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RESEARCH ARTICLE

Artificial Intelligence and Nanomedicine: Legal and Ethical Challenges in India

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ABSTRACT

Nanotechnology deals with the study and manipulation of structures at the extremely small or at a nano level i.e. the analysis of structures that cannot be seen through naked eyes. It focuses on the application of extremely tiny things that can be utilized across a wide range of various science fields, such as chemistry, physics, engineering, and so on. Nanotechnology is extensively used in numerous industrial and consumer sectors and has the potential to grow further and expand globally. It has increased the speed of memory chips, clean the environment, cure cancer, or concoct super-weapons of untold horror, revolutionized the entire spectrum of life having a big impact on digital assets. It is used not only to store and transmit data but also for tiny Nanomaterials or sensors that are now being used in clothing and textiles to repel harmful pollutants. Despite having great development in nanotechnology, there are a handful of very specific legal concerns, including public trust, Information transparency, issues of environmental impact, potential risks & ethical concerns, some are the determination of hazards and risks, justice, privacy and promoting respect for persons. In medicine, nanomaterials can be used to deliver drugs to targeted areas of the body needing treatment, however, it poses few threats also. Nanomedicine is a novel as well as a challenging field of research in terms of its governance. Its multidisciplinary essence poses challenges for the regulatory framework for legislature and judiciary. In India, a clear framework for the regulation of nano-medicine is lacking. The research paper sketches some of the regulatory challenges which affect the current development within the field of nanotechnology and highlights the suggestions dealing with such challenges. (277 words)

Keywords: Nanotechnology, Nanomedicine, Regulatory Challenges, Law, Artificial Intelligence

INTRODUCTION

Nanomedicine, a combination of nanotechnology and diagnostic, diagnostic, and therapeutic drugs, has greatly improved the effectiveness of the treatment of more complex and deadly diseases by keeping the therapeutic dose in the target area [1]. It is a hub for a variety of technologies that attract worldwide attention because of its tangible benefits such as efficiency and effectiveness. Nanomedicine is not new to the market but can be traced back to ancient times which means Bhasma - an ayurvedic metallic or mineral remedy treated with herbal juices or decoction and produced a certain heat by the puta system of Ayurveda, which is itself well known in the Indian subcontinent and is widely recommended for the treatment of many diseases. Bhasma is said to be made from naturally occurring nanoparticles, which are supplied with many other Ayurveda drugs [2]. The market of Nanomedicine in India is expected to grow to USD 1.6 Billion in another 10-15 years. And also, expected that India to be among the top three healthcare markets by 2020 [3].

Artificial intelligence (AI) discusses the mimicry of human mental processes through machines, especially computers that include speech recognition, learning, consultation, problem-solving, learning from experience, and self-improvement without any specific action. AI has a wide range of medical applications and is useful for diagnoses, especially to detect small differences from baseline, to detect outbreaks of early epidemics, and imaging diagnoses. Medical AI, for example, the IBM Watson that will be used in oncology, helps oncologists produce appropriate and customized treatments for cancer patients. IBM Watson gathers information from medical journals, leading oncologist technology, textbooks, and clinical data and analyzes patient medical records, and provides treatment options based on this information. An oncologist can use his or her information and expertise to search for simple treatment options [4]. The Government of India has been supporting the R&D Departments for further research on Nanomedicine but when it comes to the regulatory framework there are no specific guidelines/ laws/ acts which deal in the usage and manufacturing of nanomedicine [5]. The authors specifically in this paper, identify the existing laws related to nanomedicine and what are the challenges in them, and the requirement of specific law for nanomedicine.

Concept of Nanomedicine

There is no internationally accepted definition of nanomedicine, so in layman, nanomedicine can be defined as a nanoscale intervention in humans to diagnose, prevent and treat disease. Scientific analysis was used to test new nanomedicine methods in India using a two-step strategy that included quantity and analysis for a period of 5 years from 2010 to 2015 to identify participants, market styles, and patent filing [6]. There are some methods used to map the nanomedicine innovation landscape in India mentioned in Figure 1 [7].

Nanomedicine also provides certain benefits to citizens in numerous ways such as in the form of drug or the form of treatment of critical disease by using nanotechnology, some of the benefits are listed below [8].:

- Drug Delivery
- Small Size of Nanomedicine Devices
- Repairing Tissues within the Body
- Early Detection for Disease

Relation of Nanomedicine and Artificial Intelligence

Artificial Intelligence - the intelligence displayed by machines, in contrast to the natural intelligence observed by humans and animals which includes consciousness and sensitivity [9]. In simple terms, to build a machine integrated with human intelligence designed in such a way that you think like humans and imitate their actions [10]. AI (Artificial Intelligence) applications are limitless - used in many different sectors and industries. However, nanotechnology incorporates the knowledge of engineering, chemistry & physics; AI relies heavily on biological stimulation to make some of the most effective paradigms such as neural networks or evolution algorithms [11].

Artificial Intelligence in the medical field has been used extensively for the benefit of citizens, from online appointment planning, online access to medical facilities, digital medical records recordings, reminders including follow-up appointments, and immunization dates for women and pregnant women on drug scale algorithms and drugs and also opposing effect warnings while prescribing a combination of many drugs. Because the technology is developing similarly the treatment of assorted disease also getting simpler with the assistance of algorithms employed in AI [14]. Nowadays, devices have developed in such a way that heath function is inbuilt such as smartwatches which calculate the heart rate of the person or blood pressure and much more. These smart watches are AI-based, it collects data of from the watch and stored in a mobile application installed from there the person can check his previous status report and work accordingly to improve his health.

Nanomedicine has been a controversial topic these days, in the medical research field, used in many fields including drug delivery, vaccine development, antibacterials, diagnostics and imaging tools, high-performance testing platforms etc. biometric, or hybrid objects [15]. To provide more enhancement in the field of nanomedicine, artificial intelligence is also linked with the same. Not only AI but also related technologies used to select the right combination of nanomedicine and to maintain the appropriate level of medication in the blood or target area to improve the efficacy of treatment [16]. However, it is also believed that Nanomedicine-enabled AI will lower the translation bench to the bedside level [17]. Combining both AI and Nanomedicine fields can enhance not only research but also study in each discipline that might lead to all sorts of new tools for gaining insight and communication technology [18].

Existing Indian Framework

Besides the benefits of nanomedicine there is a need for laws or guidelines to regulate nanomedicine, the Indian Government framed certain laws that indirectly deal with nanomedicine, there is no specific regulation in place related to nanomedicine. The DST (Department of Science and Technology), created a functioning group for the regulation of nanotechnology, settled a program called the Nano-mission, developed the National Regulatory Authority Framework Roadmap for Nanotechnology. The Nano-mission is uniquely responsible for the development of draft guidelines and best practices for the safe management of nanomaterials [17] [18]. The CSIR promoted the Nano-SHE project, which is "Nanomaterials: Application and Impact on Safety, Health and Environment" – toxicological evaluation of nanomaterials [19]. In 2006, the Department of Medicine commissioned the development of nanomedicine vaccines at the NIPER Mohali, which later in 2012, handed over to NIPER Kolkata. A national center for pharmaceutical nanotechnology is proposed by the DOP to be established in NIPER Kolkata which will deal with nano-toxicology testing and drug and devices [20].

Researchers have explored, since 2009, the challenges that Indian policymakers and regulators need to address to effectively regulate nanomedicine. *For example,* patents for nanotechnology have been extensively tested, and Sharma and Chugh[21]. have explored the challenges associated with patenting nanoparticles in therapeutic and therapeutic applications. Several researchers in India have pointed out the issue of nanotechnology risk management concerning human health in terms of labor, environmental, and toxicity safety. The appropriateness of the analysis of the various actions, policies, and guidelines of nanomedicine is listed in Table 1. All medications, delivery systems, diagnoses, and medical devices inclusive of traditional medicine are regulated in India under the 1940 Drugs and Cosmetics Act. However, nanomedicine is not explicitly defined, it works based on its drug definition which includes drugs and devices - intended for the diagnosis, prevention, and treatment of diseases. The Drug Price Control Order 2013 and the Essential Commodities Act 1955 assured public access to drugs. The proposed Consumer Protection Bill 2015 which seeks to replace the Consumer Protection Act 1986 places a responsibility on the product to ensure the consumer is safe [22].

Legal Issues Involved in Nanomedicine

The major issue in nanomedicine which India is facing is no specific laws for regulating nanomedicine. A nanotechnology control framework that can serve as a potential template for nanomedicine management. Linked

directly to human health, nanomedicine creates unique challenges and calls for the formation of a specific management framework. Also, the current law of drugs and medical devices does not specify nanomedicine and is not sufficient to deal with complex problems with nanomedicine. Additionally, integrated products such as nano-device and drugs are not enclosed by a single law, and difficulties with the combination of biological and electronic products have not been discussed. *Let's say*, in Europe and the USA, nanomedicine is treated as a drug or a tool or like both, leading to the use of medical devices and drug regime regimes. This adds to the uncertainty in the regulatory approach affecting the research and development and profitability of nanomedicine [23] [24].

Another issue is the lack of debate about ethical, and public health and safety, concerns about new technologies may be the high position that science and its employees enjoy in the world. Not surprisingly, products such as silver-nano washing machines or insecticides containing nanoparticles are still being marketed within the Indian market without the opportunity analysis related to their use. This is without being a govt. has admitted that nanoparticles of the same size as human cells are inserted into the lungs and "can cause damage by direct operation of the corpse by passing through other organs or by absorbing blood."[25].

CONCLUSION

Nanomedicine is a combination of nanotechnology and medicine, diagnostic and therapeutic drugs, and the field of technology that combines fields that attract global attention because of its tangible benefits such as efficiency and effectiveness. It provides numerous benefits to the citizens and combining with AI i.e. Artificial Intelligence has boosted the research and the usage of the same. India ranks in 3rd position in the Nanomedicine market. However, with the advantages, there are some issues involved in Nanomedicine, in regard to its regulatory framework. Existing Indian laws and legislative enactments are not sufficient to provide the proper regulatory framework. There is no specific guidelines describing or dealing with Nanomedicine. India needs a proper law to regulate to overcome the legal challenges and also ethical issues involved therein.

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Table 1: Analysis of different statutes and guidelines

ACT	SCOPE	SHORTCOMINGS
Drugs and Cosmetics Act, 1940	Importing, producing, selling, distributing drugs	Description of nanomedicine is not included Only in vitro diagnostics are controlled Note of active ingredients only; in the case of encapsulated drug, the drug is the main ingredient, not the nanomaterial General drug marketing requires authorization based on equity studies without regard to safety studies Excludes compound product Nutraceuticals and cosmaceuticals are not currently regulated under the Act This Act provides for post-marketing action but has no effect
Drug and Cosmetics Bill, 2013	It extends to RNA, genetically modified	Does not cover combination product Does not define nanomedicine

	organisms, vaccines, stem cells, genetic therapeutic products. Proposes to specify medical devices	
Drug Price Control order, 1995	Controls pricing of drug	Describes "active pharmaceutical ingredients or bulk drug" as any chemical, biological, herbal, or herbal medicine including salts, esters, analogs, isomers, and derivatives, corresponding to the standards set in Drugs and Cosmetics Act, 1940 According to this definition, most nanomedicine can be replaced
Guidelines on Similar Biologics, 2012	Similar biologics	Nanomedicine is not described in the guidelines The guidelines have a back-to-back marketing action, but are limited to responding to biologics or allergies; however, there are no provisions for their demolition or environmental impact assessment
Bio-Medical Waste (Management and Handling) Rules, 1998	Management and handling of bio-medical waste	The rules did not extend to institutions
Draft Bio-Medical Waste (Management and Handling) Rules, 2016	Management and handling of bio-medical waste	"Occupiermeans the person in charge of the management of the facility and the facility of medical waste, including the hospital, nursing home, clinic, veterinary center, veterinary facility, veterinary laboratory, blood bank, health care facility and clinic establishment, regardless of their medical system whatever name they are called Due to this definition, the rules do not apply to institutions
Draft Guidelines and Best Practices for Safe Handling of Nanomaterials in Research Laboratories and Industries, 2016	Safe management of nanomaterials	Guidelines state that hazardous nanomaterial waste containers will be collected and disposed of as hazardous waste following standard procedures However, it is not yet known what is the best way to dispose of nanomaterial waste No precautionary or enforceable measures are provided to ensure compliance with these guidelines

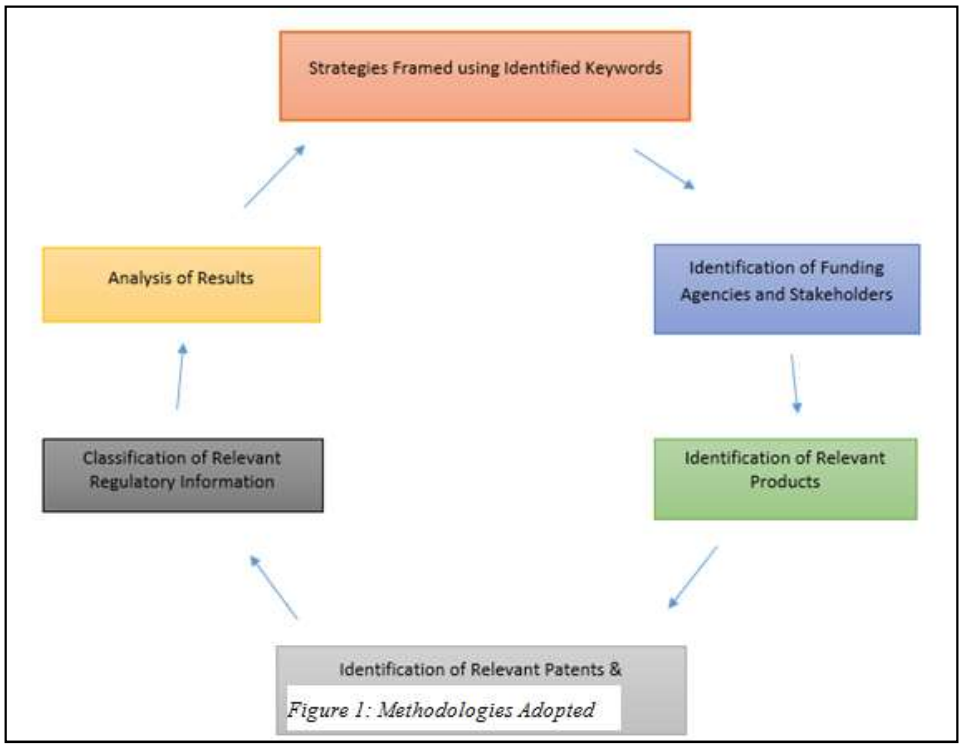

Figure 1 : Methodologies Adopted