GREEN GOVERNANCE APPROACH TO PHARMACEUTICALS IN ENVIRONMENT: AN EMERGING TREND

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Introduction

Pharmaceutical sector is considered as one of the highly-regulated sectors in almost all the nations. It is managed and regulated by several important agencies of the governments. To protect the life of the individuals against diseases through availability of medicines at competitive prices resulted into the growth of pharmaceutical industries around the world. The lifespan of the men might certainly be referred as a positive outcome of expansion in the pharma sector yet it has resulted in germination of a conundrum due to its contrast with efforts to save environment against pollution. It is true that the availability of medicines for promising therapies has added substance to realization of right to health and medical assistance yet the cost of harm caused to the environment cannot be underestimated. Recent studies have revealed that direct emission from the drug manufacturing as a source of much higher environmental discharges substantially exceeded the permissible limits of toxic concentrations.[1] A wide range of pharmaceutical compounds including antibiotics, analgesics, blood lipid-lowering agents, antiepileptic, and β-blockers have been found in the effluents and surface waters of several countries.[2] Other main reason of environmental concentrations of pharmaceuticals in environment, in addition to toxic discharges by manufacturing sites, is excreted by human beings. Paracelsus in 16th century recognized that the 'dose makes the poison'. Though the environmental concentrations of pharmaceuticals excreted by humans are limited as a defined dose is administered that is even to a part of population. The discovery of estrogens in sewage effluents resulting into the feminization of fish in 1990 sparked the issue of pharmaceuticals in the environment. Thereafter discovery of diclofenac residues in cattle carcasses leading to the collapse of the vulture population in India and Pakistan also raise the concern.[3] These findings accelerated a cascade of investigations of the presence of human and veterinary pharmaceutical products in the environment and of endangering to humans and the environment.[4] Studies revealed that long-term exposure to the lower concentration of complex pharmaceutical mixtures on stream biota might result in acute and chronic damages, behavioral changes, and accumulation in tissues, reproductive damage and inhibition of cell proliferation.[5]

In addition to above, several factors such as global warming, climate change, loss of flora and fauna and other environmental implications press the need for revisiting the traditional methods of socio-ecological governance. Relying on conventional approaches indicating passive management based on predictability and consistent stability of norms appear inadequate and disproportionate in view of alarming situation. The present article aims to explore alternative governance mechanism based on resilience theory. It impels for the need to change means and ends concerning legal regime on pharmaceuticals in the environment.

Pharmaceuticals in the Environment (PIE): Emerging Global Issue

The modern age of technology has brought with it tremendous immediate benefits and equally serious long-term recovery costs in return. The rapid development of pharmaceutical industry and its effects on the environment paved the way for the present study. The issue has become a major challenge and endangered the social-ecological system with no nation remaining unaffected. Earlier, the quest for rapid industrial development and now the development of pharma sector especially has placed the environmental quality in subordination under the veil of sustainable development. Emergence of dichotomy is inevitable in context of consistently increase demand and usage of medicinal products requiring massive production and preservation of environment. It carries not only substantial probabilities of economic growth, profit margin, meeting out the demands of medicines but also its adverse effects on the environment. Presence of pharmaceuticals in surface, waste, drinking water and sediments was little known before preliminary studies that measured levels of pharmaceuticals in the environment, published in 1977 conducted by Hignite & Azarnoff [6] and in 1985 by Richardson & Bowron.[7] Though the work in this field with a systematic approach came to light in the 1990s which deals with levels of pharmaceuticals in local rivers in Germany by Ternes in 1998[8] and Hirsch *et. al.* [9] Thereafter global community has raised its concern regarding eco-toxicity of PIE.[10]

- **Pharmaceuticals into the Environment: The Pathway**

Pharmaceutical residues enter the environment through three modes:

- Through excretion of patients, either as the original compound or as a derivative of that compound,
- The release of effluents by manufacturing units.
- Disposal of unused or expired medicines.

Environmental discomfort caused by PIE: Sensitizing the Issue

D.G.Joakim Larsson opines that major cause of pharmaceuticals in environment revealed through recent studies is direct emission from drug manufacturing. It is a source of much higher environmental discharges and toxic concentrations. Larsson further clarified that environmental concentrations of pharmaceuticals excreted by humans are limited, most importantly because a defined dose is given to just a fraction of the population.[11]The presence of pharmaceuticals in the environment (PIE) creates significant health hazards. The studies reveal major emissions are on account of the release of residues from drug manufacturers. Pharmaceutical residues have also been found in bio-solids used in land remediation. Use of wastewater for irrigation near industrial hub also results in contamination of soil. It sets back the biologic system which ultimately affects physiology and behavior of organisms.[12] Referring the report of European Agency for Health and Consumers, it has been highlighted that Anti-Microbial Resistance (AMR) residue in the environment is hazardous and endangers the health of human beings.[13] It advocates the need for proper monitoring and regulatory mechanism.

Work by Merita Dauti, Edita Alili-Idrizi et al. introduces with the practices of pharmaceutical waste management and treatment in European countries along with a review of the legislation and official guidelines concerning the management of pharmaceutical wastes. To minimize the impact of such wastes on the environment, regulation 2150/2002 was adopted.[14] The regulation aims at monitoring the implementation of waste policy and principles for a proper disposal of wastes. Along with municipal waste, Health Care Waste (HCW) also poses a potential danger. Health Care Waste means all medicinal wastes generated by healthcare institutions, research centers and laboratories.[15]

Chanti Babu Patneedi, K. Durga Prasadu takes into consideration toxicity, health risk and assessment of environmental hazards caused by pharmaceutical pollutants. The work uncovers the effect of pharmaceutical effluents especially in the vicinity of pharmaceutical industrial zones on human health and environment. Different classes of pharmaceutical compounds like analgesic, contraceptive, antibiotic, steroids and hormones etc. have been detected in water samples of drug manufacturing units. There is a need for

regular monitoring of the concentration of pharmaceutical compounds into drinking water sources. Adopting as a measure, the United States Environmental Protection Agency has added four pharmaceutical compounds to the most recent contaminant candidate list (CCL 3) which includes three birth control substances and one antibiotic. The high degree exposure of complex pharmaceutical mixtures on stream biota may result in acute and chronic damages, behavioral changes and accumulation in tissues, reproductive damage and inhibition of cell proliferation.[16]

Kirstie Murdoch in his work takes into consideration presence of multiple pharmaceutical compounds in treated wastewater, river systems, marine sediments and sewage sludge (bio-solids) in Australia and New Zealand and Island countries. The work in hand reveals harmful effects of antibiotics in the environment.[17] But to minimize the harmful effects of pharmaceutical pollution, norms and implementation are required. For this purpose, adequate disposal system, advance wastewater treatment plants, technologies for eliminating pharmaceutical pollutants along with policies for quality/rational use of medicines that include environmental considerations, and quality sewage treatment and binding guidelines, issued from time to time, for the use of bio-solids and recycled water are needed.

As the various studies concerning the presence of pharmaceuticals into the environment have shown crucial effects on the ecological systems, it becomes the need of the hour that regulatory framework should adapt to the environment realities. If not entirely, at least up to some extent they must become more flexible to cope with changing ecological systems.[18]

Green Governance Approach Integrating Adaptation and Resilience Approach

Complexity and uncertainty are important factors in the socio-ecological governance. Varying nature of complexities in the domain of ecological studies certainly require adaptability in the socio-legal framework. Environmental governance is *the sine qua non* for the very existence of the socio-ecological system. Environmental governance may be defined as a "set of regulatory processes, mechanisms and organizations through which political actors influence environmental actions and outcomes."[19] Thus, rules, laws, regulations, social norms, policy framework and institutions and organizations involved in the process of governing environmental resources including their use, protection and preservation fall within the ambit of environmental governance. Structure, substance and procedure are three basic aspects of governance and it is

the balance between stability and flexibility factor that determines the success of a given system. 'Stability' means persistency over a period of time either in same or similar form among various branches of government and the agencies responsible for implementing the rules, regulations and policies etc.[20] 'Flexibility' connotes a degree of latitude possible, within a given governance structure, provided such latitude to be exercised without affecting the system as a whole.[21]

The concept of resilience provides for the integration of ecosystem management with ecological response to achieve sustainability.[22] Walker defines Resilience, as a measure of the amount of deviation that a socio-ecological system can withstand and still maintain the same structure and functions. Resilience means the ability of a complex system to continue to provide a full range of ecosystem services in the face of change.[23] To foster the resilience, the system of adaptive governance is emerging as a new approach. Adaptive governance is a process where through the process of monitoring, incremental changes and adjustments to the ecosystem management are introduced.[24]

Adaptive Governance Embracing Resilience Theory: The traditional approach of socio-ecological governance provides that ecosystem is managed by the social system in return for services provided by it. This approach focuses on the concept of "optimization" i.e. it intended to prevent loss of a particular component of the ecosystem, but it becomes unable to work in case of the system behave in an emergent manner.[25] Thus, it is unable to handle uncertainty and complexity of the socio-ecological system. Resilience theory, on the other hand, envisions a framework which is based on the adaptive form of management, recognizing the complexity of an ecological system. It provides a mechanism where governance system is designed to prevent adverse effects and adapt in the face of change.[26] Governance based on resilience theory implies laws, regulations, rules, policies, institutions and institutional structures involved in the process of implementation and governance.[27]

The concept of adaptive governance based on resilience theory can be better understood with the help of following defintions:

- Huitema defines governance "as a process of resolving trade-offs and of providing a vision and direction for sustainability" and adaptive management "as the operationalization of this vision."[28]
- According to Folke, Adaptive governance includes the process of adaptive management. It also includes the collaboration and co-operation across different levels of government and

agencies exercising overlapping authorities, non-governmental and individual action that are apparent in a complex system.[29]

- Boyle defines adaptive governance as the process of choosing among conflicting interests over resource use and non-use and of setting goals for a particular social-ecological system.[30]
- As per Cosens and Williams, adaptive governance refers to action by multiple jurisdictions and the process where multiple non-actors are involved in decision making.[31]

Thus, the concept of adaptive governance embodies the approach required to foster resilience in the socio-ecological system. The system of adaptive governance needs to increase the amount of flexibility in the delegation of powers. But such delegation must be exercised in transparent, legitimate and responsive manner demanding more accountability.

Striking Balance among Stability and Flexibility: A Key Challenge

To foster resilience, adaptive governance has to strike a balance among stability and flexibility factors otherwise it may be perceived as disruptive or unfair.[32] Studies suggest that the Anthropocene warrants detailed and comprehensive examination of stability-flexibility balance in the process of adaptive governance of the social-ecological system.

While stability is considered as one of the most important structural aspects of governance, flexibility is also a mandatory requirement for accommodating the change in the social-ecological system. Advocating stability, Levi-Faur[33] Stated that static laws and regulations provide predictability. They ensure compliance and enforcement. Besides, they provide the foundation of security and also encourage investment in productive enterprises. However, too much stability may result in rigidity, making governance institution handicap to adapt to changing environmental and social values.

Holling in his work states that social systems are complex and adaptive, therefore governance systems require flexibility.[34] Cosens also, suggests that flexibility in governance in pre-requisite to adjust according to change.[35] But flexibility in excess may result in arbitrariness. Therefore, adaptive governance regime should be based on a fine balance between stability and flexibility for attaining the object of green governance.

Adaptive Governance into Legal Regime concerning PIE

Law is assumed as central facet in promoting adaptive governance.[36] At implementation stage, the law establishes substantive requirements and standards along with procedural requirements and opportunities. Though procedural requirements create room for flexibility[37] but through different calibrations balance of the stability-flexibility can be achieved in substantive requirements which otherwise exist in the form of binding rules e.g. some substantive laws consist of standards instead of rules. In such a case choice between a rule and a standard creates room for adaptation. According to Camacho, rules are preferable when clarity, precision and ease of enforcement are the primary concern and standards are better under varying conditions and circumstances.[38]

The legal regime can calibrate flexibility within stability more easily in federal institutions because of distribution of powers among various bodies. Different governance agencies have different responsibilities from implementation to interpretation e.g. U.S. Constitution provides that laws are enacted by Congress, implemented by executives and interpreted by the judiciary. In this kind of structure delegation of powers play a centric role. Congress while enacting pollution control laws, make use of legal floors and ceilings. States are to comply with minimum federal requirements, but are permitted to set regulatory requirements.[39]

Sometimes law evolves through judicial pronouncements in the form of the collection of rules and principles. A magnificent example of such kind of law is "Common law." In *Brooks* v. *Robinson[40]* It was recognized that "the strength and genius of the Common law lie in its ability to adapt to the changing needs of the society it governs."

Existing regulatory mechanism seems poorly suited to handle the problem of PIE due to weak adaptive capacity. Agencies are incapable to foster intra-agency learning. There is a need to shift the paradigm from passive management to active management. Here law plays pivot role to shift this momentum by cultivating agency and stakeholder learning e.g. in Australia, Return Unwanted Medicines (RUM) Project has been set up by Commonwealth Government to provide a system of disposing of unwanted or expired medicines through community pharmacies. After collection, pharmaceuticals are sent to Environmental Protection Authority (EPA) which approved high-temperature incineration facilities in Victoria and Western Australia for destruction.[41]

Procedural elements assure legitimacy in adaptive governance and co-ordination across scales assures that legitimacy runs through inter-jurisdictional scales. As the pharmaceutical sector is governed by a network of multiple agencies, there is much scope for resilience-based management because this approach allows room for co-ordination and co-operation across multiple jurisdictions.

Conclusion

Adaptive Governance is the emergent form of legal regime on environmental protection especially when the new categories of contaminants like pharmaceutical compounds are making their robust presence in the environment. The conventional approach to environmental governance seems incompatible to cope with divergent ecosystem problems. Procedural and substantive limitations of the traditional legal system may cause disharmony with uncertainty and change. To address the issue of PIE concerned legal regime need to be revisited and restructured by incorporating the characteristics of flexibility and adaptability. Adaptive governance is strengthened with the integration of resilient approaches recognizing the varying complexities of the social-ecological system. It prompts a regulatory process that promotes stakeholder involvement and agencies accountability and responsiveness to the emerging challenges.

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