

**Regulation of Health related Nano Applications in India:  
Exploring the limitations of the Current Regulatory Design**

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## **Regulation of Health related Nano Applications in India: Exploring the limitations of the Current Regulatory Design\***

Nidhi Srivastava and Nupur Chowdhury<sup>λ</sup>

### **Abstract**

The burgeoning generic drugs and pharmaceuticals sector in India is one of the foremost industrial sectors of the new economy in India along with the IT sector. The growing manufacturing capacity of the health sector in concomitance with the aggressive international expansion strategies through mergers and acquisitions have meant increasing investment in core R & D activities. Industry leaders as well as commentators have reiterated the need to invest in R & D activities especially focusing on harnessing new and emerging technologies like nanotechnology in improving current drug delivery systems and other health related products. This trend is also partly a response to the government policy that supports and incentivizes the fundamental research and application of emerging technologies. This has been followed by consequent proliferation of nanotechnology R& D and application in pharmaceuticals and other related sectors, such as cosmetics, directly impacting health. Nanotechnology applications in drugs and equipment have the potential to have a huge impact on healthcare in India. Recently, nano particle drug delivery system in the form of nanotech-based chemotherapy has been introduced in the Indian markets.

Textiles is another sector, which has witnessed a spurt of nanotech applications in the readymade garments market. This partly reflects the global trend of launch of a series of fabrics with nano applications in the market. A number of Indian textiles producers in India have been aggressive in adopting nanotechnology in textile products and have also been competitive in striving for parity with their developed country counterparts in launching such products in the Indian market at a relatively short span of time. Further also in terms of public R & D spending, nanotech applications within the textiles sector viz. spill and stain resistance, moisture management and anti static capabilities have been supported by the government through R&D funding extended to publicly funded scientific research institutes. The government has therefore sought to provide technology incubator services to the industry. This is not surprising since, textiles is one of the key export related sectors and therefore the government's keenness to provide the necessary institutional support to technology development in this sector. However there exist several critical concerns specifically with reference to the health implications of such applications of nanotechnology both within the drugs and pharmaceuticals sector and the

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\* This has been developed as a Working Paper under the Project "Capability, Governance, and Nanotechnology Developments: a focus on India", Science and Technology Area, RGS Division, TERI.

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textiles sector. In this regard it is imperative to understand the underlying logic of state action within the context of the drive towards national economic development and thus necessarily, prioritising of certain public policy actions over others.

As is evident from above, the role of the state has been instrumental in supporting and facilitating market initiatives in the promotion and adoption of nanotechnology within specific sectors. The government at both central and state level has been active in promoting nanotechnology through several programmes, policies, strategy documents and vision statements. The department of science and technology is the nodal agency for development and promotion of nanotechnology. The department provides the secretariat to the Nano Mission Council, which is the highest advisory policy making body for nanotechnology in India. Besides the Council, the Nano Mission includes two other advisory groups, *viz.*, Nano Applications and Technology Advisory Group and the Nano Science and Advisory Group.

Several state level governments have set up several taskforces and missions to strategize and direct R & D funding for nanotechnology applications in key sectors like health. This elucidates the mandate and over all policy stand of the government towards nanotechnology, which is streamlined towards promoting enhanced research capability and wider application of the technology across key sectors of the economy. Thus the entire orientation of the current institutional and policy framework is towards strengthening technology development and its uptake by the industry. This has meant a significant neglect of the regulatory aspects relating to environmental, health, safety and ethical dimensions, while the technology *per se* has developed at a very fast pace.

This kind of frenetic activity spearheaded within the DST has not been reflected in the ethos of the nodal agency for health, *i.e.*, Ministry of Health and Family Welfare, which regulates health affairs at the central level. Drugs, pharmaceuticals and healthcare is overseen by the Directorate General of Health Services (DGHS) with Central Drugs Standard Control Organization (CDSCO) and the Indian Council of Medical Research (ICMR) looking after the regulation and research respectively. Besides, there is also a separate regulatory regime for consumer rights under the Consumer Protection Act.

Therefore there are three distinct areas, in which nanotechnology policy operates, *viz.*, promotion of nanotechnology R&D and application, regulation of healthcare, and protection of consumer interests. This consequently creates multiplicity and overlap in mandates and jurisdictions institutionally as well as in terms of substantive regulation. Given that technology development *per se* is the primary concern of the Department of science and technology, which is the nodal ministry overseeing nanotechnology in India, significantly narrows down (and redefines) the role of ministries regulating other aspects of nanotechnology, such as health and environment. This results in a decision making process that lacks interdisciplinary inputs from health and other related sectors impacted by nanotechnology. There is a clear privileging of “expert opinions” from technocrats working with nanotechnology in lieu of inputs from sectoral experts. This also adversely impacts the national preparedness at two levels; firstly, providing national experiential based inputs at forums developing international regulatory guidelines, norms, and future

proposals with reference to nanotechnology applications; secondly, a capacity deficit to envisage the regulatory needs and implement actions in this regard.

Therefore, the regulatory culture and the political economy of decision making vis-à-vis nanotechnology has a single focus on promotion of technology, ignoring other significant aspects such as health, environmental and social risks associated with technology development and adoption across sectors. In this context this paper explores the crucial political dynamics, institutional structures and capacity aspects of the regulatory regime governing the health related nanotechnology applications in India. The primary objective is to provide a clear idea of the regulatory governance structures and mechanisms at play and also to draw attention to the embedded limitations of the current regulatory structure in terms of its capacity to respond to and address the rapidly multiplying health related nanotechnology products and processes in India.

## I Introduction

Public debates and discussions on Nanotechnology developments in India have had an overwhelming focus on the range of applications which nanotechnology could enable and also on the enormous business opportunities that it promises.<sup>1</sup> Prominent science establishment luminaries have reiterated the need for Indian government to enable development and application of this technology - "We missed the opportunity during the semi conductor revolution. We should not repeat that with nano technology".<sup>2</sup> Admittedly the government has itself been a major contributor and has also enthusiastically responded to this call by unveiling an ambitious programme – “Nano Mission” based on the three prongs; first, investment in basic science research; second, education and human resource training and third, offering incubation support facilities.<sup>3</sup> Almost concomitantly but much more silently (and with less fanfare), the last few years have witnessed the launch of a range of consumer products, including medical applications (diagnostics, new drug delivery systems, etc), cosmetics and textiles using nano-materials.<sup>4</sup> Although in comparison, to their first world counterparts, the number of applications and products is not widespread, this is only half the story. Several direct tie-ups between Indian and foreign enterprises as well as between educational institutes are expected to have a definite impact on the manufacture and distribution capacities of indigenous firms and consequently the market is expected to witness a spurt of nanotechnology based products and applications over the next few years.

In this paper we would limit the analysis to applications in health related sectors. However, we would like to draw the attention of the readers towards other sectors where direct impact on health can be placed such as food, cosmetics and textiles. Textiles is of particular importance, considering the size of the industry and already available products in the market. The choice of these two sectors (health and textiles) is also based on its possibility of rapid proliferation on account of two factors; first, the pharmaceutical sector is one of the foremost industrial sectors of the new economy and therefore enjoys a unique position to leverage its strength in generic pharmaceuticals to focus on new vistas in medical applications in order to consolidate its position in the global market. Further, it has both the financial muscle and the risk appetite to invest in nanotechnology. Second, textiles constitute one of the largest indigenous manufacturing sectors and the main

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<sup>1</sup> Refer to the nanotechnology related news reports appearing in the media within this year - [http://www.teriin.org/div/Nano\\_Vol1.pdf](http://www.teriin.org/div/Nano_Vol1.pdf), accessed on 6th February 08.

<sup>2</sup> Prof. CNR Rao, Honorary President of Jawaharlal Nehru Centre for Advanced Scientific Research (Bangalore), while speaking at the eve of the Bangalore Nano event, Press Trust India, 5 December 07, <http://www.dnaindia.com/report.asp?newsid=1137400>, accessed on 25<sup>th</sup> February 2008.

<sup>3</sup> Chowdhury N, Regulatory Supervision of Emerging Technologies, *Economic and Political Weekly*, 18 November 2006.

<sup>4</sup> See for Medical Technology, Subramanian B; Perspectives on Future Directions in Nanotechnology: Implementation to Medical Applications, presented at B2B in Bio and Nanotechnology, ASSOCHAM, 20 September 2007. Also see for Textiles, Vigneshwaran N; Nanotechnology Finishing in Textiles, Nanowerk LLC, 13 October 2006, <http://www.nanowerk.com/spotlight/spotid=912.php> accessed in 6<sup>th</sup> August 2007.

export good from India. It is therefore imperative that the government is keen to ensure that the sector does not lose its economic edge to other fiercely competitive nations (like Sri Lanka, Bangladesh, China, etc). In this sense, developing stain resistant (along with other properties) textiles using nano-materials is a necessary enhancement of a traditional export product to ensure its edge in the market. Thus in the case of both the sectors the proliferation of technological applications is linked to the economic imperatives underlying the construction and operation of these sectors within the Indian context. In the international context the EU report on Nanotechnologies<sup>5</sup> provides a reasonable overview of the nano products. It classifies them into three categories - diagnostic systems (biochips and nano arrays), biomaterials and therapeutic systems (includes targeted drug delivery). The current research areas focus on synthesizing naturally occurring biological compounds with that of nanostructures and biomimetic nanostructures, the interface between biological-electrical, mechanisms for early detection of disease and also scaffolding techniques made possible by tissue engineering.<sup>6</sup>

In the Indian context, Dr. A N Mitra, one of the leading nanotechnology researchers in India has identified the use of nanotechnology for targeted drug delivery, in vitro diagnostics (through the use of gold nano particles), smart and multifunctional biomaterials and imaging and active implants as the most important areas of nano research and use the term “nano medicine” to refer to these applications.<sup>7</sup> Though there are a number of products and applications, which are in the pipeline – in terms of the products currently in the commercially available in the market, there are not many. Drug delivery systems and diagnostics seem to be the most popular applications (apart from textiles) involving nanotechnology available in India today. Within the field of textiles, nano applications include nano-fibers, nano-polymers and nano-finishes.

It would also be appropriate herein to highlight some specific cases in which the application of nanotechnology has been propounded to be an improvement over the current state of the art medical technology. In the case of integrated drug delivery systems, for instance, the gold nano particles will be able to facilitate early stage diagnostics of cancer.<sup>8</sup> Further the carbon nanotubes would be able to ensure target specific delivery of cancer drugs (therefore eliminating the need for a large dosage and this would protect the non-disease cells from getting affected by the dosage).<sup>9</sup> Similarly glucose sensor and insulin delivery system are able to manage diabetics insulin levels automatically.<sup>10</sup> It is believed that the potential of nano applications in health is much

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<sup>5</sup> European Commission. Nanotechnologies: A preliminary risk analysis on the basis of a workshop organized in Brussels on 1-2 March by the Health and Consumer Protection Directorate General of the European Commission. 2004, [http://europa.eu.int/comm/health/ph\\_risk/documents/ev\\_20040301\\_en.pdf](http://europa.eu.int/comm/health/ph_risk/documents/ev_20040301_en.pdf).

<sup>6</sup> *Ibid.*

<sup>7</sup> Information given by Prof. A N Mitra, Department of Chemistry, University of Delhi, in a personal meeting with the authors. November 2007. Further Prof. Mitra specified that cancer nanotechnology, nanomedicine applications in tuberculosis and children's diseases followed by orthopedic nano implants will have the most short term impact in the Indian hospitals.

<sup>8</sup> Brannon-Peppas, L. Recent advances on the use of biodegradable microparticles and nanoparticles in controlled drug delivery. *Int J Pharm*, **116**, 1-9., 1995.

<sup>9</sup> <http://www.thehindu.com/2008/03/23/stories/2008032359350500.htm> accessed on 25 February 2008.

<sup>10</sup> Chowdary M, *Diabetes Technology & Therapeutics*, 3(4): 651-654, December 1, 2001.

more than other sectors like IT or biotechnology and the cost of medical devices would also come down if the devices were to be built with the help of nano technology.<sup>11</sup>

Thus there has been a considerable excitement amongst the scientific research community around nanotechnology in India. It has been touted to be potentially an even bigger success story than the ICT (Information and Communication Technologies) and bring about a second technology revolution in India. It is interesting to note that, like the ICT, nanotechnology is a platform technology that potentially enables a wide range of converging experimentation and therefore applications. In this context the government has also been enthused by the potential economic benefits of the technology, to launch a dedicated mission solely for the promotion of nanotechnology spearheaded by the Department of Science and Technology. In the following section we discuss the cumulative impacts on the political economy of both the central and (certain) state government's promotional focus of nanotechnology development as a national technology developmental agenda. However, there is a certain silence on the issue of regulation of the technology, even though (as is seen above) several applications of the technology have already appeared in the market and are available directly to the consumers.

## **II Nanotechnology Development as a State Agenda: Institutional Structures, Policies and Vision Statements**

Speaking at the Indo-US Conclave on nanotechnology in 2006, the then India President Dr. APJ Kalam suggested the '*government to set apart sufficient funds on non-lapsable basis for nano-technology commercialization*', and asked the industries to have '*separate funds which can be used primarily for commercialization and develop innovative managerial mechanism to utilize these funds with utmost speed and with commercial success in mind... The project should be market driven*'. Dr. Kalam called for mounting '*a mission mode operation to deliver tangible products to meet our national demand as well as to be beneficial to the other countries*'.<sup>12</sup> These views can very well be linked to the vision of the departments under the aegis of Ministry of Science and Technology.

The Ministry of Science and Technology is the nodal ministry for promotion of research and development in the area of technology and administers its functions through three departments – department of science and technology (DST), department of biotechnology (DBT) and department of scientific and industrial research (DSIR).

With technology development, commercialization and support to basic and applied research, DST has been the most instrumental agency within the government for encouraging nanotechnology development and application through both financial and institutional support. The Department, with the agenda of promoting nanotech as a thrust area, has declared an investment of 100 crore INR over the next five years for basic and

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<sup>11</sup> Statement by DRDO Chief Controller (R&D) in **Tamil Nadu to be India's Nanotechnology hub** reported in *Indiaedunews*, June 15, 2007

<sup>12</sup> Dr. A.P.J. Abdul Kalam's address at the inauguration of the Indo-US Nanotechnology Conclave held on Wednesday, February 22, 2006 at New Delhi. [Source](#): Press Information Bureau, Govt. of India

applied research promotion, infrastructure support, education and international collaboration in this regard. Nano Mission is an umbrella programme implemented by DST for capacity building towards overall development of the field of nanotechnology research in India. Out of the total 141 projects that have received funding from the NSTI and mission since the year 2000, it is only since the past one and a half years that four projects on nanotech applications in health have been taken up<sup>13</sup>. Although this is a very small proportion of the total R&D in nanotech in India, it is reflective of a trend that is set to grow. Half of the public private partnerships in the form of industry-linked projects under the mission are with companies dealing with drugs and pharmaceuticals.<sup>14</sup> The Working Group on Drugs and Pharmaceuticals for India's XI five-year plan too observes that the '*drug delivery industry has dramatically changed in the past three years. The market may see profitable drug delivery companies using their proven technologies marketing products on their own account*'.<sup>15</sup>

DBT and DSIR too have been supporting some research in nanotech, although not in any organized manner. While DBT has focused essentially on nano-biotech research, most of the nano research funded by DSIR pertains to materials and metals and chemicals (DSIR Annual Report 2006-2007).

The Defence Research and Development Organisation (DRDO), which has fullerenes & Nano tubes as one of the thrust areas in Materials research, has developed diagnostics tools for TB and typhoid, by using nanotechnology.<sup>16</sup> The Ministry of Commerce and Industry and especially the Department of Industrial Policy and Promotion (DIPP), aims at facilitating investment and technology flows in industrial development. Recently, the commerce secretary also has made a public statement emphasizing how '*India would not be able to do without it (nanotechnology), and Indian companies should be encouraged to get into it at the earliest*'. (Economic Times, 2008<sup>17</sup>)

Industry associations have also joined in the pursuit of promoting nanotechnology in different industrial applications. The Confederation of Indian Industries (CII) launched the nanotechnology initiative in 2002 to to forge partnerships for collaborative research and product development, explore the possibilities of Indian industry to take part in these and setting up joint ventures in India with focus on bio-nanotechnology, drug discovery and delivery.<sup>18</sup> Like CII, other industry associations and business promotion organizations such as the Associated Chambers of Commerce and Industry of India

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<sup>13</sup> 2006-2007 – Designing and generation of novel efficient biotags and drug carriers; preparation and characterization of bio-polymeric nano particles for use in drug delivery. 2007 -2008 Jan. – magnetic nano particulates for controlled and targeted drug delivery; establishing centre for nano sensors and nano drug delivery. *Source*: Nano Mission

<sup>14</sup> IIT Madras is working with Murugappa Chettiar & Orchid Pharma, University of Hyderabad with Dr. Reddy's Labs and NIPER, Chandigarh is also working with Pharma industry. *Source*: Nano Mission

<sup>15</sup> Report of the working group on drugs and pharmaceuticals for the eleventh five-year plan (2007-2012) URL: [http://planningcommission.nic.in/aboutus/committee/wrkgrp11/wg11\\_pharma.pdf](http://planningcommission.nic.in/aboutus/committee/wrkgrp11/wg11_pharma.pdf)

<sup>16</sup> [http://www.business-standard.com/common/news\\_article.php?leftnm=8&bKeyFlag=BO&autono=316211&chkFlg=](http://www.business-standard.com/common/news_article.php?leftnm=8&bKeyFlag=BO&autono=316211&chkFlg=)

<sup>17</sup> Nanotechnology is the future for Indian firms: Commerce Secretary. 25 Mar, 2008, The Economic Times Planning Commission WG On drugs and pharmaceuticals.

<sup>18</sup> Confederation of Indian Industries (CII); URL <http://cii.in/documents/Technology/page1.pdf>

(ASSOCHAM) are also looking at pharmaceuticals, FMCG and electronics as focus areas for nanotechnology applications.

These associations have been promoting nanotechnology not only at national level but sub national levels as well. In Tamil Nadu, a joint programme of Tamil Nadu Technology Development & promotion Centre (TNTDPC) and CII is building awareness about and facilitating the technology amongst other things. The Tamil Nadu government is proposing a nanotechnology park, on lines of Hsinchu Science Park in Taiwan.<sup>19</sup> In the state of Kerala, a new centre has been established as the first Government of India-funded initiative for nanotechnology in tissue engineering and stem cell research in India.<sup>20</sup>

Therefore, currently the Indian government, public funded and private institutions and industry, all of them are looking at nanotechnology as a thrust area for R & D and applications in varied sectors. A statement, rather caution, made by an eminent scientist and the chairman of the Nano Mission Council captures the mood of the Nanotech situation in India. Speaking at the 93rd Indian Science Congress, Prof CNR Rao said, “*If we don't join the (nano) race, we will be left behind*”. It is this fear of being left behind by other countries in the nano revolution that has triggered a single point agenda for giving a thrust to nanotechnology R&D and application. Unfortunately, this bandwagon is being joined by several researchers, institutes, industries, and government departments without giving enough thought to the possibility of risks. Undoubtedly, nanotechnology is a promising technology but all the initiatives around it have been so concerned with the promotional R & D activities that any engagement with the risk and regulatory studies has been significantly ignored. One key feature responsible for this phenomenon is the sharp division of activities and mandates amongst different wings of the government, so much so that often these work in isolated water-tight compartments. DST, DSIR, MoC, in line with their departmental and ministerial mandates, have focused on greater R& D and technological applications by providing endorsements, support to research institutes, R&D laboratories and state led initiatives. However, this process has been far from being inclusive and therefore, the need to examine and regulate the possible risks associated therewith has been overlooked, except for a few activities by IITR and NIPER.

Institutionally, Ministry of health and family welfare (MoHFW) is in charge of prevention and control of health related hazards. The MoHFW has a large mandate that includes inter alia drug regulation administered under the directorate general of health services (*discussed in detail in part III*). In India, medical devices such as implants and stents are considered to be drugs and included under the drug regulatory legislation. However, considering that nanotechnology is being used in drug delivery and being promoted by the science and technology departments, the focus is on promotional aspect only. There have been several initiatives towards developing the technological applications but owing to the lack of coordination between ministries and otherwise burdened agenda of MoHFW, not much has happened on the regulatory side of nanotechnology. Rules and regulations already in existence extend to nanotech

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<sup>19</sup> “Tamil Nadu plans nanotech park” *News item* in Business Standard November 07, 2007

<sup>20</sup> Amrita Centre for Nano sciences inaugurated on 17 February 2007 Source: News item in the Hindu Date:18/02/2007 URL: <http://www.thehindu.com/2007/02/18/stories/2007021819880300.htm>

application in health sector too. Whether they are sufficient or not for addressing the concerns of regulatory governance are a different issue and is discussed in the following section.

### III Regulatory Governance of Health Related Nanotech Applications

The Report of the National Commission on Macroeconomics and Health (2005)<sup>21</sup> identifies “weak regulatory environment” as one of the impediments to access to essential drugs and medicines. It further states the following:

*“Spurious and substandard drugs have been a longstanding concern. Poor enforcement of regulations is due to inadequate and weak drug control infrastructure at the State and Central levels. Only 17 of the 31 States and Union Territories have drug-testing facilities, and in all states there is an acute shortage of manpower for enforcement.”*

This in essence quite clearly elucidates the critical regulatory and capacity failure of the state in the health sector. The Commission, in line with several others reports<sup>22</sup>, recommended setting up of an oversight authority that is autonomous in laying down standards and quality certification processes and in directing resources use in an optimal manner. Keeping in mind the need for standardization and quality control of nanotech related health applications, establishment of a National Commission for Quality Assurance was also suggested.

With this exposition as a background, this section seeks to not only give an overview of the current regulatory context but also comment on its capacity to respond to the new challenges that accompany such developments.

There are three essential arenas of regulatory confluence vis-à-vis nano applications in health. The first would be through the regulatory sieve that all health products and devices have to pass through before they can become commercially available. Second, would be through the regulation of clinical testing and other testing procedures that are proscribed for drugs and other health products. Third, would be in terms of contract research. In such cases the manufacturers who do not directly deal with the commercial aspects are also required to follow certain regulatory stipulations in terms of their handling and distribution of such products. In this regard it would be prudent to first provide a detailed study of the Drugs and Cosmetics Act. In this part, we would also discuss in some detail, the National Pharmacovigilance System that was put into place by the government recently in 2005 and which has the potential to provide regulatory oversight to health related nano applications in India. This would be followed by an overview of the regulatory bodies including the CDSCO (Central Drugs Standards Control Organization), the DGHS (Director General of Health Services) and the National

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<sup>21</sup> Report of the National Commission on Macroeconomics and Health, Ministry of Health and Family Welfare, Government of India 2005.

<sup>22</sup> Government of India. Mashelkar Committee Report, 2003; Indian National Science Academy, Committee on Instrumentation in India Report, June 2004, [http://psa.gov.in/writereaddata/11913305721\\_Final\\_20report\\_on\\_Instrumentation.pdf](http://psa.gov.in/writereaddata/11913305721_Final_20report_on_Instrumentation.pdf) accessed on 25 February 2008.

Pharmaceutical Pricing Authority. Research bodies such as ICMR, CSIR and INSA (which is a science advisory society) will also be studied in terms of their functions and their regulatory impact.

- ***Legislative Acts and National Programmes***

*Drug and Cosmetics Act, 1940*

The primary objective of the Act is to regulate the “import, manufacture, distribution and sale of drugs and cosmetics.” In this sense, the Act provides a comprehensive coverage of all aspects of manufacture and right up to the sale of drugs and cosmetics in India. The Act is one of the few legislations that clearly differentiates between the function of the authorities at the state and at the central level. The Central Drugs Standards Control Organization (CDSCO) is the apex central authority that is responsible for new drugs approval, overseeing clinical trials, laying down standards for drugs and quality control for imported drugs. Further it also provides expert advice to the state authorities with a view to ensuring uniformity in the enforcement of the Act. The state authorities (State Drug Controllers)<sup>23</sup> on the other hand have the primary responsibility of overseeing the regulation, manufacture, sale and distribution (including licensing) of Drugs.<sup>24</sup> The Act provides for an expanded definition of the term “drug”, which also includes medical devices for internal uses such as diagnostics and treatment.<sup>25</sup> This is therefore sufficiently broad to include those nano-related health applications. The Act also empowers the central government to prohibit import and manufacture of drugs and cosmetics in public interest. Risk to human beings/animals has been mentioned as one of the circumstances under which the government can do so.<sup>26</sup> The Act also enables the government to specify a quality standard. Information disclosure forms an important part of the regulatory apparatus and is especially important in case of entities, which use or apply or deal with nano-related health applications. The Act provides for detailed penalties in case of adulterated and spurious drugs usage. The Act prohibits manufacture and sale of adulterated drugs and cosmetics, which include cases where the *container is composed of any poisonous or deleterious substance which may render the contents injurious to health or where it contains any harmful or toxic substance which may render it injurious to health.*

Carbon Nanotubes for targeted drug delivery and nano gold particles used for diagnostics, if found to be potentially hazardous, can fall within this explanation. In this regard it useful to draw attention to the term “may” used in the above sections as this considerably waters down the requirement for any substance (that is *per se* deemed to be toxic) to prove that it is harmful to health for it to be deemed adulterated. The threshold set refers to “potential” or “possibility” of adverse health impact and not the requirement of absolute proof.

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<sup>23</sup> List of State Drug Controllers, <http://cdsco.nic.in/html/STATE%20DRUGS1.htm>, accessed 4<sup>th</sup> January 08.

<sup>24</sup> Section 18 of the DCA, 1940.

<sup>25</sup> Section 3.b.iv and section 3.b.iii *Ibid*.

<sup>26</sup> Sections 10A and 26A *Ibid*.

There exists adequate support under the Act to undertake measures ranging from labelling requirements to the prohibition on manufacture and sale of nano-related health applications in India in cases where there is uncertainty about the safety of the nano drugs. Nevertheless as stated in the beginning of the section, it is the state drug controllers, who have the responsibility to oversee the regulation of drugs within the country, and only 17 of them have access to drug testing facilities within the State. This brings into sharp focus the capacity deficits faced by the regulatory authorities. This problem is further compounded in the case of nano-particles since there exists limited information on the toxicity studies of nano-particles in India. Further, known capacity for testing nano-particle toxicity exists only at NIPER (National Institute of Pharmaceutical Education and Research) and at the IITR (Indian Institute of Toxicology Research).

Several high level committees<sup>27</sup> appointed by the government over the years have had the opportunity to review the functioning of the drug regulatory regime under this act. Amongst some of the recommendations made, the following three needs urgent attention. First, there is a basic problem of un-uniformity in the interpretation of the provisions of the related legislations amongst the various state drug controllers. This is squarely the failure of CDSCO to provide for adequate coordination between state units. This consequently reflects on the varying level of implementation of the statute by the states. Second, there is a disconnect between the number of manufacturing and selling establishments licensed within the state territory and the number of drug inspectors overseeing such establishments. Most of the states are in this case unable to provide for adequate number of personnel, testing facilities and support systems in accordance to the recommendations. Third, the importance of post-marketing surveillance by the regulatory authorities has also been reiterated by a number of high-level committees, as against the current regime. Under the current regime, indirect supervision has been mandated through the information reporting requirements by the R&D institutions and the pharmaceutical companies.

#### *National Pharmacovigilance Programme*

Pharmacovigilance refers to the monitoring systems that are put into place to oversee the safety of new pharmaceutical entities (NCEs) or even generics manufactured by domestic pharmaceutical companies. Most countries have such systems since it serves as an important tool to collect data relating to the risk profile of the drug generated under real conditions. In this regard it is important to mention that, Indian regulators have previously had a dependence on data generated in other countries. However since the last decade it has been recognized and largely accepted that the Indian population is distinctive in both its physiological composition and genetics makeup and therefore populations effects data generated in other countries cannot be taken as a correct index of the effect of those drugs on the Indian population. All these reasons were paramount to the government decision to incorporate and launch a National Pharmacovigilance Program (NPP) in 2004. Thus the program was first launched as a voluntary initiative and

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<sup>27</sup> Hathi Committee Report 1975; 1982 Task Force on Health Regulation Report; Pharmaceutical Research and Development Committee Report 1999.

then later incorporated into the legal regime through the review and amendment of Schedule Y, under the Drugs Control Act in 2005.

The primary aim of the of the programme is to create and manage a database of reports of Adverse Drug Reactions (ADRs) that would form the basis for regulatory decisions for market authorizations of drugs in India. This is intrinsically safety measure that was instituted based on the WHO report – “Safety Monitoring of Medicinal Products – Guidelines for Setting and Running a Pharmacovigilance Centre”<sup>28</sup>, in the scenario of the increasing reports of spurious and adulterous drugs proliferating the market. This is carried out by providing for detailed obligations on the part of the pharmaceutical company marketing the drug (i.e. holding the marketing licence of the drug) to collect collate and evaluate safety information regarding suspected adverse reactions.<sup>29</sup> This legal obligation on the pharmaceutical companies essentially shifts the costs of the regulatory burden from the authorities to the former while retaining the right to oversight for the latter in case the information submitted is found to be inadequate or false.

Researchers have supported the spontaneous reporting of adverse drug reaction (SADR), as an excellent tool for enabling the collection of safety information for detection of early signals.<sup>30</sup> Though it is not considered a qualitatively effective tool, however it is very useful in conducting risk benefit analysis especially in case of new drugs. Given that there is still widespread uncertainty as to the health implications of such applications, these reporting requirements make it obligatory on the part of the pharmaceutical company marketing such products to be more vigilant and create systems for early detection of any adverse reactions. Nevertheless since most of the drug formulations are not identified or more specifically there is limited consciousness of the fact that the nano ingredient within drugs could trigger adverse health reactions makes it difficult to track such reactions and then relate them to their nano inputs. Thus it is imperative that the government adopts a more interventionist policy position in closely scrutinizing nano related health applications in case of PSUR requirements. This would also send the signal to the pharmaceutical companies to adopt protocols and practices that would allow detection and establishing cause and effect reactions in the case of nano related health applications in drugs.

- ***Standard Setting and Regulatory Agencies***

*Central Drug Standard Control Organization*

The CDSCO is the primary drug regulatory authority in the country. It essentially coordinates all the functions relating to quality control of imported drugs, coordination of activities between the state authorities, new drug approvals for drugs manufactured and imported. The approval of new drugs entails examination of the clinical trial reports and

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<sup>28</sup> Uppsala Monitoring Centre, *Safety Monitoring of Medicinal Products – Guidelines for Setting and Running a Pharmacovigilance Centre*, 2000. Accessed from, <http://www.who-umc.org/graphics/4807.pdf> on 25 February 2008.

<sup>29</sup> Arora D. Pharmacovigilance obligations of the pharmaceutical companies in India. *Indian J Pharmacol* 2008; 40:13-6.

<sup>30</sup> *Supra Note* 30; 3-4.

checking them for bio-equivalence, etc before granting marketing approval. As discussed above the CDSCO is also the implementing agency for the National Pharmacovigilance Program. In this context, it would be useful if CDSCO pushes for a more intensive program in tracking information on nano applications in the health sector.

CDSCO, although a separate organization, works within the structure of DGHS and its mandate, activities, infrastructure etc. fall under the purview of the directorate. DGHS is the agency overseeing the implementation of the various health programs and schemes and provides technical inputs to the ministry on various aspects of their functioning and implementation and serves as a coordinating agency for all the specialized health related matters including drug regulation and standard setting.

#### *Bureau of Indian Standards*

The Bureau of Indian Standards (BIS) is the chief Standard Setting body in India and sets voluntary standards to indicate the quality of a product. BIS standards are generally voluntary but some of the BIS standards become mandatory when notified to that effect by the government. It is engaged in formulation of Indian Standards for the 14 sectors including Metallurgical-Engineering. Under this, a sectional committee<sup>31</sup> has been set up with scope of standardization in the field of nanotechnology. The committee is meant to liaison with Technical Committee 229 of International Standards Organization (ISO) and represents India in the international standard setting process for nanotechnologies. It is crucial that the representatives at international standard setting fora are equipped to voice the concerns of developing countries. Standardization is also of prime importance, since without the relevant support in terms of metrology, regulatory oversight cannot be developed.

- ***Research Bodies***

#### *Indian Council of Medical Research*

The ICMR under MOHFW is the apex government body engaged with the development and implementation of biomedical research in India. With public health as its key mandate, it invests in research that has been identified as national health priorities, such as, control and management of communicable diseases, fertility control, maternal and child health, control of nutritional disorders, alternative strategies for health care delivery, containment within safety limits of environmental and occupational health problems; research on major non-communicable diseases like cancer, cardiovascular diseases, and drug research.<sup>32</sup>

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<sup>31</sup> Nanotechnologies Sectional Committee, MTD 33

<sup>32</sup> For more details see <http://www.icmr.nic.in/abouticmr.htm> accessed on 25 February 2008.

**Table 1. List of Nano Related Health Research Funded by ICMR 2006-07<sup>33</sup>**

S.No.	Project Details
1.	Oral delivery of cyclosporin G, an immunosuppressive peptide by entrapment as liposomes and nanoparticles.
2.	Nano particle delivery of bioactive constituents and drug by supercritical fluid system.
3.	Solid lipid nanoparticles as surrogate carrier for bioactive agents
4.	Nanoparticle mediated drug therapy to the brain for the management of Alzheimer's Disease.
5.	Treatment of visceral leishmaniasis with engineered nanoparticulate carrier containing amphotericin B
6.	Design, development and evaluation of nanoparticulate drug delivery system of antiviral drugs for improvement of oral bioavailability

A key question is whether ICMR would invest in R&D with regard to nanotech applications in health in terms of determining the toxicity and other aspects. The possibility of such a development is quite low, as nanotech is not a widespread technology and is not a national priority in terms of health care. However, in case of environmental and occupational health problems, the potential exposure and toxicity effects of nanotechnology. ICMR is currently funding a few nanotech related health research (Table 1) and there exists a responsibility to ensure that ICMR supported research is in conformity with the occupational health and safety standards. However the larger question is whether the ICMR as a government body is obliged to invest in the toxicity aspects of health related nano products. A look at the information in Table 1 seems to suggest that the ICMR is also directing its research funds into projects dealing generally with drug delivery services based on nano particles. This is clearly a good investment strategy but does not contribute anything as such to ICMR's responsibility towards public health. To reiterate, ICMR's moral responsibility lies in investing in research that would address public health aspects and in that sense toxicity and other effects of health related nano applications in the market.

#### *Council for Scientific and Industrial Research*

Another premier government research body is the Council for Scientific and Industrial Research (CSIR), which was established with the idea of providing scientific industrial R&D for economic, environmental and societal benefits for the people. It has been supporting research in several areas including health and as per the CSIR reports, eleven of the fourteen new drugs developed in independent India are from CSIR.<sup>34</sup> Although no major drug research involving nanotechnology is being carried out under the aegis of CSIR at present<sup>35</sup>, considering the past record of CSIR in drug research, there is a

<sup>33</sup> Information sourced from ICMR Annual Report 2006-07, Appendix IV; *Research Fellowships Funded During 2006-07*. ICMR, 2007.

<sup>34</sup> [http://www.csir.res.in/External/Heads/csir\\_faqs.htm](http://www.csir.res.in/External/Heads/csir_faqs.htm)

<sup>35</sup> Most of the nanotechnology related studies under the CSIR relate to metals and metallurgy and chemicals only with occasional studies in other development areas such as water and energy.

possibility of greater involvement of the Council in nanotech related health applications as well.

#### *Indian National Science Academy (INSA)*

INSA is the only government scientific body that has a clear mandate of liaisoning between science and humanities and has a specific committee set up for drawing ethical guidelines for pursuing Science. The Academy has had a considerable role to play in influencing the overall policy making for technology over the years and it would be worthwhile for it to set up a specific committee on ethical issues involved in nanotech applications in key sectors.

#### *Other Research Institutes*

Besides these government research bodies, several institutes<sup>36</sup>, both public funded and private have launched programmes in nano sciences at various levels. The Indian Institute of Technology in Chennai, Delhi and Kanpur and a few other scientific research institutes are getting into nanotechnology by undertaking research projects or running courses. Separate specialized centres for nanotechnology have been set up in as many as seven institutes science and technology. These centres are working on a whole range of nanotech applications including Nanodevices, Nanocomposites, Nanobiosensors, Nanoelectronics, Implants, Tissue Engineering and Stem Cell Research.<sup>37</sup>

## **IV Technology Development and the Regulatory Culture**

The question, which arises in the mind of any ritualistic lawyer, is why is there a need to look into issues of regulation and culture while explicating the components of the legal regime and its cumulative regulatory effects. The need arises in order to gain a deeper understanding of the origin of such regulations, their implementation techniques, how sustainable are they, the possibility of change, etc. In this sense, locating technology regulations (and for that any sector specific regulation) squarely within the specific national/regional/sub-regional/local context explores the possibility of providing a more organic perspective into the whys and wherefores of regulation.<sup>38</sup> Specifically in the case of technology regulation, it is important to note that the extensive drive for industrialization that was taken up post-independence in India had a number of economic and social implications, however the most important of them, was that of development of technology. Interestingly however (but not surprisingly – See the national development

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<sup>36</sup> IIT Chennai, IACS, Kolkata, University of Pune, NCL, Pune, JNCASR, Bangalore, BHU, Varanasi, IIT Kanpur, Kanpur, IISc, Bangalore, IIT, Delhi, SINP, Kolkata, Bose National Centre for Basic Science, Kolkata are working on nano science.

<sup>37</sup> Centres for nanotechnology have been set up at Amrita Institute of Medical Sciences, Kochi, Kerala, S N Bose National Centre for Basic Sciences, Kolkata, Tata Institute of Fundamental Research, IIT-Bombay, Mumbai, Indian Institute of Science, Bangalore, IIT, Kanpur, Indian Association for the Cultivation of Science

<sup>38</sup> See Pickering A, ed. *Science as Practice and Culture* University of Chicago Press; 1992.

trajectory in Japan for similarities)<sup>39</sup> most of the technology development was driven by indigenisation of foreign technology. Thus adaptation of technology for indigenous needs was the primary aim of the scientific establishment in India and to an extent this continues to be true even in the private sector (witness the burgeoning generics pharmaceuticals sectors).<sup>40</sup>

However before discussing the nature of technology development, it is important to comment on the agenda of technology development in post-independent India itself.<sup>41</sup> One of the main architects of the technology development map of India was Nehru, who was deeply impressed and driven towards the adaptation of technology for India's development needs. Consequently, first, technology development (focussing on adoption and adaptation of western scientific breakthroughs) was given a prominent place within the national development agenda.<sup>42</sup> Second, the founding fathers of the Indian scientific establishment were given considerable leverage power of a civil servant.<sup>43</sup> This formed the basis of the tradition of requiring technocrats to be at the helm (and also make up for a majority of the departmental workforce), that continues till today.<sup>44</sup>

There is a certain amount of locational dynamics that have come into play in the case of the inclusion of technology development within the national development agenda. This privileging of technology was also based on an implicit assumption of the neutrality of technology in terms of its inert (therefore value neutral) nature and as the only tool for development.<sup>45</sup> The positing of nanotechnology within the discourse of national development has meant that its regulatory aspects in terms of environment, health and social aspects has faced systematic neglect. The unquestionable importance of the national development agenda and its primal position in the list of national priorities has meant that the government efforts have focussed on the development and dissemination of this technology. This is a trend similar to the one, which was witnessed in the case of biotechnology in India. In this context it would be useful to examine a closely the development trajectory of biotechnology in India to give us a better understanding and a chance to predict whether nanotechnology would be going the same way.

In the case of agro-biotechnology, the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous micro-organisms/Genetically engineered organisms or cells

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<sup>39</sup> For a detailed analysis See Uchino A; *Technological Innovation in Post War Japan*, Developing Economies 7 (4), 406–427, 1969.

<sup>40</sup> *Supra Note 3*, 4730.

<sup>41</sup> Nandy A, *Alternative Sciences*, Allied Publishers, 1980. Panikkar K, *Culture, Ideology, Hegemony: Intellectuals and Social Consciousness in Colonial India*, Tulika Publications 1995. Also Kumar D, Also Kumar D, *Reconstructing India: Disunity in the Science and Technology for Development Discourse, 1900-1947*, University of Chicago Press, 2000.

<sup>42</sup> Ashraf K and Belluardo J, eds. *An Architecture of Independence: The Making of Modern South Asia* New York: The Architectural League of New York, 1998 pp 16.

<sup>43</sup> Prakash G, *Another Reason: Science and Imagination of Modern India*, Oxford University Press, 2000.

<sup>44</sup> See Kumar D, *Science and the Raj*, Oxford University Press, 1995. Also Jasanoff S. *The Fifth Branch: Science Advisors as Policymakers*, Harvard University Press 1990.

<sup>45</sup> Shallis M *The Silicon Idol: The Micro Revolution and its Social Implications*, Oxford University Press, 1984. See also Pacey A, *The Culture of Technology*. Basil Blackwell, 1983. Also Prakash G, *Another Reason: Science and Imagination of Modern India*, Oxford University Press, 2000.

was enacted and implemented in 1989. At that point of time there was an absence of any domestic pressure and also India did not have any home grown indigenous pharmaceutical or agro-biotechnology sector to talk about. This was then a clear case of regulatory foresight, wherein the government recognized the need for regulation of a technology. The essential triggers for such a regulatory response was international developments wherein there were a number of GM related public health disasters and which was the primary reason for the regulatory backlash the Europe witnessed during the eighties in the context of biotechnology. However since the entry into force of the GM notification there has been a steady drive towards the negation of the regulatory regime. There have been repeated and wide spread demands by civil society groups on the capacity of the regulatory regime to provide for more effective and transparent decision-making processes by the regulatory authorities (viz. the RCGM and the GEAC).<sup>46</sup> However the government has been accused of dragging its foot and the attitude has been not to be seen antagonizing the biotechnology industries lobby<sup>47</sup>. The latest proof of such trends has been the promulgation of Notification N.S.O. 1519(E)<sup>48</sup> dated 23<sup>rd</sup> August 2007, under which the ministry exempted the importers of GM food from all regulatory oversight under the Ministry of Forests and Environment, Government of India. This was almost a u-turn from the stand that the government had formally advocated in the past. It was also against the government's own standing in the international organizations like CODEX, etc. Further there was no suitable rationale provided by the ministry in doing so. This also illustrates the government's willingness to ignore and subvert its own regulatory mechanisms governing biotechnology.

In this context it is also imperative to explore the role of the industry associations in lobbying government to scale down regulations and have increasingly gained prominence in advocating for a more aggressive public sector backing of technology development and providing for infrastructure support to private sector technology enterprises. In this case the role of state governments have been especially worth noting. This however does not fully explain the regulatory block that exists among developers and promoters of technology in India. Despite the fact that regulatory certainty seems to be a more rational and economically stable situation, it is not desired usually. The primary reason for such a reaction from the private sector is not surprising if traced to our own structural history of regulations. A study of the structural and procedural history of most Indian legislations would support the contention that they were developed and implemented from a classic command and control regime – that was itself a remnant of the colonial period. The infamous state control exemplified during the time of *license raj* further cemented such notions of an interventionist state.<sup>49</sup> Thus the term “regulation” is implicitly assumed to

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<sup>46</sup> The Recombinant DNA Advisory Committee and the Genetic Engineering Approval Committee respectively.

<sup>47</sup> See Goswami B, *GEAC's poor record of regulation*, Regulating GM Crops, India Together, August 2007 <http://www.indiatogether.org/2007/aug/agr-geac.htm> accessed on 25 January 2008.

<sup>48</sup> Since then the notification has been “kept in abeyance for a period of six months” until the Food Safety and Standards Authority functioning under the Ministry of Health, issues further regulation of GM processed food. This has been as under Notification No. S.O. 411 (E), issued under the GM Rules under the Environment Protection Act 1986.

<sup>49</sup> Soo, K, *From License Raj to Market Forces: The Determinants of Industrial Structure in India after Reform*, *Economica*, Vol. 75, Issue 298, May 2008. pp. 222-243.

mean government intervention and generally meddling with the market mechanisms. This regulatory block although implicit in most cases, is reflected in regular efforts made by industry organizations to lobby with the government and engage quite vigorously in the rhetoric of technology development and its functionality in national development and consequently in consistently in undermining efforts to bolster regulatory oversight of these technologies.<sup>50</sup>

This phenomenon is further compounded by the presence of several (sometimes) competing departmental interests within the central government. Not only at the ministerial level, but also at sub ministerial levels, there are several agencies involved in governing different facets of technology R&D and applications. DBT was established to look at biotechnology exclusively. DST under its Nano Mission is promoting development of nanotechnology but not looking at the toxicological issues involved. Even the DBT, despite being an exclusive department for biotechnology, does not engage with these issues pertaining to biotechnology. After all these years, it has not become capable of regulatory oversight, which is an area still looked after by the Ministry of Environment and forests.<sup>51</sup> Thus, the very existence of a specialized department for a particular technology is questionable. The fact that the responsibility for nanotechnology within the government resides with the Department of Science and Technology (henceforth DST) also implies that there is privileging of certain objectives in conformity with those of the department. The primary objective of the department is to play a frontal role in the *promotion of science and technology in the country*<sup>52</sup>. Essentially this involves directing high-end basic research by providing for research funding in R&D activities, development and incubation facilities for technologies and also human resources development through science education and training. The DST is therefore clearly a science promotion and development support agency, ill-equipped to provide regulatory controls and mechanisms which the technology needs for it to ensure a responsible use of the technology. Specifically in the case of health related nano applications, it is the Ministry of Health and Family Welfare that is the nodal ministry that would be in charge of overseeing such developments. However given that it is the DST, which is in overall charge of government initiatives on nanotechnology, this creates certain organizational disconnect. It is necessary that the Ministry of Health and Family Welfare functions in tandem and in close cooperation with the DST to ensure adequate and comprehensive regulatory oversight. However this would not be so easily achieved since the regulation *per se* is largely perceived to be anti-promotion and therefore something opposed to the essential mandate of the DST. This also means that the DST has favored the line of argument, that regulation should be postponed because the technology is still at its nascent stage and therefore not only is there a lack of information for regulators<sup>53</sup> but also there is wariness about regulation being seen as having a dampening effect on private sector involvement in the technology. Thus, there has been too much of an emphasis on

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<sup>50</sup> See for similar argument in the case of biotechnology, Damodaran A, *Re-Engineering Biosafety Regulations In India: Towards a Critique of Policy, Law and Prescriptions*, 1/1 Law, Environment and Development Journal 2005.

<sup>51</sup> Personal communication with Dr. Ravi Srinivas, RIS, New Delhi

<sup>52</sup> See website for more detailed information <http://dst.gov.in/> accessed 26 February 2008.

<sup>53</sup> See *Supra Note 3*, Presentation made by P Asthana (scientist SERC, DST) at the India Nanotechnology Conclave, February 22-23, 2006, New Delhi. 4733.

addressing the development concerns through technology by adopting a Mission mode, which is essentially a vehicle for technology privileging. Moreover, in such privileging of technology, there is little space for engaging with risk and toxicological issues.

Another major driver that could potentially drive nanotech regulation in India is developments at the international level. However one of the inherent limitations of reacting to an international regulatory pull/demand is the possibility of local factors, priorities and variables being totally ignored in its adoption. It is important the development of a national regulatory regime would become the basis for sharing experiential data in the development of international regulatory regimes. There has been a growing trend towards the acceptability of international forums/institutions as efficient and effective sites of regime creation. These sites are characteristically sub-political in nature in as much as they lack effective legitimacy and formal rule making power. The World Health Organization (WHO) and International Standards Organization (ISO) are two such sites. The ISO under its technical committee 229 has been involved in the process of developing standards for nanotechnology. Although very different in nature and scope, WHO too can influence the regulation of health related nanotech applications. WHO has within its scope of activities, medicines regulation and safety of medicines whereby its activities relate to the *'development of internationally recognized norms, standards and guidelines and providing guidance, technical assistance, and training in order to enable countries to adapt global guidelines to meet their specific drug regulatory environment and needs.'*<sup>54</sup> It acknowledges that "rapidly evolving science and technology are likewise creating problems for regulatory authorities everywhere" and the need for norms and standards for use in new areas of health technology and product development.

## VI Conclusion

It is well established that considering the scale of nano related research and availability of a number of nano-related drugs and medical health devices in the Indian market within the span of next five years is almost certain. There already exist a number of products in the market. India is being identified as a key emerging country, which is making rapid and significant investments in nanotechnology.<sup>55</sup> Therefore, research in nanotechnology and its commercial applications is not a distant likelihood any longer as it has already arrived and India is moving ahead in this direction at a rapid pace. Also noteworthy is the fact that most of the current research and initiatives are largely government driven. Public funds are providing a thrust to the nanotechnology development in India, which is giving tremendous support from the government. However, this support, despite being substantial, is very narrow in its scope and does not take a holistic approach to promotion of technology. Unprecedented investments from all sources are being poured in for the development of nanotech research and applications across sectors so as to capture its applied potential. There is such an emphasis on the promotion of nanotechnology that other aspects involved in commercial application – socio-economic issues, risks, potential environmental and health hazards, occupational safety etc. are being ignored. A small

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<sup>54</sup> [http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/norms\\_standards/en/index.html](http://www.who.int/medicines/areas/quality_safety/quality_assurance/norms_standards/en/index.html)

<sup>55</sup> Nanotechnology Market Forecast to 2011, RNCOS, April 2008.

amount of risk and toxicity research is also being funded but they are confined to select institutes like NIPER and IITR and are not yet a part of mainstream nano related research.

In light of the uncertainty surrounding nano applications it is imperative that the government undertakes a review of the current regulatory regime to identify frameworks and capacities, which would be required to enable regulatory oversight of such products. One such framework is the Pharmacovigilance Protocol, which is already in place, and as a short-term measure, can provide mechanisms through which oversight of nano related medical health applications could be strengthened. In order to make the practitioners responsible and engaged with the risk issues involved in nanotech, what is vital is a government guideline to that effect. Currently, the obligation to submit clinical trial test data and report post-marketing approval adverse drug reactions data, are all not being adhered to. Neither is there any action or interest taken by the government vis-à-vis policy intervention to redesign the protocols, standards and categories so as to address the nano specific products and processes so as to enable manufacturers and marketing entities to substantively address such regulatory requirements.

As discussed in this paper, there is a multiplicity of departments and institutions looking after nanotechnology. With little coordination and an umbrella programme for regulatory oversight of technology, there are bound to be overlaps and even repetitions. Different activities are being undertaken by various departments but there is not streamlining of these efforts despite the presence of a Nano Mission.

In terms of regulation of drugs and pharmaceuticals, there is an utter lack of capacity. Only 17 of the 31 States and Union Territories have drug-testing facilities and even those that have the institutional framework, there is either a shortage in terms of trained human resources or proper enforcement. This is the scenario for drugs, which have been into the market for years and are already into usage. It is a matter of serious concern that with this regulatory capacity deficit, there is little possibility that the current regulatory mechanism will be equipped to address the worries associated with application of emerging technologies like nanotechnology in health sector.

It is also important that the government is fully aware and actively involved in processes and mechanisms that are currently functioning and those in the process of being set up at the international level. As we have mentioned international regulatory developments have a tendency to develop faster than national regimes and could also be in a position to drive the latter. This is not necessarily a critique, however it is important that international regulatory mechanisms that are developed are based on national experiential data and are evolved and implemented with due consideration to local priorities and capacities.

Given the occupational health and safety concerns that are associated with the technology it is necessary that action cannot be restricted to the ministry of health (although this ministry could take a lead on this issue) and would have to involve other ministries and government departments. The government therefore has to formulate oversight plans across ministries and this purpose it is imperative that a medium term government

strategy if formulated that is linked to the government research strategy on nanotechnology and also well grounded within the existing market conditions. This would not only enable government to streamline its own strategy and functioning of its oversight mechanism but also establish an organic linkage between public research in nanotechnology and regulatory imperatives that needed to be addressed. Any such inter-ministerial body could function either as a specialized committee of the Planning Commission or from within the Science Advisory Council attached to the Prime Ministers Office. In the case of the latter, it is also important that any such body should have sufficient representation of public policy, health regulation and industry experts. Role of nationally recognized advisory bodies such as INSA should be strengthened and their participation should be institutionalised and made an integral part of the policy formulation for nanotechnology. Addressing these issues would contribute to a responsive framework for robust regulation of fast developing nanotechnology product regime.

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