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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 Srivastav and Nupur Chowdhury

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 that 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 incentivises 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 textiles sector. In this regard it is imperative to understand the underlying logic of state

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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

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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.