Review

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A multilevel governance framework for regulation of nanomedicine in India

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Abstract: Nanomedicine is a novel and challenging field in terms of its governance. It is gradually emerging that the existing regulatory regimes may not be able to accommodate the requirements of nanomedicine without amendments or supportive measures. Further, its multidisciplinary essence poses challenges and indicates a need for an adaptive regulatory framework for governance as well as promotion of innovation system. The best strategy to govern nanomedicine remains highly debatable across the globe. Although, major challenges posed by nanomedicine are universal, some of them are specific to each country, hence, making a jurisdiction-based framework essential to address unique needs of a nation. In India, a clear framework for the regulation of nanomedicine is lacking, as this governance gap has been realized through various studies. Keeping this in view, the authors propose a multi-level national governance system for regulation of nanomedicine in India based on four principles. The hierarchical governance model proposed involves regulatory space, policy regime, sites of governance and lifecycle of nanomedicine. The proposed system is inclusive of its various stakeholders. The system can play a significant role in sustainable growth of nanomedicine in India.

Keywords: ethical issues; legal aspects and societal implications; monitoring; policy.

1 Introduction

Nanotechnology enables medical intervention at nanoscale for prevention, diagnosis and treatment of a disease. This application of nanotechnology in the field of healthcare has been termed as nanomedicine [1]. However, till date there is no universally accepted definition of nanomedicine. It has been defined differently by various organizations (Figure 1A). In the present study, the authors have considered nanomedicine as "medical intervention at nanoscale for diagnosis, prevention and treatment of disease in human beings". We have classified nanomedicine on the basis of application as drugs, drug delivery, medical devices, diagnostics and biosensing, biomaterials and imaging or a combination of any of these (Figure 1B). Nanomedicine offers advantages over conventional medicine system in terms of efficiency [2]; for instance, a single bacterium can be detected by a bioconjugated nanoparticle-based bioassay within 20 min [3]. To increase bioavailability and targeted delivery of drugs, nanomaterials ranging from liposomes, dendrimers, cell penetrating peptides, nanoparticles such as metallic, polymeric and non-metallic have been employed [4]. Undoubtedly, nanomedicine is promising in terms of innovative solutions that it may offer; however, it is imperative to consider the risk(s) involved with its development. The exact mechanism of interaction of nano-based products with the biological system is still not fully understood [5]. For example, Doxil®, a PEGylated form of liposomal doxorubicin, was initially developed to reduce the toxic effects associated with the drug. However, due to long circulation properties of PEGlyated drug, hand foot syndrome has been reported [6]. This apprehension towards biosafety of nanomedicine has led to the development of field of nanotoxicology and protocols to study nanotoxicity. Similarly, appraisal of dual use potential of nanomedicine is important from the point of view of biosafety and biosecurity. Thus, risk(s) and impact assessment of nanomedicine becomes pertinent.

A number of reviews have evaluated application of current regulatory laws for nanotechnology in general and its application in healthcare; however, no nanospecific law has been enacted till now [7–14]. A regulatory framework for nanotechnology can serve as a potential template for the governance of nanomedicine. Since it is directly associated with human health, nanomedicine poses unique

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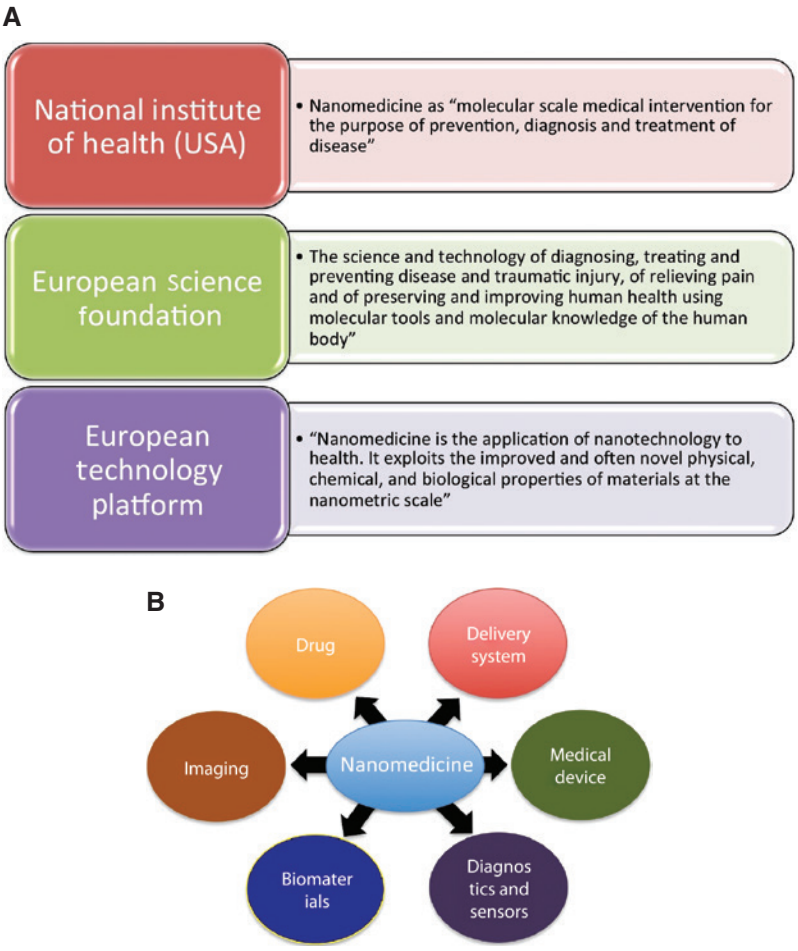

Figure 1: (A) Definitions of nanomedicine by different agencies; (B) various applications of nanomedicine.

challenges and solicits development of a specific governance framework. Further, current legislations for drugs and medical devices are neither nanomedicine specific nor sufficient to address complex issues of nanomedicine. As mentioned earlier, there is no standard definition of nanomedicine, nor is it specified in any of the legislations. Further, combinatorial products such as nanodevice and drug are not covered by a single legislation, nor are issues pertaining to a combination of biological and electronics products addressed. For instance, in Europe and the United States of America (USA) nanomedicine is treated either as a drug or a device or as both, resulting in application of medical device as well as pharmaceutical regulatory regimes [15, 16]. This adds to uncertainty in the regulatory pathway affecting research and development as well as commercialization of nanomedicine [11, 17]. Therefore, it is critical to have a clear regulatory pathway. Addressing concerns at the right stage is essential, or else nanomedicine may also encounter the same fate as genetically modified crops, where large amount of investments were made; however, the crops and products have not been readily accepted by the end user due to socio-ethical concerns [18, 19]. Biosafety, nanotoxicity and accessibility emerge as universal issues associated with nanomedicine; however, there are a few country-specific challenges as well. Law being territorial in nature necessitates a country-specific regulatory framework. USA, United Kingdom (UK), Canada, Russia, Australia and Europe are working on regulatory and risk assessment of nanomedicine [20]. US Food and Drug Administration (FDA) and European Medicines Agency (EMA) have framed guidance documents for the companies working on development of nanomaterial-based drugs and medical devices [21, 22]. It is noteworthy that even Asian countries including India, Thailand, Taiwan, Japan and China are in the process of identifying appropriate governance arrangements and framing regulatory policies to address issues related to nanotechnology and its applications [23].

It is predicted that by 2019 the global nanomedicine market will be worth US$ 177.60 billion [24]. A number of

products have been approved by FDA and EMA such as Myocet®, Emend®, Mepact®, Doxil®, Pegasys® and Abraxane® [25]. At present, in India 17 nanomedicine-based products have been introduced in the Indian market, while 19 products are undergoing clinical trials (paper under communication). The Government of India has invested to promote nanomedicine for technology advancement and societal benefits. The Government has also established specialized research and incubation centers. Therefore, it is important to assess risk(s) and set mitigation systems in place to ensure safety and effective commercialization. Keeping this in view, the authors in the present study have made an attempt to examine regulatory initiatives and lacuna of existing regulatory structure in India as a case study. The present study proposes development of a field-specific framework involving various stakeholders in India, which would play a significant role in sustainable growth of this emerging application of nanotechnology. In the section below, various initiatives for regulation of nanotechnology and its application in healthcare in India are discussed.

2 Existing and emerging regulation for nanomedicine in India

As discussed earlier, nanomedicine is an application of nanotechnology in the field of healthcare and, therefore, inevitably shares overlapping issues with nanotechnology. Thus, a regulatory framework for nanotechnology in many instances can provide useful insights to address governance challenges presented by nanomedicine. Notably, nanomedicine is delineable from the other fields of nanotechnology on the basis of intentional human exposure, as it is meant for diagnosis, prevention and treatment of diseases. Keeping this in view, the authors in the present section have critically assessed the initiatives and studies on regulation of nanotechnology and nanomedicine that may influence the governance of nanomedicine in India.

Currently, India does not have any nanospecific regulation in place [26]. Lately, initiatives for regulation of nanotechnology in India have been taken up. The Department of Science and Technology (DST), Government of India, created a working group for regulation of nanotechnology [27]. Nanomission, a program of DST, announced establishment of a National Regulatory Authority Framework Roadmap for Nanotechnology [28, 29]. Nanomission has also framed draft guidelines and best practices for safe handling of nanomaterials [30]. The Council for Scientific and Industrial Research (CSIR) initiated a project Nano-SHE that is "Nanomaterials: Application and Impact on Safety, Health and Environment" for toxicological evaluation of nano structured materials [29, 31]. The Department of Pharmaceuticals (DOP), Government of India, in the year 2006 had assigned the task of framing regulations for nanomedicine to the National Institute of Pharmaceutical Education and Research (NIPER) Mohali, which was later given to NIPER Kolkata in the year 2012. A national center for pharmaceutical nanotechnology has been proposed by DOP to be instituted at NIPER Kolkata that will be responsible for nanotoxicology assessment and regulation of nanodrugs and devices [32, 33].

Since 2009, researchers have examined the challenges that the Indian policy makers and regulators need to address for effective governance of nanomedicine. For instance, patentability of nanotechnology was assessed in general [34, 35], while Sharma and Chugh [36] have examined challenges associated with patentability of nanoparticles for therapeutic and diagnostic uses. Many researchers in India have raised the issue of nanotechnology risk regulation in the context of human health with respect to toxicity, work force and environment safety. Vivekanandan [37] has identified key issues such as lack of integrated research, poor policy coordination, funding constraints, limited role of private sector, low priority to risk research, pressure of globalization and polarization of public debate. Jayanthi et al. [38] have indicated the relevance of identifying stakeholders who would facilitate development of this field. The applicability of Factory Act 1948, Environment (Protection) Act 1986 and Bio-Medical Waste (Management and Handling) Rules 1998 of India has already been assessed and found to be adequate by other groups [37, 39]. We have examined the suitability of various acts, policies and guidelines for nanomedicine (Table 1). All drugs (including traditional medicine), delivery systems, diagnostics and medical devices are regulated in India under the Drugs and Cosmetic Act 1940. Although, the Act does not explicitly define nanomedicine, it is applicable on the basis of its definition of drug that covers medicines and devices intended for diagnosis, prevention and treatment of disease. In India the Drug Price Control Order 2013 and the Essential Commodities Act 1955 ensure public accessibility to drugs. The proposed Consumer Protection Bill 2015 that intends to replace the Consumer Protection Act 1986 imposes product liability on the manufacturer to ensure safety of the consumer.

Similar biologics are governed through the "Guidelines on Similar Biologics, 2012" laid down by the Central Drugs Standard Control Organization and Department of Biotechnology. These guidelines provide for their manufacturing process, quality aspects, clinical and postmarket regulatory requirements. It is noteworthy that the Drugs

Table 1: Analysis of different statutes and guidelines that may be applicable to nanomedicine.

Act	Scope	Shortcomings
Drugs and Cosmetics Act, 1940	Import, manufacturing, sale, distribution of drugs	– Definition of nanomedicine is not included – Only *in vitro* diagnostics are regulated – Labelling of active ingredients only; in case of encapsulated drug, the drug is the main ingredient not the nanomaterial – Generic drug marketing requires approvals based on equivalence studies without considering safety studies – Does not cover combination product – Nutraceuticals and cosmaceuticals are not regulated under the Act currently – The Act provides for postmarketing step, but it lacks implementation and enforcement
Drug and Cosmetics Bill, 2013	Extends to vaccines, RNA, living modified organisms, stem cells, gene therapeutic products. Proposes to delineate medical devices	– Does not cover combination product – Does not define nanomedicine
Drug Price Control order, 1995	Controls pricing of drug	– Defines "active pharmaceutical ingredients or bulk drug" as any pharmaceutical, chemical, biological or plant product including its salts, esters, isomers, analogues and derivatives, conforming to standards specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) – In light of this definition most of the nanomedicine may be excluded from its ambit
Guidelines on Similar Biologics, 2012	Similar biologics	– Nanomedicine not defined in the guidelines – The guidelines have a postmarketing step, but it is restricted to adverse reaction of biologics or allergy; however, there are no provisions for its disposal or assessment of effect on environment
Bio-Medical Waste (Management and Handling) Rules, 1998	Management and handling of bio-medical waste	– The rules do not extend to institutes
Draft Bio-Medical Waste (Management and Handling) Rules, 2016	Management and handling of bio-medical waste	– "Occupier" means a person having administrative control over the institution and the premises generating bio-medical waste, which includes a hospital, nursing home, clinic, dispensary, veterinary institution, animal house, pathological laboratory, blood bank, health care facility and clinical establishment, irrespective of their system of medicine and by whatever name they are called – In light of this definition, the rules do not extend to institutes
Draft Guidelines and Best Practices for Safe Handling of Nanomaterials in Research Laboratories and Industries, 2016	Safe handling of nanomaterials	– The guidelines mention that the nanomaterial hazardous waste containers shall be collected and disposed of as hazardous waste following the standard procedures – However, currently it is not known what the best possible way of disposing nanomaterial waste is – No monitoring or enforcement mechanism is provided to ensure adherence to these guidelines

and Cosmetics (Amendment) Bill 2013 would extend to vaccines, recombinant deoxyribonucleic acid-derived products, living modified organisms, stem cells, gene therapeutic products etc. It is also proposed to delineate medical devices from drugs by defining medical devices separately. Despite these amendments, there may still be lacuna in regulating nanomedicine especially in case of combinational products or nanomedicine that have multiple functions, for instance, iron superoxide dots as theranostics, therefore creating uncertainty on the regulatory pathway to be followed for such products. This uncertainty would also arise in case of nanosimilars or generic

nanomedicine, as there are differences between nano and bulk forms of drugs [25], which may affect the innovation quotient of nanomedicine in India. The existing Drugs and Cosmetics Act 1940 and Drug Price Control Order 1995 exclude nanoscale medicines and hence require further amendments to recognize (a) nanomedicine and (b) nano as an ingredient and to ensure labeling of the product containing nanomaterial.

Anand et al. [40] have pointed out the weakness of Indian regulatory mechanism in the context of regulatory implementation and oversight. It has been emphasized that there is a need of an effective risk governance system because of complexities associated with nanomedicine and inadequate information regarding regulation of nanotechnology in general [41]. Moreover, since nanomedicine is interdisciplinary, it converges through different disciplines; thereby, multiple legislations are applicable. Hence, it is desirable to simplify the process and reduce uncertainty. Keeping this in view, an institutional framework for regulation of nanotechnology in the healthcare sector in India has been proposed that considers parameters of environmental safety, occupational safety, product specificity, hazardous chemicals, waste disposal, intellectual property rights (IPR), R&D and information disclosure [42, 43]. The multi-tier system proposed by The Energy Research Institute (TERI) lays more focus on the infrastructure of regulatory framework rather than the mode of function and lifecycle of the product [43, 44]. Another regulatory framework proposed for nanotechnology by Purushotham and Karanam [45] is restricted to approval of material or product either for commercialization or R&D purpose on submission of dossier by the company, but neither the complete lifecycle of the product/service nor the entire range of stakeholders has been considered [45].

Notably, nanotechnology poses complex challenges that also need immediate attention due to potential commercialization of products. Most researchers have emphasized the need for a regulatory body responsible for governing development and commercialization of nanotechnology products [40, 46, 47]. Purushotham and Karanam [45] proposed Nanomission taking over this function of approval or establishing a separate authority for regulation [45]. Bhattacharya and Bhatti [48] have expressed their concern on uncertainty in institutional structure of the regulatory authority and proposed establishment of a department of nanotechnology to assist coordinated action and development of roadmaps and policies [48]. The studies discussed above emphasize the need for risk assessment and generation of data but fail to provide solutions for effective enforcement to enhance growth of nanomedicine in India. The regulatory framework that may be suitable for India is debatable [33]. As nanomedicine is evolving and it is too early to comment on the possible amendments, we propose a regulatory framework to govern nanomedicine from different angles. The authors propose establishment of a separate national regulatory authority independent of any funding agency that can have separate divisions for each thematic area. Further, for state-level implementation, state regulatory authorities can coordinate and report to the national regulatory authority. The authors elucidate a multi-tier regulatory framework considering India as a case study. The next section discusses the governance framework proposed for regulation of nanomedicine in India and its components. The presented framework intends to promote an efficient ecosystem for nanomedicine innovation and policy development.

3 Multi level governance framework for India

We propose a multi-level national governance system to regulate nanomedicine at the level of research, premarket and postmarket that involves regulatory space, policy regime, site of governance and lifecycle (Figure 2). The framework aims to (i) promote responsible research and innovation, (ii) enhance public and social acceptability of the products as well as research and (iii) ensure safety of human beings and environment. The illustrated framework is applicable for all applications of nanomedicine as shown in Figure 1B. Both products and services are to be governed by the framework presented here. The sections below discuss the principles on which the framework is based and its architecture.

3.1 Architecture of governance system for nanomedicine

The authors propose a three-tier architecture of governance mechanism for regulating nanomedicine in India. Tier 1 represents regulation at the research level, Tier 2 at the premarket level and Tier 3 at the postmarket level (Figure 3). The hierarchical structure is easy to implement and expand to accommodate any sub-emergent technology. As discussed in Table 1 there are gaps in terms of guidelines for waste disposal and handling. Institutes do have biosafety committee(s) for microorganisms established under the Environmental (Protection) Act 1986; however, nanomedicine does not fall under the purview of this committee.

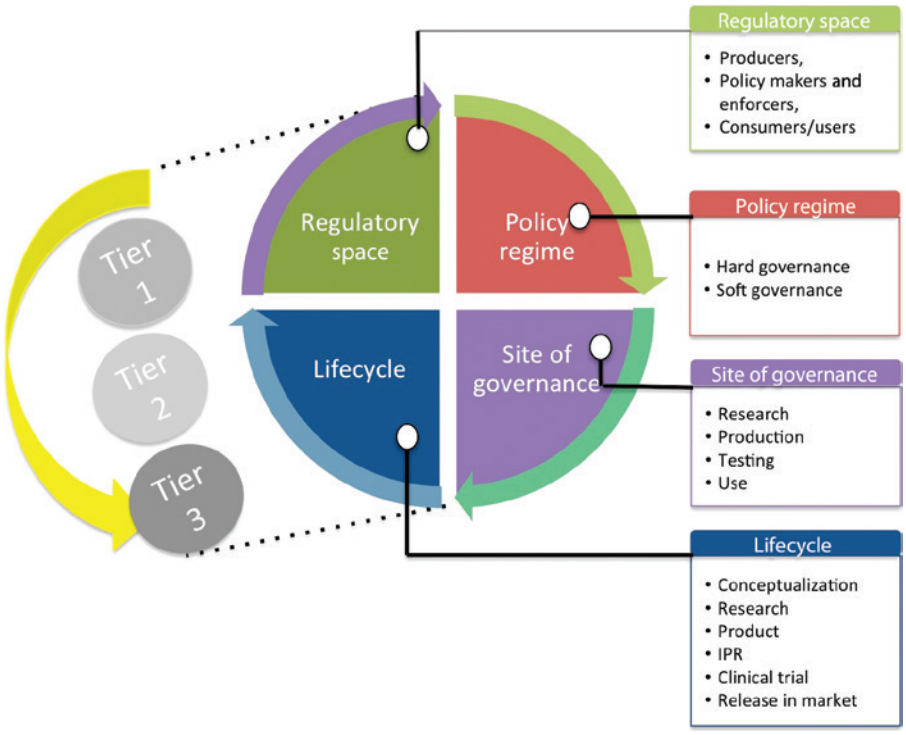

Figure 2: Proposed governance framework for regulation of nanomedicine in India. The framework is based on four components and comprises three tiers.

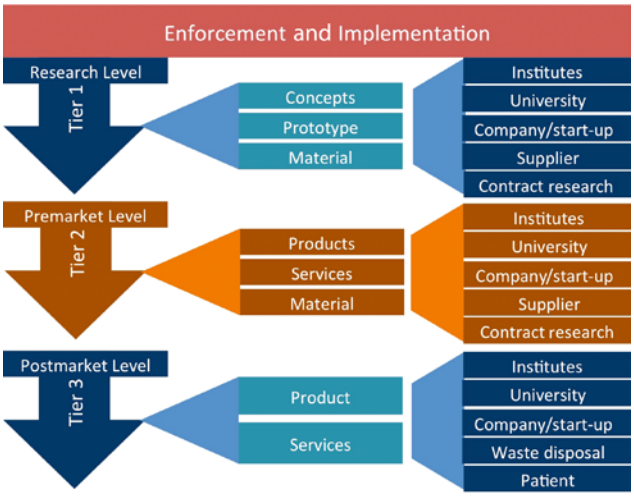

Figure 3: Three-tier governance framework for nanomedicine in India. The framework comprises three-tier regulating at research, premarket and postmarket levels.

3.1.1 Tier 1: research level

The first tier regulates at research level where the product is not completely developed or is at different stages of its development. Regulation at research level entails governing research and development both at company and institute levels. Additionally, it can be applied to suppliers and contract organizations that provide facilities for research, prototype development or component manufacturing. In order to address biosecurity issues, lone inventors and "do it yourself" projects can also be monitored. Although, in India, Factory Act 1948 provides for hazardous material, there are no specific guidelines for nanomedicine. Also, there are no particular laws applicable to individuals; thereby, it is important to govern at research level to control safety of worker(s), researcher(s), individual(s) and the environment. The authors through a survey observed that there are no guidelines at institute level for waste disposal and nanomedicine handling.

3.1.2 Tier 2: premarket level

In the proposed framework premarket level regulation covers clinical trials, approvals from authorities, production, risk assessments, disposal mechanisms and intellectual property (IP) protection. In case of services, contract research and manufacturing organizations, suppliers and manufacturers can be regulated. All premarket activities of universities, institutes and companies can be regulated to ensure quality and safety.

3.1.3 Tier 3: postmarket level

The framework has a component to administer overseeing compliance, enforcement and postmarket monitoring. Post release in market includes monitoring use by consumer, effect on environment and disposal. There are no laws on waste disposal by the end user or methods for its disposal. Additionally, pricing of the product and IP enforcement can also be monitored.

It is very essential that the framework be implemented at each level through various stages of the lifecycle of the product and at central and state level in the country. Governance mechanism can be improved by periodic review of the framework.

3.2 Pillars of the framework

The proposed multi-level governance system for regulation of nanomedicine in India is based on four principles that are regulatory space, policy regime, sites of governance and lifecycle of nanomedicine.

3.2.1 Regulatory space

Regulatory space refers to a landscape where a variety of stakeholders and interest groups may have resources, capacity and ability to exert influence over the governance of issue areas in the landscape [49]. In India, in the context of nanomedicine there are three important stakeholders that may influence the governance framework: (i) producers (ii) policy makers and enforcers and (iii) consumers (as shown in Figure 4). Producers include universities, institutes, small and medium enterprises, companies, start-ups or lone entrepreneurs, that are engaged in the research and development of nanomedicine-based products. The second group of stakeholders comprise policy makers and law enforcers at the central and state levels who have a critical role in the regulatory regime. The third set covers the consumers, that is, the research organizations, patients and public in general.

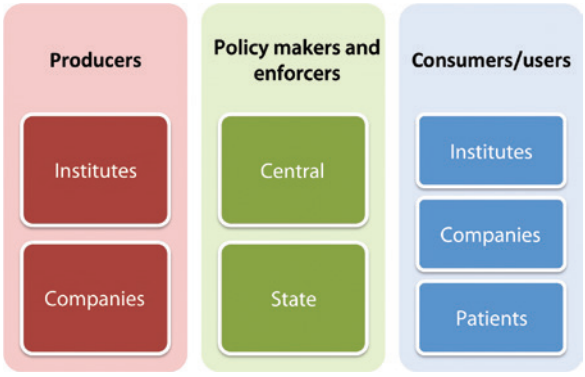

Figure 4: Regulatory space of nanomedicine in India. It comprises producers, policy makers and users.

3.2.2 Policy regime

Policy regime has been conceptualized as governing arrangements for addressing policy problems [50]. These governing arrangements can be either hard or soft form of governance. Nanomedicine in India can be regulated through a mixture of both the arrangements, as it is an emerging technology [15]. In the absence of nanomedicine-specific regime or provisions in existing laws that may cover nanomedicine, soft governance can supplement the regulation. We have proposed nanocertification as an effective soft governance tool for nanomedicine in India, and it has been discussed in detail elsewhere (paper communicated).

3.2.3 Site of governance

It is very critical to assess at which target site to regulate technology, and in case of nanomedicine we have proposed governance at the site of research, production, testing and use (Figure 5). At each site it is essential that the usage and disposal of waste be monitored to ensure biosafety.

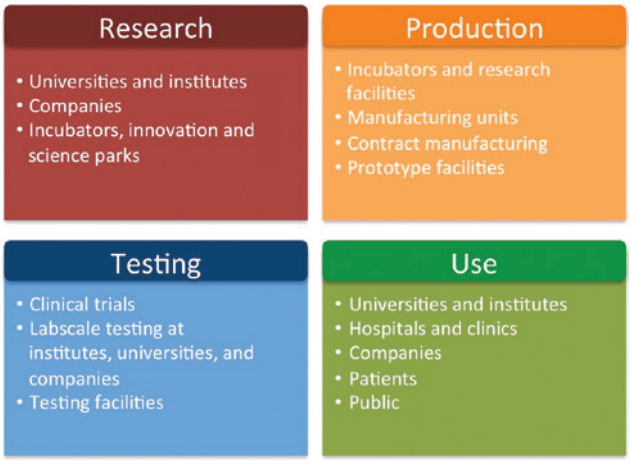

Figure 5: Sites of governance of nanomedicine in India. The sites comprise research, production, testing and use.

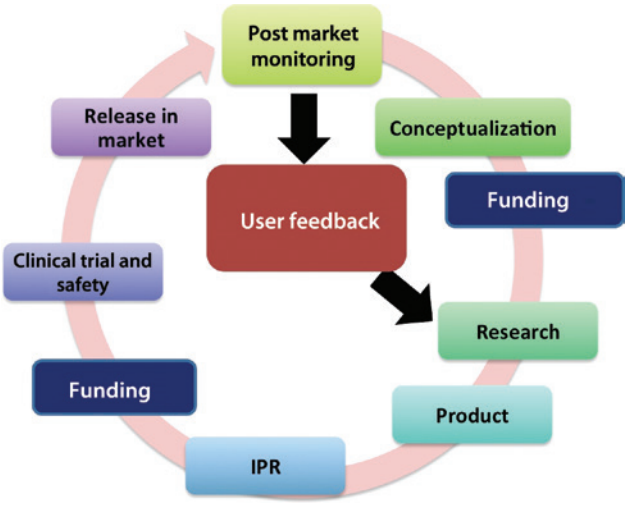

Figure 6: Lifecycle of nanomedicine in India. The lifecycle comprises different steps – conceptualization, research and development, IPR, clinical trials, safety, release in market and postmarket monitoring.

3.2.4 Lifecycle of nanomedicine based product

The lifecycle of a nanomedicine product can be divided into seven major stages: conception, research, product development, protection of IPR, clinical trials and safety assessments, release in the market and postmarket monitoring (Figure 6). The lifecycle of nanomedicine initiates with conception of an idea and ends with postmarket monitoring. A key role can be played by the postmarket surveillance in enabling further research to mitigate the issues based on user feedback or on callback of the products. Investments or funding are required for two critical stages of the lifecycle, that is, conversion of concept to establishment of proof of concept and product development to clinical trials. It is proposed to monitor throughout the lifecycle of the product including funding for effective governance of nanomedicine. Nanotoxicity information reporting by the recipient may be made mandatory upon completion of the project.

4 Conclusion

Each emerging technology needs to balance the risk(s) it poses and benefits that it offers to the society. Nanomedicine being a multidisciplinary field poses various challenges with regards to its regulation. To overcome this concern, India like many other nations has initiated steps to characterize the regulatory landscape for nanotechnology and its applications including nanomedicine. Organizations such as TERI and Center for Knowledge Management of Nanoscience and Technology have proposed a framework for governance of nanotechnology; however, neither of these are suitable for every application of nanotechnology nor do they cover the entire lifecycle. It is important to have a globally accepted definition and classification system for nanomedicine. To promote global trade, interoperability and harmonization of standards for products, manufacturing processes and nanotoxicity testing assays are critical. In India, the Bureau of Indian Standards and CSIR-National Physical Laboratory have been assigned the task of developing standards [41]. Nanomission has framed draft guidelines and best practices for safe handling of nanomaterials. The International Standard Organization and Organization for Economic Co-operation and Development (OECD) have also proposed standards for handling nanomaterials that would be applicable to all the OECD member countries. But an implementation and enforcement plan to ensure adoption of these guidelines is essential.

Keeping in view that nanomedicine is emerging and challenges are yet to be fully unraveled, a soft governance strategy such as nanocertification system to supplement the hard regulation may be adopted. Therefore, a three-tier governance framework, which can be used by the policy makers for developing a pathway for regulation of nanomedicine in India, is proposed in the present study. The model is based on regulatory space, policy regime, sites of governance and lifecycle of the nanomedicine product. The proposed framework has a combination of hard and soft governance mechanisms and regulates at three levels starting from research, premarket and postmarket with an essential component of implementation and enforcement. The governance framework regulates in terms of biosafety, biosecurity, regulatory pathway, accessibility and intellectual property. Such a framework aims to ensure further growth of the technology and address risk(s) effectively.

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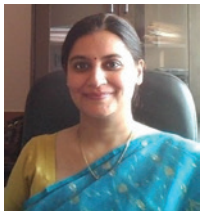

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