1.4nm were found to be toxic, while same particles having 15 nm diameter did not display toxicity.[24] Due to their smaller size, nanomaterials have the ability to travel from the target place to various parts of the body. This may lead to accumulation in the other parts of the

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18 *Id.*

19 Joy Wolfram et al., *Safety of Nanoparticles in Medicine*, 16 CDT 1671 (2015), https://pmc.ncbi.nlm.nih.gov/articles/PMC4964712/ (last visited Dec 17, 2024).

20 *Id.*

21 David B Resnik & Sally S Tinkle, *Ethics in Nanomedicine*, 2 NANOMEDICINE 345 (2007), https://www.researchgate.net/publication/6124213_Ethics_in_Nanomedicine (last visited Jan 29, 2024).

22 Soares et al., *supra* note 8.

23 Karunakaran, Krithikadatta, and Doble, *supra* note 17.

24 Wolfram et al., *supra* note 19.

body, potentially causing adverse effects and may result in various health issues in the future. Apart from gold nanoparticles, other metal-based nanoparticles also cause certain cytotoxic issues. For example, various studies have shown that silver nanoparticles cause toxic effects that affect the liver, kidney and intestinal tract and cause argyrosis, where the skin turns to blue or grey in colour.[25] Moreover, orally administered nanomaterials can accumulate in the intestine and cause damage.[26]

Moreover, nanomedicines that are safe for a particular animal may not be safe for human beings. For instance, in 2006 a phase I clinical study was conducted on six human volunteers in the U.K. for a CD28 superagonist antibody TGN1412[27]. After receiving the dose, all of them became critically ill and faced life-threatening conditions, including multi-organ failure. The dose given to the volunteers was 500 times smaller than the dose that was found safe in animals.[28] Moreover, the scientific community has not yet fully understood the entire life cycle process of nanomedicine. As a result, the long-term effects of its use remain uncertain. This uncertainty poses risks that outweigh the benefits. Therefore, it is imperative that this issue has to be addressed as it adversely affects the efficacy of drugs for which nanomaterials are intended.

Additionally, nanomaterials not only pose risks to human health but also pose safety and environmental hazards. The toxicity levels of nanomaterials and the manufacturing processes involved in their production, contribute to pollution. It is difficult to track and monitor nanowaste as it is invisible to the naked eye.[29] Nanomaterials are often more chemically reactive and toxic compared to their ordinary

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[25] Karunakaran, Krithikadatta, and Doble, *supra* note 17.

[26] Chunhua Yang & Didier Merlin, *Challenges to Safe Nanomedicine Treatment*, 13 NANOMAT- ERIALS 1171 (2023), https://www.mdpi.com/2079-4991/13/7/1171 (last visited Dec 18, 2024).

[27] H Attarwala, *TGN1412: From Discovery to Disaster*, 2 J YOUNG PHARM 332 (2010), https:// www.ncbi.nlm.nih.gov/pmc/articles/PMC2964774/ (last visited Apr 15, 2025).

[28] *Id.*

[29] Linda Jiang & Kim A. Carmichael, *Innovating Nanoethics*, 21 AMA JOURNAL OF ETHICS E313 (2019) doi:10.1001/amajethics.2019.313(last visited April 15 2025)..

counterparts.[30]Also, it is more difficult to predict the reaction of nanoparticles with different environmental conditions. The excretory materials of nanoparticles are mainly disposed off in water and air. It may be present in the atmosphere for longer periods of time, which may cause respiratory disorders and affect people's health.[31]

In emerging technologies like nanomedicine, there is a lack of information at every stage, that is from production to distribution, until it reaches the end-user.[32] This poses a significant challenge in obtaining informed consent from patients. During clinical trials of nanomedicine, the researcher should be fully aware of the risks and challenges that arise from the applications of nanomedicine and these should be communicated to the trial subjects. Only then can the participants give voluntary consent to be involved in the clinical trial. Otherwise, ethical challenges regarding patient autonomy and beneficence may arise.[33] Thus, assessment, management, and communication of risks are major challenges in the application of nanomedicine.

Another major ethical issue emerges when a new medicine enters the market after research and development. The main concern is with respect to the high price of patented medicine.[34] A drug patent is an exclusive right granted to the patent holder, who has invented a new drug, for a certain period, and it presents others in the society from manufacturing, using, and marketing the patented drug during this period. But after that period, the patent expires and the price of the drug declines when the generic drugs enter the market. However, in the case of nanomedicine, because of its complexity and uniqueness and costlier manufacturing method, it may take a long time for their

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30 *Id.*

31 Bala Krishna Prabhala & Jain Dharmendra, *Ethical Issues in Nanomedicine*, 2 THE HOLISTIC APPROACH TO ENVIRONMENT 171 (2012), https://hrcak.srce.hr/file/137698 (last visited Apr 12, 2025).

32 Irit Allon et al., *Ethical Issues in Nanomedicine: Tempest in a Teapot?*, 20 MED HEALTH CARE AND PHILOS 3 (2017), http://link.springer.com/10.1007/s11019-016-9720-7 (last visited Apr 15, 2025).

33 Jiang and A. Carmichael, *supra* note 29.

34 Roger Collier, *Drug Patents: Innovation v. Accessibility*, 185 CMAJ E379 (2013), https://www .ncbi.nlm.nih.gov/pmc/articles/PMC3680575/ (last visited Apr 15, 2025).

generic counterparts to enter the market and the reduction in the cost of nanomedicine. Consequently, the majority of the patients lack access to such medicines. For example, Abraxane, a widely used nanoparticle formulation of paclitaxel, which is used for the treatment of various cancers, cannot be accessed by many patients due to its high cost.[35] Therefore, this new nano-based treatment raises ethical issues of justice and fair access. In the coming years, only the people in developed countries will get access to these expensive nanomedicines and the population in developing countries will find it tougher. This will worsen economic inequalities globally. Thus, to distribute the benefits of this technology fairly by making it more affordable to all, is of great ethical consideration. Long-term follow-up is also needed to ensure the safety of nanomedicine. Apart from that, the use of micro-electromechanical systems (MEMS) chips and other devices used in In vivo disease detection and monitoring also raises issues concerning privacy and confidentiality in our healthcare system.[36] During these processes, information from patients is collected, and there arises major concerns about health information systems. In order to protect the privacy and confidentiality of the patients, it should be ensured that the information collected should not be intercepted or misused by third parties.

4. Current Regulation of Nanomedicine in India

Nanomedicine is a relatively new and complex field when it comes to regulation. At present, India has no specific law that defines or governs nanomedicine. Depending on its therapeutic effect, it falls under the legislative framework that governs drugs. The Drugs and Cosmetics Act, 1940 (D and C Act 1940) is the primary legislation in India that regulates drugs. The ultimate aim of this Act is to ensure that standard quality drugs are readily accessible and available

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[35] Ranil Vikraman Kumarasamy et al., *Clinical Applications and Therapeutic Potentials of Advanced Nanoparticles: A Comprehensive Review on Completed Human Clinical Trials*, 6 FRONT. NANOTECHNOL. 1479993 (2024), https://www.frontiersin.org/articles/10.3389/fna no.2024.1479993/full (last visited Dec 18, 2024).

[36] Francisco J. Jaime et al., *Strengthening Privacy and Data Security in Biomedical Microelectromec hanical Systems by IoT Communication Security and Protection in Smart Healthcare*, 23 SENSORS 8944 (2023), https://www.mdpi.com/1424-8220/23/21/8944 (last visited Apr 15, 2025).

to the public at large. It mainly regulates the import, manufacture, distribution and sale of drugs in India. Although the Act does not provide a specific definition for 'Nanomedicine', due to its therapeutic nature, it is categorized as a 'drug' as per Section 3 (b) of the D and C Act, 1940. As per the provision, all medicines that are used internally or externally in human beings or animals for diagnosis, treatment, or prevention of diseases are considered as drugs. It also includes the medical devices that are used for the purpose of diagnosis or the treatment. Therefore, all the provisions of the Act are also applicable to nanomedicine.

However, the major challenge is that the current legislation is not sufficient to address the complex issues relating to nanomedicine. In the United States, the Food and Drug Administration categorizes medical products based on their functions. That means, if the product has a chemical mode of action, it is considered as a drug; if the product has a mechanical mode of action, it is considered as a device; or as a biological source.[37]While applying this categorization, nanomedicine can either be treated as a drug or a medical device or biologics.[38] There are various guidelines in India that specifically deal with each of these categories. When the applicability of nanomedicine is a combination of some of these categories, uncertainty arises regarding the applicability of the law.

4.1. Legal framework for clinical trial

The clinical trials conducted in India are governed by several regulations. In addition to the provisions of the D and C Act 1940 and Drugs and Cosmetic Rules 1945 (D and C Rules 1945), 'the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017)' which was issued by the Indian Council for Medical Research (ICMR Guidelines), and 'the Guidelines on Good Clinical Practice in India (2001) (GCP)' also regulate the clinical

[37] Jordan Paradise, *Regulating Nanomedicine at the Food and Drug Administration*, 21 AMA Journal of Ethics E347 (2019) doi :10.1001/amajethics.2019.347 (last visited April 13 2025).

[38] Pooja Bhatia & Archana Chugh, *A Multilevel Governance Framework for Regulation of Nanom- edicine in India*, 6 Nanotechnology Reviews 373 (2017), https://www.researchgate.net/ publication/310050240_A_multilevel_governance_framework_for_regulation_of_nanomedicine_in_India (last visited Feb 5, 2024).

trial of new medicines in India. In 2019, the New Drug and Clinical Trial Rules were enacted which replaced the Part XA and Schedule Y of the D and C Rules, 1945 which dealt with clinical trials.[39]

The Indian government has implemented several initiatives to regulate nanotechnology. The Department of Science and Technology (DST) established a working group to monitor and regulate nanotechnology. As part of the Nanomission program, draft guidelines and best practices have been created to handle nanomaterials more safely. The Council for Scientific and Industrial Research (CSIR) has introduced a project called NanoSHE, which stands for "Nanomaterials: Application and Impact on Safety, Health and Environment." The project aims to evaluate the toxicological impact of nanostructured materials.[40] In 2006, the Department of Pharmaceuticals (DOP), Government of India, assigned the National Institute of Pharmaceutical Education and Research (NIPER) Mohali, the task of framing regulations for nanomedicine. Later in 2012, this task was transferred to NIPER Kolkata. Department of Pharmaceuticals has proposed the establishment of a national center for pharmaceutical nanotechnology at NIPER Kolkata, which is responsible for the assessment of nanotoxicology and the regulation of nanodrugs and devices.[41]

In 2019, the Guidelines For Evaluation of Nanopharmaceuticals in India was adopted to specifically regulate aspects of nanomedicine.[42] This guideline is in tune with the D and C Act, 1940, Schedule Y of D and C Rules, 1945 and also the second schedule of the New Drug and Clinical Trial Rules, 2019. It provides a definition for nanomedicine and categorizes nanopharmaceuticals according to the degradability and nature of nanomaterial and also according to the nanoform of the ingredient. The guideline provides specific requirements for

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[39] The New Drugs and Clinical Trials (Amendment) Rules, 2023. See The Gazette of India: Extraordinary Part II—SEC. 3(i), G.S.R. 227 (E), dated 9th March, 2023.

[40] CSIR-Central Scientific Instruments Organisation, Ministry of Science and Technology, Govt. of India

[41] Bhatia and Chugh, supra note 38.

[42] Guidelines For Evaluation of Nanopharmaceuticals In India, 2019, Department of Biotech-nology Government of India, (2019), https://dbtindia.gov.in/sites/default/files/uploadfi-les/Guidelines_For_Evaluation_of_Nanopharmaceuticals_in_India_24.10.19.pdf (last visit ed Jul 12, 2021).

nanopharmaceuticals, such as product specifications, including the nano-size range, detailed methods of the manufacturing process, studies regarding toxicity, etc. The guidelines also say that the stability testing of nanopharmaceuticals must focus on functionality, size, carrier material stability, drug stability, and degradation of the nanomaterial.[43]

When conducting clinical trials for nanopharmaceutical drugs, it is important to consider their toxicity and efficacy profile. The data required for the evaluation of nanopharmaceuticals may vary depending on the specific case. The guideline also specified that the pharmacovigilance studies should be conducted throughout the life cycle of the nanomedicine.[44] However, the Guidelines for Evaluation of Nanopharmaceuticals, 2019 apply only to drugs and they do not apply to medical devices. Therefore, in the case of medical devices, an investigation should be conducted as per the Medical Device Rules, 2017 to assess its safety, performance and effectiveness. However, devices that have not been explicitly notified under the Medical Device Rules cannot be regulated.[45] Rather, they can only be regulated as drugs under the D and C Act 1940 and the D and C Rules 1945. This difference in the regulatory approach towards drugs and medical devices raises questions about the classification of nanomedicine. There is an ambiguity regarding the category that can be regulated. As there is no legislation that specifically governs nanomedicines, each application may be categorized based on the functions they perform. Thus, any nanotechnology application that resembles the devices and helps in diagnosis, mitigation, and treatment will be treated as medical devices by the application of Medical Device Rules 2017.[46] Currently, the majority of the applications of nanomedicine focus on enhancing drug delivery in the targeted area for various diseases in the human body. This raises questions regarding the categorization of a combination product, such as a smart pill, which performs functions both as a medical device in assisting with the diagnosis of

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43 *Id.*

44 supra n.42

45 Medical Device Rules, 2017, r. 2(iii).

46 Medical Device Rules, 2017, See G.S.R. 78(E), Ministry of Health and Family Welfare dated 31st January, 2017.

diseases and identification of the target area and may also act as a drug with pharmacological efficacy. The ambiguity lies in whether these products will be considered as a medical device under the Medical Device Rules 2017. In cases where a product combines the function of a drug and a medical device, its classification will depend on an evaluation of the similarity of its function. The categorisation should be determined based on the specific functions of the product, on a case-to-case basis. However, in the case of nanomedicine, such classification may become challenging.

4.2. Regulation on manufacturing and distribution

As per Rule 4 of the Medical Device Rules, 2017, medical devices are categorized into four classes based on risk as follows - the medical devices having low risk are classified as Class A, those having low, moderate risk as Class B, those having moderate-high risk as Class C, and medical devices possessing high risk as Class D.[47] This classification determines the regulatory requirements for getting approvals for a license. This is also applicable in the case of nanomedicine if it is used as a medical device.

Nanomedicine can also be used as biologics which are preparations derived from living organisms for medical use, which include vaccines, serum, antitoxins, etc. This is governed under Schedule C of the Drugs and Cosmetic Rules.[48] In addition to that, in 2016, Guidelines for Similar Biologics were adopted to regulate engineered biologics.[49] It provides guidelines for the manufacturing process of biosimilars. It also mentions the guidelines to ensure the quality, safety, and efficacy of similar biologics. It also highlighted the regulatory requirements of similar biologics during their premarketing and post-marketing stage.[50] Similar Biologics are also

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47 Medical Device Rules, 2017, r. 4

48 Drugs and Cosmetic Rules, 1945, Schedule C. It deals with the regulation of Biological and Special Products.

49 *Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India*, Department of Biotechnology and Central Drugs Standard Control Organization, Government of India (2016) https://ibkp.dbtindia.gov.in/DBT_Content_Test/CMS/Guid- elines/20181115140059519_Guidelines-on-Similar-Biologics-2016.pdf (last visited June 30, 2025).

50 BikashR Meher et al., *Biosimilars in India; Current Status and Future*

governed by the Rules for the Manufacture, Use, Import, Export, and Storage of Hazardous Microorganisms or Genetically Engineered Organisms or Cells, 1989, which is mandated under the Environment Protection Act, 1986. As biologics are classified as drugs, the procedures outlined in the D and C Act,1940 and Rules for import and manufacture of drugs, will be applicable. Part X of D and C Rules provides for additional compliances such as packaging and labelling of biologics. In addition, all biological products should obtain a license from the Genetic Engineering Approval Committee under the Genetically Engineered Microorganisms Rules.[51] These regulations refer to the manufacturing, import, sales, and export of biologics in accordance with the provisions of the D and C Act and its allied rules. The rules primarily govern aspects of safety and handling procedures of biologics.[52]

The Essential Commodities Act 1955 has laid down specific rules to regulate the prices of drugs and ensure their accessibility and affordability. The act provides procedures to fix the cost of medicines and methods to enforce the prices that the Government has decided. The National Pharmaceutical Pricing Authority (NPPA) is responsible for implementing the provisions of the Drug Price Control Order by fixing and revising the prices of pharmaceutical products. They also ensure that the availability and cost of drugs are maintained. The Drug Price Control Order also classifies scheduled and non-scheduled formulations. Scheduled formulations refer to drugs that are mentioned in the Schedule-I, i.e., the National List of Essential Medicines. Formulations not included in Schedule-I are non-scheduled Formulations. Both drugs Schedule and non-scheduled drugs are covered under DCPO, 2013.[53] However, these provisions

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Perspectives, 11 J PHARM BIOALL SCI 12 (2019), https://www.researchgate.net/publication/331041654_Biosimilars_in_India_Current_Status_and_Future_Perspectives (last visited Feb 27, 2024).

51 Rules for the manufacture, use, import, export, and storage of hazardous microorganisms or genetically engineered organisms or cells, Ministry of Environment & Forest (1989).

52 *Id.*

53 NPPA monitors the prices of scheduled as well as non-scheduled medicines under DPCO, 2013, Ministry of Chemicals and Fertilizers, PIB Delhi, 30 July 2024, https://www.pib.gov. in/PressReleasePage.aspx?PRID=2038955 (last visited June 30, 2025)

do not apply to patented drugs and fixed-dose combinations. As nanomedicine is considered a drug, it is subject to these price control regulations.

In the absence of specific laws regulating nanomedicine and nanotechnological applications, the major regulatory framework concerning safety standards is the Environmental Protection Act 1986. The provisions of the Act aim to prevent and prohibit activities that may cause environmental hazards. As per the definition of 'hazardous substance' under section 2(e) of the Act, it means 'any substance or preparation, which because of its chemical or physico-chemical properties or handling, is liable to cause harm to human beings, other living creatures, plant, micro-organisms, property or the environment.'[54] Thus nanoparticles that cause environmental hazards come under the ambit of this Act. In addition to the Environment Protection Act, 1986 the Hazardous Waste (Management, Handling, and Transboundary Movement) Rules are also applicable for regulating nanomaterials. It identifies nanotechnology waste as a hazardous substance and thereby provides guidelines for regulating nanotechnology waste. The Central Pollution Control Board and respective State Pollution Control Boards have the authority to monitor and implement these environmental legislations. As nanoparticles used in nanomedicine possess unique chemical properties, they can also be regulated by 'the Manufacture, Storage, and Import of Hazardous Chemical Rules, 1989'.[55] However, due to the complexity of the nature of the nanoparticles and the lack of expertise in this particular area, the existing regulatory and institutional mechanism may not have the ability to handle the hazards related to nanomaterials effectively.

5. Ambiguities in the Existing Legislation

The gaps in the regulatory framework for nanomedicine give rise to several issues that remain unaddressed. Some of these legal concerns are:

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[54] The Environment (Protection) Act, 1986, No. 29, Acts of Parliament, 1986 (India)

[55] The Manufacture, Storage, and Import of Hazardous Chemical Rules, 1989, See S.O.966(E), Ministry of Environment and Forest dated 27th November 1989.

5.1. Lack of universally accepted definition and classification of nanomedicine

The lack of a commonly accepted definition can be considered as a major challenge as far as regulation of nanomedicine is concerned. This is because of the lack of a proper definition and categorization, which makes difficult to decide the regulatory boundaries relating to the application of nanomedicine.[56] In India, the categories of nanomedicine have not been defined anywhere. Each category is subject to different regulations. Hence, the absence of established legal definitions and categorization poses a challenge to the regulatory authorities in comprehending the functionality of nanomedicine applications. This understanding is crucial for properly classifying them as drugs, medical devices, and biologics.

While there is a debate regarding the applicability of the existing regulation to the medical uses of nanoparticles, it is evident that in certain instances the current regulation may not be adequate. Therefore, more specific regulation may be necessary to prevent a situation of inadequate monitoring.[57] The lack of clear classification poses significant challenges. For example, a nanocarrier may function as both as a drug and as a carrier, thereby possessing inherent therapeutic properties. In such cases, categorizing it solely as a traditional drug molecule or as a drug carrier may result in ignorance of all potential risks and lead to insufficient regulation.

5.2. Risks to health

Contrary to the chemicals found in drugs, which have predictable reactions and toxicology at specific dosage levels, nanomaterials have the ability to cause potential risks to human health as a result of their increased reactivity. Certain studies indicate that

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[56] Stefan Muhlebach, *Regulatory Challenges of Nanomedicines and Their Follow-on Versions: A Generic or Similar Approach?*, 131 Advanced Drug Delivery Reviews 122 (2018), https://www.sciencedirect.com/science/article/pii/S0169409X18301637 (last visited Apr 15, 2025).

[57] Rachel Foulkes et al., *The Regulation of Nanomaterials and Nanomedicines for Clinical Application: Current and Future Perspectives*, 8 Biomater. Sci. 4653 (2020), https://www.researchgate.net/publication/342828422_The_Regulation_of_Nanomaterials_and_Nanomedicines_for_Clinical_Application_Current_and_Future_Perspectives (last visited Feb 29, 2024).

nanoparticles may increase the level of toxicity in the body, which causes clotting of blood in the blood vessels and sometimes causes severe DNA damage. The toxic effects and safety issues relating to nanomedicine have already been highlighted. The composition, size and physiochemical properties of nanomedicine play a crucial role in determining their safety and toxicity.[58] Hence, toxicity is way more complex in nanomaterials to determine the standard mechanism of dosage and size. The safety of nanomedicine has to be thoroughly examined before conducting trials in humans due to its complex and unpredictable nature.

5.3. Consent in nanomedical research

Research and exhaustive studies are essential for the advancement of technology. However, the research related to nanomedicine raises some unique challenges. Emerging technologies frequently pose unforeseen risks that may only become apparent when applied on individuals with specific conditions. Conducting clinical trials for novel therapeutics seems to be more difficult because of their complicated nature and the long-term pros and cons, which are still unknown. There is significant concern regarding the effective communication to the research participants regarding the potential risks. The researcher must be aware of the possible risks while conducting trials on the trial subjects and should effectively communicate about the risks to the participants. However, in the case of clinical trials of nanomedicine, the associated risks and their effects are still unclear. Hence, obtaining informed consent effectively from individuals proves to be more difficult.

5.4. Privacy of patient

As nanotechnology and nanomedical devices are more advanced, there is a concern regarding the generation and storage of patient data. The application of nanotechnology in the healthcare sector can generate massive amounts of health data that can be used to compare. In such cases, the health data can be stored in a large digital storage system, which will affect the privacy of the patients. It should also be ensured that a third party does not misuse the personal data of patients. So, there is a need for specific and stringent legislation to protect the privacy and confidentiality of the patients more effectively.

[58] Kumarasamy et al., *supra* note 35.

5.5. Accessibility and affordability of nanomedicine

The high cost associated with nanomedicine can often make it difficult for patients to afford these kinds of medications. This creates serious healthcare gaps between the countries, affecting equitable access to medicine. People living in developed countries, who can spend more on their healthcare have more accessibility to nanomedicine technology. However, people living in developing countries who cannot afford expensive drugs will have limited access. This demands the strong implementation of a regulatory framework which should ensure equitable access to nanotechnology in the healthcare sector.

5.6. Regulation of combinational nano products

As mentioned earlier, due to its diverse nature, nano products cannot be put under a single category. Sometimes two or more applications might have to be combined, such as a drug or device or nanomedicine that have multiple functions. For example, the application of iron oxide nanoparticles as theranostics, which is used for both diagnosis and therapy.[59] Currently, there is a lack of specific regulation for combination products of nanomedicine. This creates an uncertainty regarding the applicability of regulation, as there are various specific regulations dealing with each category of drugs. In such cases, the authorities must pay attention to the unique features of the nanoproduct and regulate them accordingly.

6. Regulation of Nanomedicine: A Comparative Analysis

The field of nanomedicine is advancing at a rapid pace. However, there is no uniform definition and regulatory standards governing this field. As its application is directly associated with human health, a globally harmonized approach to nanomedicine is crucial for its smooth governance. It will ensure patient safety and also promote innovation in this field. For this purpose, a comparative analysis relating to the regulation of nanomedicine in various jurisdictions is necessary. This section analyses the regulation of nanomedicine in some countries, such as the United States, the European Union and Australia.

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[59] Seyed Mohammadali Dadfar et al., *Iron Oxide Nanoparticles: Diagnostic, Therapeutic and Theranostic Applications*, 138 Adv Drug Deliv Rev 302 (2019) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7115878/ (last visited Apr 15, 2025).

In a 2008 report, the United States proposed more stringent regulation of nanotechnology.[60] In the U S, nanomedicines also fall under the existing statutes and guidelines for drugs and medical devices and it is regulated by the United States Food and Drug Administration.[61] In 2011, the Food and Drug Administration issued its first draft guidance on nanotechnology titled 'Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology: Draft Guidance for Industry' and it was finalised in 2014.[62] Later, in 2017, the US FDA issued a draft guidance on pharmaceuticals that contain nanomaterials, including biological products. It categorizes medical products as drugs, devices, and biologics based on their functions. Because of this diverse nature, it evaluates nanomedicines on a case-by-case basis.[63] For tackling the issues and regulating nanotechnology globally, the Nanotechnology Task Force and Nanotechnology Interest Group was created by the US FDA.[64] The group consists of officials from various regulatory centers. Later in 2022, The Food and Drug Administration released draft guidance for nanomedicine based on a risk-based framework. Despite this, a clear set of guidelines is yet to be implemented.[65]

No legislation in the European Union specifically deals with the aspects of nanomedicine. The Communication from the Commission "Towards a European Strategy for nanotechnology" in 2004 highlighted

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[60] The National Nanotechnology Initiative: Second Assessment and Recommendations of the National Nanotecnology Advisory Panel, Report of the President's Council of Advisors on Science and Technology, 2008 https://obamawhitehouse.archives.gov/sites/default/files /microsites/ostp/PCAST-NNAP-NNI-Assessment-2008.pdf (last visited April 15 2025).

[61] C. Lee Ventola, *The Nanomedicine Revolution: Part 3: Regulatory and Safety Challenges*, 37 P T 631 (2012), https://pmc.ncbi.nlm.nih.gov/articles/PMC3498993/ (last visited June 30 2025).

[62] Considering Whether an FDA-Regulated Product Involves the Application of Nanotechno- logy: Draft Guidance for Industry, Guidance for Industry, 2014, US Food and Drug Administration, 2014 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considering-whether-fda-regulated-product-involves-application-nanotechnology (last visited April 14 2025)

[63] United States Food Drug Authority, Nanotechnology Fact Sheet, 2018, https://www.fda.gov/science-research/nanotechnology-programs-fda/nanotechnology-fact-sheet (last visit ed Feb 22,2024)

[64] C. Lee Ventola, Supra note 62.

[65] *Id.*

the potential risks associated with nanotechnology. Following this, The European Group on Ethics in Science and Technology was asked to undertake an ethical review of nanomedicine. They highlighted the problem with regard to the lack of a uniform definition of nanomedicine and highlighted the practical problem in regulating nanomedicine. [66] In 2015, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) put forward guidelines for assessing nanomaterials in medical devices. The guidelines highlight the need for special consideration when evaluating the safety of nanoparticles. Despite this, there is no specific regulation governing nanomedicine in the European Union.[67]

In Australia, nano health products are classified as therapeutic goods, and nanomedicine is considered as a type of medicine. [68] Hence, the existing legislation governing conventional medicines also applies to nanomedicines. The primary legislation that deals with these is the Therapeutic Goods Act, 1989.[69] The aspects of nanoparticles in therapeutic goods and medical devices in Australia are closely monitored by the Therapeutic Goods Administration (TGA).[70] At present, Australia has a working definition for nanomaterials. In simple terms, no specific legislation has been issued to address the detrimental effects and possible threats associated with the nanomedicine industry in Australia.

7. Conclusion

In this world, with rapidly advancing technology, a uniform specific regulation should have to be adopted for the smooth regulation of

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66 Jean V Mchale, Nanomedicine—Small Particles, Big Issues: A New Regulatory Dawn for Health Care Law and Bioethics, LAW AND BIOETHICS / EDITED BY MICHAEL FREEMAN, (Michael D. A. Freeman ed., 2008).

67 Sravanthi Pasumarthi et al., *Nanomedicine Clinical Use, Regulatory and Toxicology Issues in Europe*, 9 J. DRUG DELIVERY THER. 846 (2019), https://www.researchgate.net/publication/335850727_Nanomedicine_Clinical_Use_Regulatory_and_Toxicology_Issues_in_Europe (last visited Feb 29, 2024).

68 Mia M Rahim, *Nanomedicine Regulation in Australia*, 44 ALTERNATIVE LAW JOURNAL 133 (2019), http://journals.sagepub.com/doi/10.1177/1037969X18815737 (last visited June 30, 2025).

69 The Therapeutic Goods Act, 1989, No.21, 1990 (Australia)

70 Nanotechnology Regulation In Australia https://www.science.org.au/curious/technolog-y-future/nanotechnology-regulation-australia (last visited Feb 28, 2024).

nanomedicine globally. In India, nanomedicine is covered under the eighty-year-old Drugs and Cosmetic Act 1940, and its allied rules. As the area of nanomedicine is rapidly growing, these old legislations are inadequate to monitor and regulate their manufacture and distribution. While the authorities have put efforts in updating the legislation by amending various provisions and adopting various guidelines, these efforts are still insufficient to regulate the research, manufacturing and use of nanomedicine in India. Even the newly drafted 'Draft New Drugs, Medical Devices, and Cosmetics Bill, 2022' does not mention the aspects or regulations of nanomedicine. There is also lack of clear guidelines for various agencies regulating nanomedicine. Furthermore, categorizing nanomedicine is challenging due to its complex nature. When nanomedicine combines the application of drugs and medical devices, uncertainty arises regarding its regulation. Since the understanding of long-term effects of nanomedicine and detailed studies on nanotoxicity in humans are very limited, monitoring its application is necessary to ensure the health of patients. For this purpose, it is crucial to conduct post marketing surveillance for identifying the adverse effect. It is imperative that the law should evolve with the rapidly growing fields of science and technology. Specific regulations and rules must be implemented to address and regulate the unique characteristics of nanomedicine, including waste disposal and handling of nanomaterials used in the healthcare sector.