Chapter 1

Introduction

Reaching the third level of environmental governance

…………achievement or failure?

1.1 Introduction

The answer to above question lies in the relationship between human and its environment. Nature has everything in abundance to fulfil the needs, but not lust of human beings. Errant nature of humankind has altered the environment to such an extent that the previous two stages of environmental governance fell short to preserve it for the present as well as the future generations. Now, the third-generation environmental law, popularly known as ‘law on sustainable development’ is being envisioned as a viable solution to protect the environment and ensure the development. Envisioned in ‘Sustainable Development Goals’ it is agreed that “By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment.”1 Protection and preservation of the environment previously a time-honored goal of the governments around the globe that has been substituted by the concept of sustainable development in modern perspectives. Deterioration in the quality of the environment has posed a grave threat to the health, lives of all organisms on this planet earth and further the sustenance of the species as well.

The interaction of the human with nature resulting into rapid industrialization, over-exploitation of resources, poverty, under-development, deforestation, coal-burnt thermal plants, radio-active pollution reminds the Preambular truth that human has acquired the capacity to transform his surroundings.2 Despite warning encapsulated in the language of the Preamble to the UNCHE, 1972 ‘…….. wrongful or heedless application of science application may do irreparable harm to the


environment’, human interference with natural equilibrium has resulted into drastic climate change patterns, global warming, extinction of various species and so on.

The idea of undertaking the present study entitled ‘A Study of Legal Regime on Pharmaceuticals in Environment: International and National Perspectives’ owes its origin to an eye-opener revelation of findings as to the effect of pharmaceuticals in the environment (PiE). The studies revealed that the increasing use of pharmaceuticals globally, which are designed to have biological effects at low concentrations, have the potential to lay potent effects on the wildlife and ecosystems. The Report of World Wildlife Fund published in 2014 revealed that in last 40 years, half of the world’s wildlife has disappeared. The report presented that 75% of the fish and amphibians have lost their lives due to their exposure to drug residues in freshwater bodies. Distressing incidents of the feminization of male fish by the synthetic estrogens in birth control pills and treating menopause-related problems in many parts of the world and extinction of vultures (a bird of prey) due to consumption of anti-inflammatory painkiller diclofenac through animal carcasses have jolted the world.

Vultures are known for their unpaid role and contribution to the preservation of ecology and cleansing the environment as ‘Natural Scavengers’, ‘Nature’s

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Sanitation Engineer\textsuperscript{8}, ‘Nature’s Sanitary Workers’\textsuperscript{9}, ‘Nature’s Clean-up Crew’\textsuperscript{10}, ‘Nature’s Garbage Disposers’.\textsuperscript{11} Campbell in his work titled Vultures: Their Evolution, Ecology and Conservation described, vultures as the epitome of natural scavengers and valuable assets to the eco-system dominating scavenger niche and resisting the spread of diseases through undisposed carcasses.\textsuperscript{12} The studies revealed that the existence of vulture species around the world is endangered due to anthropogenic effects either dying due to humanly introduced chemicals or starving due to the removal of their food source by human beings.\textsuperscript{13} The bio-scientists all over the world with the help of ornithologists have found that some pharmaceuticals being administered to the bovine animals are the cause of the abysmal decline of the number of vultures. In many countries, vultures became the ill-fated sufferers of poisoned carcasses as hundreds of vultures usually have feast from a single carcass. In mid-90s, India experienced precipitous vultures decline with more than 95\% of vultures disappearing by early 2000. The findings revealed that if the cattle had recently been treated with diclofenac and its carcass is eaten by vultures, it is highly toxic to vultures and ultimately result into their death in few hours.\textsuperscript{14} A study published in the Journal of Genome Biology revealed that vultures have a strongly acidic digestive system and possess the ability to resist


\textsuperscript{9} Laborate Pharmaceutical India Ltd. v. Union of India AIR 2018 Mad. 1.


\textsuperscript{11} WWF Living Planet Report (2014).


\textsuperscript{14} “Loss of Vulture Damaging Humans, Ecosystem: A Study” The Hindu, May 6, 2016.
infections from pathogens present in the rotting carcasses on which they feed. It endorsed that the diclofenac – an anti-inflammatory, or ketoprofen and aceclofenac used to treat cattle resulted in fatal kidney failure of vultures within 48 hours if they consume it through carcasses.\textsuperscript{15} The studies further revealed that in a span of 15 years, coco carcasses contaminated with diclofenac nearly wiped out three of Asia's vulture species - South Asia's Gyps Vulture, White Rumped, Long Billed and Slender Billed Vultures.\textsuperscript{16} Even Oriental White Backed Vulture too has declined by more than 99.9% between 1990- 2000.\textsuperscript{17}

Against this backdrop, the present study deals with environmental contamination by pharmaceuticals and socio-legal examination of existing laws, judicial approach and level of sensitization among masses. No doubt, dosage forms prepared out of pharmaceuticals play a pivotal role in the treatment and prevention of the disease in all living beings. Nonetheless, it is because of the very nature of pharmaceuticals that may cause unintended effects in certain animals and micro-organisms in the environment. Break down of products metabolites and the combination of different biologically active compounds also produces unanticipated effects on the biotic ecosystems. The adverse effects of pharmaceuticals on human and animal health are usually identified through safety and toxicology studies as per its regulatory requirements before these pharmaceuticals are released the first time in the market.\textsuperscript{18} The potential environmental impacts of the manufacture and use of pharmaceuticals are less understood. It has recently drawn the attention of researchers, academicians and scientists from all over the world. In last two decades, the studies on effects of pharmaceuticals on the environment and a wide range of organisms have been conducted. Since the gravity and scope of this problem arising out of pharmaceuticals in the environment (PiE) is expanding, therefore, it has become the subject matter of concern not only by health care

\begin{itemize}
  \item Ibid.
  \item WWF Living Planet Report (2014).
\end{itemize}
professionals but also law and policymakers. Each pharmaceutical product is a triangle with three faces, representing the healing it can bring, the hazard it can inflict and the economic impact of each. There is need for the doctors, patients, regulators, taxpayers, insurers and policy-makers to learn how to balance these three dimensions better in order to attain the maximum benefits from this most common and powerful of all healthcare inventions.\textsuperscript{19}

1.2 Background of the Study

The population explosion and developments in the pharmaceutical sector resulted in the increase in the production and consumption of the various dosage forms. The pollution of the environment as a consequence of the extensive use of human and veterinary pharmaceuticals has posed a threat to wildlife, also humans via drinking water supplies and affecting the environment. The retail value of the market for prescription and non-prescription of human pharmaceuticals multiplied. Global per capita consumption has increased and set to continue with the aging population.\textsuperscript{20}

Different types of pharmaceutical compounds which include antibiotics, antifungals, anti-cancer pharmaceuticals analgesics, blood lipid-lowering, antiepileptic, and β-adrenoceptor blockers have been detected in the effluents and surface waters of various countries.\textsuperscript{21} Pharmaceuticals were detected even in wastewater destined for recycling, though the water is processed through advanced wastewater treatment systems. Pharmaceutical residues have also been detected in bio-solids planned for use in land remediation.\textsuperscript{22} As healthy

\begin{thebibliography}{9}
\setlength{\itemsep}{0pt}
\bibitem{murdoch2015} Kirstie Murdoch, “Pharmaceutical Pollution in the Environment: Issues for Australia, New Zealand and Pacific Island countries” (May, 2015) \textit{available at} http://www.ehh-
environment embraces adequate management of waste from industries as well as from household activities, the concern over the management and extermination of pharmaceutical residues is growing considerably. Pharmaceutical residues are measured at tens or hundreds of nanograms per litre (ng/l) in waters, and in the microgram per kilogram (μg/kg) range in sediments affected by wastewater treatment plants. As per data, 61 most frequently encountered pharmaceutical compounds in river systems around the world have been detected at median concentrations ranging from 6.2 ng/l to 163 673 ng/l. Presence of pharmaceutical residues in the environment even at ng/l concentrations may adversely impact a variety of biological systems and have broader negative effects on ecosystems.

The modern technological age has brought with it tremendous immediate benefits and equally serious long-term recovery costs in return. The rapid development of industry, science and technology has paved the way for the study of the effect of pharmaceutical residues in the environment. 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 has placed the environmental quality in subordination under the veil of sustainable development. Consistently increasing demand and usage of medicinal products require massive production and growth of pharmaceutical industry. Since it carries substantial probabilities of economic growth, therefore, less attention has ever been paid to the issue of effects of pharmaceuticals on the environment in certain countries. D. G. Joakim Larsson, a renowned Swedish scientist, opines that major cause of PIE revealed through recent studies is direct emission from drug manufacturing. It is a source of much

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24 Ibid.
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.\textsuperscript{26} The presence of PiE creates significant health hazards. The studies reveal that high emissions of pharmaceutical concentration from drug manufacturing facilities. The Ministry of Environment and Forests, Government of India, has classified pharmaceutical manufacturing as a ‘red category’ activity due to the production of hazardous waste.\textsuperscript{27}

1.2.1 Pharmaceutical Industry: Indian Perspective

In international context, it is basically the advent of Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement in 1994 that added wings to pharmaceutical sector of India for scaling new heights. The TRIPS Agreement has given a hike to a sophisticated and geographically dispersed industry reliant on a highly complex supply chain network consisting of thousands of suppliers around the world.\textsuperscript{28} Presently, India is the second largest manufacturer of pharmaceuticals after China. Whereas China is leading supplier of Active Pharmaceutical Ingredients (APIs)\textsuperscript{29} followed by India as a substantial contributor to the global manufacturing of pharmaceuticals.\textsuperscript{30}

\textsuperscript{27} Appendix 1 A: Press Information Bureau, MoEF & CC (GOI), New Categorization of Industries, March 5, 2016.
\textsuperscript{28} Nordea Report, “Impact of Pharmaceuticals Pollution on Communities and Environment in India” 1 (2016).
\textsuperscript{29} The U.S. International Trade Commission defines APIs as “the primary, active ingredient(s) of a final pharmaceutical product, produced in the first stage of pharmaceutical production and usually in bulk quantities.” (U.S. ITC, 2007). In this report, they are largely synonymous with the term “bulk drug.”; Pietro Bruni, Impacts of Pharmaceutical Pollution on Communities and Environment in India (Researched and Prepared for Nordea Asset Management By Changing Markets and Ecostorm, February, 2016) See also: available at https://www.nordea.com/ Images/35-107206/impacts 201-20 .pdf (Visited on November 30, 2016).
\textsuperscript{30} Pietro Bruni, Impacts of Pharmaceutical Pollution on Communities and Environment in India (Researched and Prepared for Nordea Asset Management by Changing Markets
industry has been found striding towards steep rise due to its low-cost manufacturing destination for multinational companies taking advantages of the lenient patent laws and rich experience of the proven chemists. Here it would not be out of place to refer to here that the bulk drug production units of India are situated in Hyderabad (Telangana), Vishakhapatnam (Andhra Pradesh) and Vapi (Gujarat). The pharmaceutical industry in Hyderabad (then Andhra Pradesh) has made its presence since 1970. Presently, Hyderabad is known as ‘bulk drug capital’ of India and credited for one-fifth of India’s pharmaceutical exports.

The development of Hyderabad as a pharma production hub owes its existence to various reasons such as the large population of English speaking workforce and vital supply of scientific & technological manpower. The political reason attributed for the growth of this region is that Distt. Medak was the Constituency of the then Prime Minister. Besides, the connectivity of the Hyderabad with road, rail, ports and airports attracted the government of India to set up Indian Drugs and Pharmaceuticals Ltd. (IDPL)—a State-owned pharmaceutical manufacturing company in 1961. Under the premiership of Pt. Jawaharlal Nehru, the government established its manufacturing plant to release India from the burden of dependence on other countries for life-saving pharmaceuticals.31 The formation of Andhra Pradesh Industrial Infrastructure Corporation (APIIC) in 1973 resulted in the establishment of Patancheru as a ‘mega industrial estate’. APIIC created 6 industrial estates in backward regions’ spreading over around a thirty-mile radius of Hyderabad, the largest of which is the 440-hectare estate in Patancheru. The IDPL was closed by that time and the number of IDPL employees established their own factories such as Dr. Reddy. Majority of the manpower from IDPL moved to Dr. Reddy’s and Aurobindo Pharmaceuticals. In addition to it, Indira Gandhi representing Medak District Constituency as a Member of Parliament in 1980s general election was a keen proponent of the industrialization of her constituency. With the passage of time, the bulk drug manufacturing units increased their

stronghold in Hyderabad region and less attention was given to the environment and health of residents of surrounding area in the wake of industrialization. Besides, China also started manufacturing and marketing the API at much cheaper values. This may also be one of the reasons for overlooking environmental considerations. Further, anti-dumping laws prevalent at that time were not implemented in the sense to protect Indian pharmaceutical manufacturers. In fact, 2015 has been declared as the ‘year of bulk drugs’.32

Indian pharmaceutical sector is a knowledge-based manufacturing sector. Its manufacturing activities can be categorized into formulations and bulk pharmaceuticals. Domestic consumption of pharmaceuticals is comparatively less as compared to exports. In 2013-14 export from the industry accounts for 60% of the sales.33 Pharmaceutical industries in India manufacture over 1,00,000 pharmaceuticals in various therapeutic categories i.e. antibiotics, antifungal, analgesics, lipid-lowering etc. in the dosage form of capsules, tablets, injections, oral and liquids etc.34 India has become a global leader in producing high-quality generic pharmaceuticals that are sold across the globe.35 According to the report of EXIM bank, India has 332 pharmaceutical manufacturing units approved by US FDA.36

As per the Sectoral Report of IBEF, Indian pharma industry is third-largest regarding volume and thirteenth largest regarding its monetary value. Indian pharmaceutical sector accounts for about 20% of the volume in terms and 1.4% value in terms of global pharmaceutical industry. It is one of the largest providers of generic pharmaceuticals. According to submission of the Bulk Drug Manufacturers Association of India (BDMAI), 45% of global needs of pharmaceuticals are catered by BDMAI and 95% of the domestic needs are being

33 Export-Import Bank of India, Study on Indian Pharmaceutical Industry (EXIM Bank of India, March 2015).
34 Ibid.
35 Vikash Batham, Regulatory Framework and Challenges in Indian Pharmaceutical Sector (CUTS Centre for Competition, Investment & Economic Regulation, New Delhi, January 2013).
36 Supra note 33.
satisfied by Patancheru based units. As per the findings of the Pharmaceuticals Export Promotion Council of India (PHARMEXCIL), the exports of this sector in 2016-17 stood at US$ 16.8 billion and are expected to grow by 30 percent over the next three years to reach US$ 20 billion by 2020. The Report estimates that the export of the industry may reach $ 55 billion by 2020. McKinsey Report presents that Indian Pharmaceuticals market is expected to grow to $ 55 billion by 2020 driven by a steady increase in affordability and a step jump in market access and it has the potential to reach $ 70 billion provided industry puts in full efforts.

1.2.2 Pharmaceutical Industry and Patent Regime

A patent is the legal right of the owner of the invention to have a monopoly over it for a limited period of time. It is an intellectual property right. Indian pharmaceutical industry became expert in the production of generic pharmaceuticals owing to the new patent regime. Till the enactment of Patent Act, 1970, the system of product patent was in existence. At that time, pharmaceutical sector in India was dominated by foreign companies. However, enactment of this new regime paved the way for pharmaceutical industry towards new heights by allowing process patent till 2005. India as the member of World Trade Organization, is a signatory to the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement, 1995 and therefore, owed a responsibility to amend its patent regime as per the terms of TRIPS Agreement. The Agreement provides for the filing of applications for Product Patent for pharmaceuticals and agrochemicals from 1995 accordingly amendment was made in the Patent Act, 1970. In 2002, the amendment as to the period of 20 years for all patents was introduced. The Patents (Amendment) Act of 2005 introduced product patent regime in India.

Against the backdrop of patent regime, Indian pharmaceutical sector can be broadly categorized into two periods i.e. pre-patent reforms regime and post-patent

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38 Indian Brand Equity Foundation, Sectoral Report (February, 2018).
reforms regime. Pre-patent regime covers the period before 2005 and post-patent periods refers to after 2005.

Before 2005, the system of process patent was prevalent in India under the Patent Act, 1970. The Patents were used to be granted for the period of 14 years. Process patent implies the system where the process to manufacture the pharmaceuticals were patented and not the pharmaceuticals themselves were patented. Other persons could use the different process on the same pharmaceuticals. This is also known as 'reverse engineering'. During this period Indian pharmaceutical industry flourished especially in the field of making generic pharmaceuticals as there was no need to incur huge amounts on the R & D. This makes access to pharmaceuticals at cheaper rates. But the TRIPS Agreement, 1995 introduced the system of product patent which means patentee can exercise an exclusive right over the product. India, as a developing country was given the transition period of 10 years to adapt to the change in the national patent legislation.

After 2005, when the product patent regime came into existence it was feared that Indian pharmaceutical industry might see the downfall. In contrast to it, the Indian Pharmaceutical industry scaled new heights. It created the room for innovative ideas and R & D in this sector. It encouraged new drug discoveries and recognition in developed markets. Thus, it provides for long-term benefits. New patent regime provides for the grant of a patent for the period of 20 years from the date of application and not from the date of award of the patent. It implies generic version need to be withdrawn after the award of patent and not before.

1.2.3 Pharmaceutical Industry Profile

42 Ibid.
43 Ibid.
44 Ibid.
46 Ibid.
Pharmaceutical industry involves various types of processes in manufacturing of pharmaceutical products. Pharmaceutical manufacturing plants generate a variety of wastes not only in manufacturing operations but during maintenance and housekeeping operations also. It includes spent fermentation broths, process liquors, solvents, equipment wash waters, spilled materials, off-spec products, and used processing aids. Following are the commonly deployed methods in the manufacturing of pharmaceuticals:

(i) Research and Development: Research and development (R&D) department includes chemical research, microbiological research and pharmacological and toxicological testing for efficacy and adverse effects repeating. The process involves production and discharge of a number of chemical and biological laboratory wastes. The wastes include halogenated and non-halogenated solvents, photo-sensitive chemicals, radio-active labelled compounds, acids, oxidizers and reducers.

(ii) Chemical Synthesis: As specified in Good Manufacturing Practice (GMP), reaction vessels and ancillary equipment are arranged into separate process units in drug manufacturing plants. The process involves the use of chemicals for chemical synthesis that includes organic and inorganic reactants and catalysts. During the process, organic solvents are used by the manufacturers and such solvents are listed as priority pollutants for product recovery, purification, and as reaction media.

(iii) Natural Product Extraction: Natural product extraction is the process whereby pharmaceuticals are extracted from natural material sources such as roots, leaves, barks and animal glands. These

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natural products include algae, insulin, morphine, alkaloids, papaverine and animal sources etc. Wastes from natural product extraction include spent raw materials such as leaves and roots, water-soluble solvents, solvent vapours and wastewaters. Extraction waste waters generally have low biological oxygen demand (BOD), chemical oxygen demand (COD) and a pH in the range of 6 to 8.51

(iv) Formulation: Pharmaceutical formulation is the process of preparing dosage forms viz, tablets, capsules, liquids, creams and ointments etc.52

(v) Fermentation: Steroids, antibiotics, Vitamin B etc. are manufactured by batch fermentation processes. This process generates a large number of wastes in the form of spent aqueous fermentation medium and solid cells. These wastes are considered very impure as they contain unconsumed raw material, fish meal and molasses.53

1.3 Statement of Problem

Pharmaceuticals enter into the environment during different phases of their life cycle. These are detected in the environment in trace quantities. The studies suggest that 90% of the pharmaceutical compounds detected in waterways result from patient use and excretion at few places whereas improper disposal and discharges from manufacturing sites account for 5-10% at other places.54 However,
these findings vary on the basis of production pattern, consumption and geographical area. In a country like India where the annual turnover of the pharmaceutical industry in 2015-16 was Rs. 2,04,627.15 crores of which domestic consumption was of Rs. 98414.4 crores and the rest was export share, pollution by pharmaceuticals is mainly on account of unsustainable production patterns. The pharmaceuticals enter into the environment through following ways:

(i) Disposal of effluents by API manufacturing units – In context of discharge of pharmaceutical waste effluents by manufacturing units, the situation in the developed countries and developing countries is different. In developed countries, the discharges from pharmaceutical manufacturing plants are minimal. As in the United State of America, the federal scientists discovered a number of pharmaceutical residues in sewage water than downstream water of rivers receiving effluents from drug manufacturers. However, this bubble of illusion was pricked in 2010 when USGS study from 2004-2009 reported that downstream water of the rivers receiving a discharge from pharmaceutical manufacturing plant contained 10 to 1000 times higher pharma pollutants than plants of New York City. Besides, it was also added that the waste treatment plants of New York City did not treat pharmaceuticals from water while industrial plants removed compounds. It was also pointed out that there were some pharmaceuticals which biodegrade slowly and these possess the


propensity to accumulate in the environment.\textsuperscript{57} While in Indian Perspectives, Ministry of Environment and Forests has already classified pharmaceutical manufacturing unit as a 'red category' carrying out the activity discharging the hazardous waste.\textsuperscript{58} There has been repeated news indicating the contamination of river water and groundwater by toxic chemicals and heavy metals such as copper, lead, mercury and arsenic around Hyderabad. The social and environmental cost of the development of Hyderabad's bulk drug industry can be seen in the form of contamination of groundwater, rivers and unavailability of potable water. The discharge of effluents by the manufacturing plants has affected the livelihoods and decreased agricultural yields in addition to damaging the health and escalation of abortion rate, birth defects and skin diseases.\textsuperscript{59}

(ii) Human excreta or release of pollutants through swimming pools and other activities – Another passage of entry of PiE is flushing down the toilet, passing of unmetabolized or metabolized pharmaceuticals through human excreta, rinsing off during the showers, bath in the swimming pools and release of personal care products. The studies conducted from time to time revealed that there are many pharmaceuticals which metabolize up to 95\% whereas others only 5\%. A report by the Centre for Disease Control and Prevention indicates that acetaminophen and the antidepressant fluoxetine are metabolized around 80\% while antibiotic ciprofloxacin is not metabolized as efficiently with approximately 50\% passed as

\textsuperscript{57} Patrick J. Phillips \textit{et. al.}, “Pharmaceutical Formulation Facilities as Sources of Opioids and Other Pharmaceuticals to Wastewater Treatment Plant Effluents”, \textit{44 Envtl. Sci. \\& Tech.} 4910-12 (2010).

\textsuperscript{58} See Appendix 1 A: Press Information Bureau, MoEF & CC (GOI), \textit{New Categorization of Industries,} March 5, 2016.

\textsuperscript{59} \textit{Kasala Malla Reddy \& Others v. State of A. P. \& Others,} Application No. 69 of 2013 (SZ)/Original W.P. No. 3158/1996 of APHC.
Therefore, unmetabolized medication is passed into sewer system along with human waste. Some pharmaceuticals enter into the environment through human excretion via wastewater, rinse off during shower and animal excretion via runoff from agriculture areas. Pharmaceuticals consumed by humans and animals do not fully metabolize and by way of excretion of unmetabolized compounds in the form of urine or faeces enters into the environment. Some topically applied antibiotics or steroid ointments enter into waterways by shower rinse off. It would not be out of place to refer here that in one case, traces of prescribed pharmaceuticals to the patients were found in excreta and treated sewage waters.

Usage of fruits and vegetables injected with oxytocin hormones results in unwanted consumption of these pharmaceuticals and end up in the form of urine or faeces. Oxytocin is a reproductive hormone which is found it almost all the mammals. Corrupt practice of injecting Oxytocin at an early stage of the yield is exercised by farmers to make their fruits and vegetables like bottle gourd, bitter gourd and cucumber etc. look fresher, bigger in size and greener too. Oxytocin is also used by the dairy farmer. They inject their cattle with this drug to obtain more milk. Oxytocin is also injected in the livestock to increase their size. Such a use of oxytocin may result

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61 Ibid.


64 Ibid.

65 Ibid.
in a hormonal imbalance in humans and animals.\textsuperscript{66} Besides, animals are also injected and administered medicines for the purpose of treatment. Problem of decline of vulture population owes its existence to administering diclofenac to animals.

(iii) Unsafe disposal of unused or expired pharmaceuticals - Another method of PiE is improper disposal of unused or expired pharmaceuticals in drain or toilet.\textsuperscript{67} As per the report of EFPIA, about 3-8\% of pharmaceuticals sold in Europe remains unused.\textsuperscript{68} In Germany, it is estimated that nearly 5700 tonnes of pharmaceuticals per year go unused.\textsuperscript{69} Associated Press study estimated that hospitals and long-term-care facilities flush 250 million pounds of unused pharmaceuticals annually.\textsuperscript{70} In view of the above, it is clear that unused or expired pharmaceuticals also adversely affect the environment.

1.3.1 Environmental Footprints of Pharmaceuticals

The problem of PiE has become a challenge not only for developing but the developed nations also. If developing countries are facing the entry of PiE through discharges and other activities, the developed countries are not immune to the problem as the environmental burden of pharmaceuticals in equally grave. The entry of pharmaceuticals even through discharge of sewage waste is equal harmful. Small quantities of drugs can potentially harm aquatic life.\textsuperscript{71} In 1994, fish with intersex characteristics were found in the water of sewage treatment plant in

\begin{itemize}
\item \textsuperscript{66} Ibid.
\item \textsuperscript{67} Ryan James Albrecht, "Pharmaceuticals in the Environment: Looking to Green Governance for a Remedy" \textit{JEEL} 182-203 (2012).
\item \textsuperscript{68} Executive Agency for Health and Consumers, \textit{Final Report on Study on Environmental Risks of Medicinal Products} (2013).
\item \textsuperscript{69} START, \textit{Project on Pharmaceuticals for Human Use: Options of Action for Reducing the Contamination of Water Bodies} (2006).
\item \textsuperscript{70} Jeff Donn, Martha Mendoza \textit{et al.}, "Health Facilities Flush Estimated 250M Pounds of Drugs a Year" \textit{USA Today}, September 14, 2008.
\item \textsuperscript{71} Bound, J.P. N. Voulvoulis "Household Disposal of Pharmaceuticals as a pathway for Aquatic Contamination in the United Kingdom" 113 \textit{Environmental Health Perspectives} 1705-11 (2005).
\end{itemize}
The studies revealed disruption of the reproductive physiology of fish exposed to natural and synthetic steroid estrogens from treated or untreated sewage effluent. Endocrine disrupting chemicals (EDC), particularly synthetic steroids and hormones, possess the potential to cause changes in sex ratios in fish and other aquatic organisms, "feminization" of male fish, production of vitellogenin (an egg yolk precursor protein) by male fish, and other changes that may affect reproduction or overall health. Experimental study by Kidd, K.A. highlighted that chronic exposure of fathead minnow (Pimephales promelas) to low concentrations (5–6 ng/l) of the synthetic estrogen 17α-ethinylestradiol (EE2, used as a contraceptive) in a freshwater lake produced reproductive failure, resulting in the complete collapse of the fish population in that lake. The loss of these small fish i.e. fathead minnow resulted in a reduction in the food supply for larger predator fish such as trout, causing subtle loss of condition in these predator species.

A study into the effect on a marine polychaete worm has demonstrated that environmental concentrations of the compounds like ibuprofen, fluoxetine and ethynylestradiol in sediments are sufficient to induce sub-lethal changes that may adversely affect the physiology of the organism. Diclofenac, commonly used human and veterinary drug was found to be the cause of extinction of Gyps species of vulture in India and Pakistan. An exponential study by Oaks and Shultz propounded that vulture, feeding on the deceased cattle, treated earlier with

Diclofenac, have extinguished almost. Amount of Diclofenac in the tissues of cattle carcass is enough to cause the death of vultures.\textsuperscript{78}

It is important to mention here that the consumption of Diclofenac across the globe is estimated to be 940 tonnes per year.\textsuperscript{79} The different countries identified approximately 631 different pharmaceutical agents, which includes antibiotic, lipid lowering pharmaceuticals, estrogens, analgesics, non-steroidal and anti-inflammatory pharmaceuticals.\textsuperscript{80}

As far as the effects of PiE on human beings are concerned, University of Rouen Medical Centre, France revealed in its research that thirty-one of thirty-eight wastewater samples containing pharmaceuticals had the ability to mutate human genes.\textsuperscript{81} A study in Davis County, Utah, linked drug dumping to virulent antibiotic-resistant germs and genetic mutations that may promote cancer.\textsuperscript{82} It is revealed that waterborne pharmaceuticals may promote antibiotic-resistant germs when they are mixed with bacteria in human sewage.\textsuperscript{83} Noteworthy Italian study discovered that by exposure of developing human cells to various mixtures of


\textsuperscript{81} Jeff Donn et. al., “AP Impact: Tons of Drugs Dumped into Wastewater” Huffington Post, September 14, 2008.

\textsuperscript{82} Ibid.

thirteen pharmaceuticals—at levels similar to those found in Italian rivers could slow the growth of the cells by about a third.84

The forthcoming table represents the effects of various pharmaceutical compounds on non-targeted species.

<table>
<thead>
<tr>
<th>Pharmaceutical</th>
<th>Therapeutic Group</th>
<th>Non-Targeted Organism</th>
<th>Effects</th>
<th>Kind of Study</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diclofenac</td>
<td>Analgesics &amp; Anti-</td>
<td>Vulture</td>
<td>Almost vanish</td>
<td>Wildlife</td>
<td>Oakes et. al. (2004)85</td>
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<td></td>
<td>Inflammatory</td>
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<tr>
<td>17α-Ethinylestradiol</td>
<td>Synthetic Estrogens</td>
<td>Feathered Minnow</td>
<td>Population collapse due to the feminization of male fish</td>
<td>Whole lake experiment</td>
<td>Kidd et. al. (2007)86</td>
</tr>
<tr>
<td>Diclofenac</td>
<td>Analgesics &amp; Anti-</td>
<td>Rainbow Trout</td>
<td>The severe reaction of kidney, liver and gills</td>
<td>Laboratory</td>
<td>Triebskorn et. al. (2007)87</td>
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<td></td>
<td>Inflammatory</td>
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<td>Sulfonamide</td>
<td>Antibacterial</td>
<td>Maize, willow</td>
<td>Adverse effects on the growth of roots, death of maize at</td>
<td>Greenhouse</td>
<td>Michelini et. al. (2012)88</td>
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Table 1.1 Impacts of Pharmaceuticals on Non-Targeted Organisms

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<tbody>
<tr>
<td>Fluoxetine</td>
<td>Antidepressant</td>
<td>Leopard Frog</td>
<td>Delay in tadpole development</td>
<td>Laboratory</td>
<td>Foster et. al. (2010)93</td>
</tr>
<tr>
<td>Oxazepam</td>
<td>Anxiolytics</td>
<td>European Perch</td>
<td>Change in behavior and feeding rate</td>
<td>Laboratory</td>
<td>Brodin et. al. (2013)90</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>Veterinary Parasiticide</td>
<td>Beetle</td>
<td>Mortality of eggs and Larvae</td>
<td>Laboratory and field</td>
<td>Liebig et. al. (2010)91</td>
</tr>
<tr>
<td>Ciprofloxacin</td>
<td>Antibacterial</td>
<td>Duckweed</td>
<td>Growth Inhibition</td>
<td>Laboratory</td>
<td>Ebert et. al. (2011)92</td>
</tr>
</tbody>
</table>

1.3.2 Toxicity Caused by Antibiotics and Anti-Microbial Resistance

Antibiotic compounds are produced by living organisms and designed to destroy microbes. An antibiotic is a chemotherapeutic agent that inhibits or abolishes the growth of microorganisms, such as bacteria, fungi, or protozoa.94 Presence of antibiotic residues in the environment causes direct impact on the viability and

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diversity of microbial populations in aquatic and terrestrial ecosystems. The presence of antibiotics in wastewater may promote antibiotic resistance in bacteria used in the wastewater treatment process and also in aquatic environments. Manufacturing of antibiotics in abundance is also posing a significant threat to the health of people living in the vicinity of manufacturing areas. Along with the discharge of antimicrobial compounds from the production facilities into the air, antimicrobial resistance is also the cause of concern. Resistance to antibiotics means earlier used concentration is no longer effective to cure the disease and thus higher and stronger concentration is required for the same ailment in other words minimal inhibitory concentration (MIC) for an antibiotic is increased. The report of World Health Organisation in 2014 on global surveillance of antimicrobial resistance revealed that "antibiotic resistance is no longer a prediction for the future; it is happening right now, across the world, and is putting at risk the ability to treat common infections in the community and hospitals." In 2015, first 'State of the World’s Antibiotics' report published by the Washington-based Centre for Disease Dynamics, Economics and Policy (CDDEP) found that 58,000 new-born babies in India died in 2013 as a result of drug-resistant infections. The study conducted by a Swedish team in 2014, in Khazipally lake of Patancheru region presents that there was a wide range of resistance to pharmaceuticals, in fact in some samples concentration was much higher than found in the blood of patients. The studies have revealed that antibiotics released from manufacturing

96 Ibid.
97 Carolin Rutgerson, Environmental Pollution from Pharmaceutical Manufacturing- Effects on vertebrates and Bacterial Communities (Ineko AB, Gothenburg, Sweden, 2013).
units combine with run-off from farms and human waste and mixes up in the water channels and thereby furnishes ground for drug resistant bacteria having capability to exchange genetic material.\textsuperscript{101} The report by Alejandro Litovsky in Guardian Sustainable Business—“Business and the Sustainable Development Goals” titled “Antibiotic Waste is Polluting India and China’s Rivers-Big Pharma must Act” states as under:

Environment pollution is now a material issue for the pharmaceutical sector. Global investors such as Nordea and BNP Paribas have raised concern about the potential damage to global health and environment and are worried that a local factory pollution scandal in India could affect the value of the global pharma company in their portfolio. As the world goes on a global request to combat Antimicrobial Microbial Resistance, the focus on industrial pollution will continue to grow.\textsuperscript{102}

The studies demonstrated that the use of unimaginable use of anti-biotics is not enviro-friendly. The use of anti-biotics result into killing of friendly microbes and micro-organisms. The exposure of extra-ordinary volume of anti-biotics may result into extremely dangerous pathogens.\textsuperscript{103} The struggle between anti-biotics may incline in favour of survival of deadliest microbes which can be resistant to many anti-biotics. According to Larsson, it has already resulted in the emergence of many multi-drug resistant micro-organisms in effluents exposed to environmentally relevant level of anti-biotics. Microbial resistance to antibiotic has become a global anathema and dangerous kind of pollution of environment.\textsuperscript{104}

\textsuperscript{101} Ibid.
\textsuperscript{102} Ibid.
\textsuperscript{103} Supra note 93.
\textsuperscript{104} Supra note 26.
1.3.3 Environmental Impacts of Endocrine Disruptors

The endocrine system produces hormones that control important physical development related to growth and reproduction. An endocrine disruptor is an "agent or mixture of agents that interfere with or alters the synthesis, secretion, transport, metabolism, binding action, or elimination of hormones that are present in the body and are responsible for homeostasis, growth, neurological signaling, reproduction and developmental processes." Endocrine disruption is responsible for the feminization of fish, resulting into:

1. a higher percentage of females in fish populations than expected;
2. changes in behavioural characteristics; or
3. the presence of male fish with female characteristics e.g. the presence of female egg cells or of a female egg protein in their blood.

Contraceptives, cancer treatments pharmaceuticals, pharmaceuticals for thyroid and nervous system diseases and various veterinary pharmaceuticals are the examples of endocrine-disrupting pharmaceuticals.

1.3.4 Gravity of the Problem

Pharmaceutical compounds discharged through various channels usually end up in waterways and thereby cause aquatic imbalance. These contain highly active compounds that target specific biologic systems and adversely impacts on the physiology and behaviour of a variety of organisms even at low concentrations.

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107 Ibid.
Freshwater systems also contain about 200 pharmaceuticals around the world.\textsuperscript{110} Pharmaceutical residues have also been detected in marine waters and sediments,\textsuperscript{111} surface and groundwater. A study by the United States Geological Survey (USGS) published in 2002, revealed that in the samples of 139 streams across 30 states, 80 percent had measurable concentrations of prescription and non-prescription pharmaceuticals, steroids, reproductive hormones, and their by-products.\textsuperscript{112} Following table represents the frequency of pharmaceutical compounds being found in the aquatic environment.

<table>
<thead>
<tr>
<th>Pharmaceutical</th>
<th>Therapy Group</th>
<th>Number of countries worldwide in which pharmaceuticals have been found in the aquatic environment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diclofenac</td>
<td>Analgesics</td>
<td>50</td>
</tr>
<tr>
<td>Estrone</td>
<td>Estrogens</td>
<td>35</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>Analgesics</td>
<td>29</td>
</tr>
<tr>
<td>Estriol</td>
<td>Estrogens</td>
<td>15</td>
</tr>
<tr>
<td>Sulfamethoxazole</td>
<td>Antibacterial</td>
<td>47</td>
</tr>
<tr>
<td>17-α-Ethinylestradiol</td>
<td>Estrogens</td>
<td>31</td>
</tr>
<tr>
<td>Ciprofloxacin</td>
<td>Antibacterial</td>
<td>20</td>
</tr>
<tr>
<td>Norfloxacin</td>
<td>Antibacterial</td>
<td>15</td>
</tr>
<tr>
<td>Ibuprofen</td>
<td>Analgesics</td>
<td>47</td>
</tr>
<tr>
<td>17-β-Estradiol</td>
<td>Estrogens</td>
<td>34</td>
</tr>
<tr>
<td>Clofibric acid</td>
<td>Lipid-lowering</td>
<td>23</td>
</tr>
<tr>
<td>Carbamazepine</td>
<td>Anti-epileptic</td>
<td>48</td>
</tr>
<tr>
<td>Naproxen</td>
<td>Analgesics</td>
<td>45</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>Antibacterial</td>
<td>29</td>
</tr>
</tbody>
</table>


Table 1.2 Pharmaceuticals Found in the Aquatic Environment of all UN Regional Groups

Fate of WWTPs is even more miserable. Following chart represents a comparison of various countries regarding the presence of commonly found pharmaceuticals in the WWTPs.

![Chart 1.1 Comparison of Commonly Found Pharmaceuticals in Wastewater of WWTPs of Different Countries](chart.png)

The chart displays that presence of ciprofloxacin and metoprolol is highest in effluents of WWTPs of India as compared to other countries. Presence of Ofloxacin is second highest in India. The quality of groundwater of Indian territory is also deteriorated due to the presence of pharmaceuticals. For this purpose, the author

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relies on the study conducted by Fick \textit{et.al.} which shows that wells around PETL contain antibiotics, certizine and citalopram in a concentration ranging from $0.021 \mu g/L$ to $28 \mu g/L$.\textsuperscript{115} Presence of ciprofloxacin in the groundwater of India is 90 times higher than China\textsuperscript{116} and 43 times higher than Spain.\textsuperscript{117}

In India, waste flowing out of a treatment plant near Hyderabad pollutes the region's waters with some of the highest levels of pharmaceuticals ever detected in the environment.\textsuperscript{118} Around 90 companies in the region that manufacture active pharmaceutical ingredients, or formulate final drug products, send their waste to the common effluent treatment plant. With permission, Larsson's team sampled the waste exiting the plant; it found pharmaceuticals including the antibiotic ciprofloxacin, at concentrations of up to 31,000 micrograms per litre, and the antihistamine cetirizine, at up to 1,400 micrograms per litre. The team estimated that the amount of ciprofloxacin entering the river from the plant could amount to up to 45 kilograms a day — the equivalent of 45,000 daily doses.\textsuperscript{119} The report of the Osmania Medical College, Hyderabad reveals that people affected in Patancheru-Bollaram region mostly belong to the socio-economic group. They have been exposed to increased risk of sickness on account of the presence of heavy metals and poisonous substances in the atmosphere. People are facing outcomes of air pollution in the form of Bronchitis, Lung cancer, skin diseases and respiratory diseases.\textsuperscript{120} The report also concluded that morbidity is higher in the

\begin{thebibliography}{99}
\bibitem{116} Keshava Balakrishna, Keerthi S.Guruge \textit{et. al.}, “A Review of Occurrence of Pharmaceuticals and Personal Care Products in Indian Water Bodies”137 \textit{Eco. & Environ. Safety} 113-120 (2017).
\bibitem{117} \textit{Ibid.}
\bibitem{119} \textit{Available at} https://www. kwikmed.org/ environmental -impact -pharmaceutical Industry/ (Visited on December 5, 2016).
\bibitem{120} Kasala Malla Reddy \textit{& Others v. State of A. P. \& Others}, Application No. 69 of 2013 (SZ).
\end{thebibliography}
female population. It opined that bore wells, tanks and stream near Nakkawagu are also polluted on account of discharge of untreated or partially treated effluents from industries.\(^{121}\) As per the opinion of the Deputy Director of Agriculture, Hyderabad, the water of the Nakkawagu and the adjoining wells is not fit for raising crops. If it is used, the electrical conductivity of the land will be increased and soil will become unsuitable for any crop pattern.\(^{122}\)

As per the findings of various studies, key systems affected by pharmaceutical pollution are:

<table>
<thead>
<tr>
<th>Bodily System</th>
<th>Relative Affect in Control Group (Higher in Terms)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nervous System</td>
<td>3 times</td>
</tr>
<tr>
<td>Circulatory System</td>
<td>2 times</td>
</tr>
<tr>
<td>Respiratory System</td>
<td>3.81 times, 1 in 20 are affected</td>
</tr>
<tr>
<td>Digestive System</td>
<td>1.98 times</td>
</tr>
<tr>
<td>Blood and Blood-forming Organs</td>
<td>2.91 times, 1 in 29 are affected</td>
</tr>
<tr>
<td>Endocrine, Nutritional and Metabolic System</td>
<td>1.84 times, 1 in 35 are affected</td>
</tr>
<tr>
<td>Neoplasms</td>
<td>11 times</td>
</tr>
<tr>
<td>Skin Tissues</td>
<td>2.67 times</td>
</tr>
<tr>
<td>Congenital malformations, deformations and chromosomal abnormalities</td>
<td>3.93 times</td>
</tr>
</tbody>
</table>

Table 1.3 Relative Affect in Various Body Systems due to Pollution \(^{123}\)

Reports also present relative rate of occurrence of diseases potentially due to pollution as follows:

\(^{121}\) Ibid.
\(^{122}\) Ibid.
<table>
<thead>
<tr>
<th>Disease Condition</th>
<th>Relative Rate of Occurrence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epilepsy</td>
<td>247.49%</td>
</tr>
<tr>
<td>Paralysis</td>
<td>349.56%</td>
</tr>
<tr>
<td>Heart Diseases</td>
<td>355.56%</td>
</tr>
<tr>
<td>Bronchitis</td>
<td>473.15%</td>
</tr>
<tr>
<td>Asthma</td>
<td>401.81%</td>
</tr>
<tr>
<td>Allergic Dermatitis</td>
<td>283.89%</td>
</tr>
<tr>
<td>Arthritis</td>
<td>311.36%</td>
</tr>
<tr>
<td>Skin Diseases</td>
<td>253.31%</td>
</tr>
<tr>
<td>Recurring Headache</td>
<td>653.14%</td>
</tr>
<tr>
<td>High Blood Pressure</td>
<td>193.80%</td>
</tr>
</tbody>
</table>

Table 1.4 Relative Rate of Disease Occurrence due to Pollution\(^{124}\)

It has been reported that 23 lakh fish have been killed by pharma pollutants in Khazipally Industrial belt for which FIR under Sections 277 and 278 of IPC has been lodged against pharmaceutical industries.\(^{125}\) Looking at the gravity of the issue, it was observed by A.P. High Court that:

It is true industrial development is important. But we believe that human life is more important. Industrial development cannot be at the cost of human beings. It then becomes counterproductive. The situation in this area has already assumed alarming proportions. The surface water, as well as groundwater in the area covering about 14 to 15 villages, has become thoroughly unfit for human consumption. The land too appears to have become unfit for raising crops and cattle are said to be dying by dozens by drinking the polluted water and by grazing the contaminated grass and plants.\(^{126}\)

\(^{124}\) Ibid.


Same is the fate of Vapi region in Gujarat. The State of Gujarat has made rapid growth in the industrial sector, with chemical and related industries playing a significant role. In 2012, Vapi has topped the list of critically polluted areas in the country, as per report of Comprehensive Environmental Pollution Index (CEPI), released by the Central Pollution Control Board (CPCB).\textsuperscript{127} In Baddi, District Solan (H.P.) the robust growth of the pharmaceutical sector has become the cause of severe anger among the people living in the vicinity. Many complaints concerning air pollution, illegal discharge of effluents and dumping of hazardous waste have been registered.\textsuperscript{128} In the case of Ghaggar river in Punjab, all along its river course, one can witness foul smell, contamination of subsoil water, the spread of water-borne diseases and chances of damage of crop due to the presence of industrial chemical from the industries in Punjab and Himachal Pradesh.\textsuperscript{129}

The upshot of aforesaid discussion is that manufacturing of pharmaceuticals is carried out for treatment of diseases yet it cannot be ignored that an irrational and unscientific approach has turned pharmaceuticals into one of the worst pollutants. It damages natural resources and threatens the sustenance of living creatures. Review of literature presented in Chapter 2 reveals that the scope of international and national legal regime on the protection of the environment is wide enough to cover PI&E. Despite the development of several principles of international environmental law aiming to protect natural resources and environment and enactment of the plethora of statutes at national levels, the problem is still persistent. It reflects the marginalization of the governance and norms developed for sustainable development i.e. harmony in the process of environmental

\textsuperscript{129} “Industrial waste: Here’s What Government must do to Stop Water Pollution-The Government needs to Involve All Stakeholders in Formulating Policies and Regulations”, Financial Express, October 23, 2016.
protection and economic development. It raises the questions on the relevance of legal norms for mitigation and adaptation of problem of pollution caused by PiE. Besides, various books, articles, research papers and work reviewed in Chapter 2 reveal that the judiciary has been proactively contributing to the cause of protection of the environment, importing the principles of international environmental law in Indian jurisprudence. The issue of PiE has recently drawn the attention of the judiciary as spelt out in the later part of this study.

1.4 Research Questions
In order to achieve the objectives of the proposed research, the researcher proposes following research questions which are nothing, but the translation of objectives of research into concrete form. The researcher has framed following research questions:

1. Pharmaceuticals are devised for the treatment of diseases of living creatures. How do these emerge as anathematic and pollutants causing an adverse effect on the environment?
2. Is it possible to introduce and maintain equilibrium between the conflicting phenomenon of the indispensable need of pharmaceuticals and preservation of the environment for the present as well as future generations?
3. What are the foundational principles underlying legal measures at international and national level to prevent and control entry of PiE?
4. What is the Indian legislative approach towards the causes and effects of PiE?
5. Has the Judiciary in India, known for its pro-environment stance, ever taken cognizance of the problem of PiE and contributed its share fairly?

1.5 Aims and Objectives of the Study
To find out the answers of the research questions, the researcher on the basis of above discussion and review of literature presented in Chapter 2, the researcher proposes the study under General Objectives and Specific Objectives. Since the foregoing discussion reveals that PiE enters the environment through three ways wherein the first route is industrial and others are human negligence and lack of awareness. The primary aim of the researcher is to evaluate the gravity of the problem and its appreciation by the legislature, executive and judiciary. Further,
the object of the researcher is to present the analysis figuring out the relevance and adequacy of legal measures on prevention and control of PiE. The relevance has to be assessed on the parameters of *adaptive* and *resilience* capacity of the natural resources. To summarize:

1. **General Objectives:**
   a. To compile and present integrated perspectives on PiE – Scientific, Technological and Legal for sensitizing the stakeholders regarding causes and effects of PiE.
   b. To explore the suggestive measures based on the socio-economic and juridical considerations for relief against the evil of PiE.

2. **Specific Objectives:**
   a. To review the relationship between principles of international environmental law and national environmental laws and relevance thereof in the context of PiE:
      i. Sustainable development
      ii. Inter-generational and intra-generational equity
      iii. Precautionary principle
      iv. Polluter pays principle
      v. Public participation and access to justice
      vi. Cost-benefit analysis
      vii. The principle of good neighborliness and co-operation.
   b. To critically evaluate the role of government especially legislature and executive in handling the issue of PIE in India, by examining legislative-cum-regulatory framework and nature of norms covering:
      i. Analysis of pollution control laws;
      ii. Analysis of functioning of pollution control Boards;
   c. To assess the contribution of Indian judiciary in protecting the environment against pharmaceuticals.
   d. To suggest the measures, based on an analytical approach for effective implementation and enforcement of laws dealing with PiE.
1.6 Research Methodology

The quality and value of research depends upon the proper and particular methodology adopted for the completion of research work. Looking at the nature of the research topic – analytical method of legal research is proposed to be adopted. To make an authenticated study of the research topic ‘A Study of Legal Regime on Pharmaceuticals in Environment: International and National Perspectives’ enormous amount of study material is required.

It is an inter-disciplinary research requiring scientific, technological and legal information on national and international aspects. To accomplish the task properly, a line has to be drawn somewhere. Therefore, the researcher for the purpose of basic understanding and finding out the answer to the first research question formulated and referred above, has gathered the substantial study material dealing with a scientific domain from secondary sources. Recognizing the fact that domain of environmental regulation is not confined to statute law, but extended to the setting, applying, enforcing, and reviewing the standards, the answers to the research questions 2-5 have been formulated by exploring the relevant information from primary sources available in the form of relevant Acts, Bye-Laws prevailing in the form of Rules, Regulations, Notifications, Circulars, Government Orders, Guidelines prescribing the Standards and Notices and other secondary sources available in the form of books, journals, periodicals, newspapers, research articles and proceedings of the seminars, conferences, conventions, annual reports and studies conducted on environment available in the libraries and online databases, websites and offices of Pollution Control Board, Good Manufacturing Practices, manual and officials documents of United Nations Environment Programme (UNEP), proceedings of international organizations working in the area, judgments of the Courts or Tribunals etc.

1.7 Scope of Study

The problem of environmental pollution is not of recent origin; however, every new day poses more serious challenges by introducing new categories of pollutants. The protection and preservation of the environment is a global issue and it is not the isolated problem of any area or nation. Environmental threats are rising in an
increasingly small world irrespective of their size, development or ideology.\textsuperscript{130} The gravity of the problem has been aggravated by the anthropocentric approach. With the rapid industrial and technological growth, mankind has disturbed the ecological equilibrium. ‘Pharmavision 2020’ sets out the target for the Indian pharmaceutical industry to grow up to $55 billion.\textsuperscript{131} Growth trends in new millennium witness that India is emerging as a global leader in drug manufacturing but at the same time, there is need to ensure environmental sustainability.

Production of a pharmaceutical product is essential not only for economic gain but also for ensuring the right to health of citizens of a country. Affordable access to healthcare is a primary social goal of the governments in the developing countries. The traditional concept of healthcare has undergone a radical change. It shifted its momentum from the individual-centric approach to public health concept, in the wake of some international achievements. The Constitution of India also promotes the concept of ‘Public health’. The right to health find its place under the umbrella of Article 21 i.e. Right to life. Directive Principles of State Policy also has several provisions concerning health matters.\textsuperscript{132} The concept of health is not just a subject of medical treatment rather it has social relevance. It covers not only medical care but pro-preventive care as well.\textsuperscript{133} As Indian pharmaceutical industry caters health care needs of people around the globe, it is supposed to be a highly regulated sector. The growth of Indian Pharmaceutical Industry has demonstrated that it has potential to accord universal access to healthcare to all, not just the rich. But at the

\textsuperscript{130} M. C. Mehta v. Union of India, (1991) 2 SCC 353.
\textsuperscript{132} Article 39 (e) states that the health and strength of workers, men and women, and the tender age of children are not abused and that citizens are not forced by economic necessity to enter avocations unsuited to their age or strength; Article 39 (f) states that children are given opportunities and facilities to develop in a healthy manner and in conditions of freedom and dignity and that childhood and youth are protected against exploitation and moral and material abandonment; Article 42 contains provisions for just and human conditions of work and maternity relief; Article 47 duty upon the State to raise the level of nutrition and the standard of living and to improve public health.
same time, environmental implications attached to the growth of pharmaceutical sector cannot be placed in the back seat. Therefore, the importance of study lies in finding out the solution of the problem on the basis of integration of law, science and technology. However, the study gives special emphasis to identify the areas for updating laws and analyze the level of implementation through the judgments and information collected through other primary and secondary sources. No doubt, humankind and living creatures are enjoying the benefit of improved medical care but the findings as to the effects of PiE cannot be ignored. Therefore, due consideration has been given to the relevant principles and rules given under legal instruments.

Law, like environment, is dynamic in nature. It cannot remain static. To keep the pace of law at par with changing environmental scenario, the judiciary has always played a pro-active role. It took cognizance of the pollution being caused by the industrial units In M.C. Mehta v. Union of India (Popularly known as Oleum Gas Leakage Case)\(^{134}\) wherein the Supreme Court suggested setting up of ‘Ecological Science Group’ and emphasized the need of having ‘Environmental Courts’. Taking ‘Environmental jurisprudence’ to the new heights, the apex court evolved the principle of "absolute liability". In Indian Council for Enviro-legal Action v. Union of India (also known as an H-acid case)\(^{135}\), the Supreme court applied one of the cardinal principles of sustainable development i.e. Polluter Pays Principle and fix the responsibility of polluting industry to repair the damages caused to the environment. The issue of environmental degradation by way of pharmaceutical pollution was taken up by the apex court in 1990, when a writ petition was filed by Indian Council for Enviro-Legal Action & Others against the Industries and CETP of PETL at Patancheru and Bolaram in Hyderabad on account of ground and surface water pollution caused by discharge of effluents. The Supreme Court directed CPCB and APPCB to jointly recommend measures to ensure the satisfactory functioning of CETP.\(^{136}\) Taking note of the role played by the judiciary

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\(^{134}\) AIR 1987 SC 982.

\(^{135}\) (1996) 3 SCC 212.

\(^{136}\) Writ Petition(Civil) No. 1056/1990.
in the preservation of the environment, the present study would incorporate the concept of judicial attitude towards pharmaceuticals in the environment.

A bird's eye view on the scope of the study carried out in subsequent chapters can be presented as under:

**1.7.1 Environment Law: International Perspectives and Relevance with PiE**

The international fraternity took this issue during the last decade of the 20th century at Rio Summit, 1992.\(^{137}\) It mobilized and drew the attention of the governments of the world towards the environmentally sound management of ‘toxic chemicals' and incorporated a Chapter 19 in Agenda 21. It acknowledged that a substantial use of chemicals is essential to meet the social and economic goals of the world community, and these can be used with a high degree of safety by adopting the best practices. Two major problems identified in Agenda 21, particularly in developing countries were:

1. Lack of sufficient scientific information for the risk assessment, and;
2. Lack of resources for assessment of chemicals.

Gross chemical contamination, with grave damage to human health, genetic structures and reproductive outcomes and the environment, has been continuing within some of the world's most important industrial areas, and restoration will require major investment as well as the development of new techniques. Accordingly, Chapter 19 contained six points of action programmes:

1. Expanding and accelerating international assessment of chemical risks;
2. Harmonization of classification and labelling of chemicals;
3. Information exchange on toxic chemicals and chemical risks;
4. Establishment of risk reduction programmes;
5. Strengthening of national capabilities and capacities for management of chemicals; and
6. Prevention of illegal international traffic in toxic and dangerous products.

Continuing the momentum, this commitment was renewed at the Johannesburg Plan of Implementation (JPOI, 2002)\(^{138}\) whereby it was resolved as under:

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\(^{138}\) The Johannesburg Declaration on Sustainable Development, 2002.
1. to adhere to sound management of chemicals throughout their life cycle and;

2. to manage hazardous wastes for sustainable development as well as for the protection of human health and the environment, *inter alia*, aiming to achieve by 2020, that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment;

3. to promote the use of transparent science-based risk assessment procedures and science-based risk management procedures, taking into account the precautionary approach, as set out in principle 15 of the Rio Declaration on Environment and Development, and;

4. to support developing countries in strengthening their capacity for the sound management of chemicals and hazardous wastes by providing technical and financial assistance.

Subsequently, Strategic Approach to International Chemicals Management (SAICM)—a policy framework was adopted by United Nations Environment Programme at its ninth special session at Dubai, UAE.\(^{139}\) It acknowledged the essential economic role of chemicals and their contribution to improved living standards need to be balanced with recognition of potential cost in pursuance of the principles 12, 14 and 15 of Rio Declaration.\(^{140}\) The purpose of SAICM was

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\(^{139}\) The United Nations Environment Programme, Governing Council Resolution 1/1 and SS.IX/1, 2006.

\(^{140}\) The United Nations Conference on Environment and Development, 1992. Principle 12 provides that States should cooperate to promote a supportive and open international economic system that would lead to economic growth and sustainable development in all countries, to better address the problems of environmental degradation. Trade policy measures for environmental purposes should not constitute a means of arbitrary or unjustifiable discrimination or a disguised restriction on international trade. Unilateral actions to deal with environmental challenges outside the jurisdiction of the importing country should be avoided. Environmental measures addressing transboundary or global environmental problems should, as far as possible, be based on an international consensus; Principle 14 enunciates that States should effectively cooperate to discourage
stated to promote chemical safety around the world. It is distinguished by its comprehensive scope; ambitious “2020” goal for sound chemicals management; multi-stakeholder and multi-sectoral character; endorsement at the highest political levels; emphasis on chemical safety as a sustainable issue; provision for resource mobilization; and formal endorsement or recognition by the governing bodies of key intergovernmental organizations. It is pertinent to note that mandate of SAICM clearly dictates that plan of action of SAICM is to be guided by principle 22 of Stockholm Declaration, Rio Declaration on Environment and Development, Agenda 21 especially its chapters 6, 8, 9, 19 and 20, UN Millennium Declaration, Bahia Declaration on Chemical Safety, Johannesburg Plan of Implementation, Montreal Protocol, Basel Convention, Rotterdam

or prevent the relocation and transfer to other States of any activities and substances that cause severe environmental degradation or are found to be harmful to human health; Principle 15 elucidates that to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.


The United Nations Conference on Human Environment, 1972; Principle 22 provides that States shall cooperate to develop further the international law regarding liability and compensation for the victims of pollution and other environmental damage caused by activities within the jurisdiction or control of such States to areas beyond their jurisdiction.


Ibid; Chapter 6 of the Rio Declaration deals with protection and Promotion of human Health; Chapter 8 is related to integration of environment and development in the process of decision making; Chapter 9 on the basis of multidimensional approach, deals with protection of the atmosphere; Chapter 19 and 20 provides for environmentally sound management of toxic chemicals and hazardous waste consecutively.


Convention\textsuperscript{150} and ILO Convention no. 170.\textsuperscript{151} Recently adopted Davos Declaration aiming to reduce environmental impact from the production of antibiotics\textsuperscript{152} also dictates to review good practices to control the release of antibiotics in the environment at the time of manufacturing and supply chains. It purports-

1. to establish a common framework for managing antibiotic discharge from manufacturing and supply chain by 2018;

2. to work with stakeholders to develop a practical mechanism;

3. to transparently demonstrate that supply chains meet the standards in the framework and;

4. to make efforts to reduce the environmental impact of manufacturing discharges by 2020.\textsuperscript{153}

In the present era, when the whole world has become a global village, the problem of PiE has gripped all over the world irrespective of the point of origin, production and consumption. Though it has drawn the attention of many governments and these governments have acted and have been acting swiftly and appropriately to control the menace, yet there are many, which have not responded adequately. On the basis of concern shown by various countries towards the issue, the Governments have been placed into three categories:

1. Developed, cognizant and responsive e.g. European Union, U.S. etc.;

2. Developing, cognizant and less responsive e.g. India, Israel;

3. Under-developed, non-cognizant and unresponsive.

The researcher has confined the area of the study to first two categories of countries. The present research work is confined to the elaboration of the principles


\textsuperscript{151} The Chemicals Convention, C 170, 1990.

\textsuperscript{152} Available at http://www.ifpma.org/resource-centre/industry-roadmap-for-progress-on-combating antimicrobial-resistance (Visited on December 6, 2016).

\textsuperscript{153} Ibid.
of customary international environmental law and international law on sustainable development, the relevance of these principles in the context of national laws with special reference to India covering statutes referred hereinafter, critical examination thereof followed by the judicial approach towards PiE.

1.7.2 Environment Law: National Perspectives & Relevance with PiE

As far as Indian Scenario is concerned, sources of legal and regulatory measures are grounded in the Constitution of India as the supreme law of the land. Environment protection is given due recognition in the Preamble, as a fundamental right in Article 21 i.e. the right to life, as an obligation on the State in Article 47 i.e. duty to raise the level of nutrition and improve public health and Article 48-A i.e. obligation to protect and improve the environment and safeguard forests and wildlife. Fundamental Duty to protect and improve the environment is also cast upon citizens under Article 51-A (g). Environmental governance of pharmaceutical residues is covered directly or indirectly by Sectoral legislations under the Water (Prevention and Control of Pollution) Act, 1974; The Air (Prevention and Control of Pollution) Act, 1981; The Factories Act, 1948; The Public Liability Insurance Act, 1991 and Solid Waste Management Rules, 2016. Framework Environment law i.e. single legislation providing for environmental management concerning the issue is the Environment (Protection) Act, 1986; The Hazardous and Other Wastes (Management and Trans-Boundary Movement) Rules, 2016. All these measures have been discussed at length in the later part of the study in Chapter 4.

1.8 Significance of the Study

PiE, being a multi-dimensional challenge on social, economic, scientific, technical, environmental and legal fronts affecting the health, lifestyle, livelihood, flora and fauna has placed the mankind at the crossroads. The significance of the instant work lies in the critique of statutory framework towards PiE in India. The study will unveil the level of incorporation of various substantive parameters covering precautionary principle, polluter pays principle, principles of inter-generational and intra-generational equity, sustainable development, public participation and access to justice. The importance of the study scales upwards with the presentation of a multipronged strategy. The strategy consists of suggestive measures devised on
the integrated foundations of law, science and technology. It will pave the way and illuminate the stakeholders regarding the threats posed by PiE and legal remedies available thereon, in India.

1.9 Limitations of the Study

During the course of study, the researcher came across various limitations. These limitations can be specified as under:

1. Lack of literature on PiE from multi-disciplinary perspectives made the task difficult. Adequate literature was available on the scientific aspects. In India, the issue failed to draw the adequate attention of the scientists, research scholars, academicians and policymakers, in proportion to the gravity of the problem. Therefore, the study has been confined to the examination and applicability of laws – international and national, on PiE.

2. False reporting, manipulation of data and information by the officials of regulatory agencies, lack of measures for fixing the accountability in maintaining the transparency, half-hearted measures for ensuring public participation and rule of law presented the challenges for carrying out the study in the proper perspectives. It is also aggravating the problem by keeping the stakeholders in dark.

1.10 Scheme of Study

In view of the foregoing discussion, the present research work is divided into five chapters. The scheme of chapters is as follows

Chapter 1: Introduction

The first chapter is introductory in nature. It gives an account of environmental pollution caused by pharmaceutical residues as implications of growing pharmaceutical industry. Emphasizing upon the sensitiveness of issue, it discusses the gravity of the problem along with its environmental footprints. Raising the concern over the issue of PiE, it covers the introduction of the issues, genesis of the problem, comprehensive discussion on the statement of the problem, its causes, aims and objectives of the study, research questions, research methodology, scope of the study followed by significance and plan of the study.
Chapter 2: Review of Literature

The second chapter is based on the comprehensive review of literature presenting the studies conducted so far. The literature has been reviewed by dividing the works already done into two parts, firstly, scientific study and second part deals with legal perspectives under two heads- international environmental law and relevancy of principles of international law in the context of PiE and the national legal regime on PiE.

Chapter 3: Juridical Overview of International Legal Framework on PiE

The third chapter underscores jurisprudential ethos in the evolution of the principles of international environmental law. The chapter begins with the articulation of the dichotomy stimulated out of the conflicting notions of the right to health, right to development on the one side and right to clean and healthy environment, access to natural resources for present as well as future generations on the other side. It elaborates the solution of the dilemma through the golden principle of sustainable development, various legislative, regulatory, strategic and policy measures developed by the international fraternity to identify the solutions of PiE.

Chapter 4: Legal Framework on PiE in India

The fourth chapter of the study presents an analysis of existing Indian legal framework on the issue of pollution being caused by pharmaceutical pollution. Beginning from constitutional foundations of right to health and right to clean and healthy environment, measures under criminal laws, the chapter highlights the key provisions of Sectoral laws – the Water (Prevention and Control of Pollution) Act, 1974; the Air (Prevention and Control of Pollution) Act, 1981; and framework environmental law titled Environment (Protection) Act, 1986 along with rules made thereunder namely Hazardous And Other Wastes (Management and Transboundary Movement) Rules, 2016; Solid Waste Management Rules, 2016; Bio-Medical Waste (Management and Handling) Rules, 2016; the Chemical Accidents (Emergency Planning, Preparedness, and Response) Rules, 1996 followed by other allied legislations i.e. Drugs and Cosmetics Act, 1940 along with Good Manufacturing Practices under Schedule M of the Act; the Public Liability Insurance Act, 1991 and the Factories Act, 1948. The judicial attitude towards the cause and concern has also been examined.
Chapter 5: Conclusions and Suggestions

This chapter precisely presents the gist of discussion made in the previous chapters. It has been designed to put forth the conclusions drawn out of the study as the gap analysis. Since it is a doctrinal study, it signifies legal framework, its objectives and actual position through the secondary data available on the implementation aspects. In order to bridge the gap, some suggestions are made. It underlines the need to devise a multi-pronged strategy applicable at multi-dimension promoting the use of multi-media and presents the suggestions for updating the laws by inserting required amendments, flexible approaches in devising standards, strengthening the impact of judicial approach towards PiE, ensuring the participation of the stakeholders and rule of law in environmental governance. The suggestions may serve to improve the impact of law.