A Study of Active Pharmaceutical Ingredients Disposition of Waste

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ABSTRACT

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API (Active Pharmaceutical Ingredient) means *the active ingredient which is contained in medicine*. For example, an active ingredient to relieve pain is included in a painkiller. Developing and producing Active Pharmaceutical Ingredients (APIs) includes various processing steps, such as *reaction, crystallization, separation and purification, solvent swap, and solvent exchange*. Active Pharmaceutical Ingredients or APIs are also known as bulk drugs and a term that is often heard in business news. An active ingredient is the ingredient in a pharmaceutical drug or pesticide that is biologically active. The similar terms active pharmaceutical ingredient and bulk active are also used in medicine, and the term active substance may be used for natural products. Active Pharmaceutical Ingredients are the active ingredients contained in a medicine.

The issue of disposal of wastes from these API companies, as well as the development and implementation of efficient collection strategies, is an important concern. This research looks into the factors that have an impact on the disposition of wastes from these companies, and how are these addressed by local government bodies.

The *pharmaceutical industry* discovers, develops, produces, and markets drugs or pharmaceutical drugs for use as medications to be administered to patients with the aim to cure them, vaccinate them, or alleviate symptoms. Pharmaceutical companies may deal in generic or brand medications and medical devices. They are subject to a variety of laws and regulations that govern the patenting, testing, safety, efficacy using drug testing and marketing of drugs.

Keywords: Active Pharmaceutical Ingredient, API, Bulk Drugs, Disposition of Waste

Introduction to pharmaceutical industry:

The pharmaceutical industry has a number of unusual characteristics that make it very different from what people normally think of as industry. It is also an industry replete with contradictions; for example, despite the undisputed fact that for over a century the industry has made a major contribution to human wellbeing and the reduction of ill health and suffering, it is still regularly identified by the public in opinion surveys as one of the least trusted industries, often being compared unfavourably to the nuclear industry. It is undoubtedly one of the riskiest businesses in which to invest money, yet it is perceived by the general public to be excessively profitable. The major pharmaceutical companies rightly promote themselves as being research-based organisations, yet most people believe that they spend more on marketing than on research. Despite the acknowledged risks and costs associated with pharmaceutical development, many citizens still believe that pharmaceuticals should be being developed to meet all human needs and that when developed they should be given away to everyone on the basis of need.

This opening chapter aims to provide a basic understanding of how the industry works and attempts to provide an explanation for some of its contradictions. The objective is to provide a backdrop to the business so that the challenges of the issue of pharmaceuticals in the environment can be better understood.

Note that the words "medicine," "pharmaceutical"

and "drug" are often used interchangeably and the word "drug" can also mean both a medicine and an illegal substance, depending on the context. In this chapter the word "pharmaceutical" is arbitrarily assigned to the end-products of the pharmaceutical industry that are used by patients. The word "drug" is mainly used for potential pharmaceuticals whilst under development by the industry.

Importance of study

Active Pharmaceutical Ingredients are the active ingredients contained in a medicine. It is that part of the medicine that produces the intended therapeutic effects. For example, in a painkiller, the active ingredient relieves pain. In the OTC drug Crocin, the API is paracetamol. Only a small amount of the API is required to produce the effect and so the medicine contains only the required amount of the API. Some drugs contain multiple APIs to treat varied symptoms.

API is the most important raw material in the production of medicines. The quality of active ingredients in a drug has a direct effect on the safety and efficacy of that drug. Poorly manufactured and contaminated active ingredients have been associated with negative health outcomes, including death, in a number of incidents over the past decades.

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Objectives of study

Pharmaceutical waste can enter the environment in following way: In effluents discharged from manufacturing sites. Detailed quantification for any individual pharmaceutical is difficult, but there is general agreement that the latter source dominates the global environmental input, with effluent discharges and the disposal of unused medicines making relatively small contributions.

1. To get to know about an Active Pharma Ingredient company & its process as regards its disposition of its wastes.
2. Also how the disposition of waste is monitored by various local government authorities & their functioning.

HYPOTHESIS

H0: Disposition of treated effluents / wastes does not have impact on sustainability of the environment

H1: Disposition of treated effluents / wastes have an impact on sustainability of the environment

Major challenges faced by pharma company: The pharmaceutical industry is economically important both for employment and for economic balance. However, it must constantly face many challenges that question the sustainability of a number of laboratories.

The pharmaceutical industry in some ways resembles an iceberg. These very well-known companies, which are loosely defined as research-based pharmaceutical companies, represent of the market in terms of finance. However, they correspond to only a small fraction of the industry as a whole, with >90% of pharmaceutical companies, known as generic companies, being largely invisible to the general public. In turn, these generic companies produce the vast majority of all pharmaceuticals sold.

Challenges faced by pharma company:

1. Water Pollution
2. Air Pollution
3. Supply Chain Disruption
4. Workforce Optimization
5. Need For Agility And Transparency

This research throws light on one of the major challenge i.e WATER POLLUTION & how the API companies treat these wastes following the Rules & Regulations given by local government bodies.

Process of waste disposition

STEP 1: The local government bodies in charge of waste disposition management have all the API companies registered with them. As in their basic details (company name, address, contact, email etc.)

STEP 2: A mail is sent out to these companies regarding the disposal of effluents from the factories. i.e. when to start the disposal of wastes and when to stop.

STEP 3: The companies have to abide by instructions of the authorities.

Government authorities handling the treatment of effluents from the pharma companies

Prevention mainly involves waste reduction by materials substitution, process modification/ optimisation, waste stream segregation and solvent waste recycling.

There are also ways that you can take action to reduce pharmaceutical waste in water. Advocating for improved technology at water treatment plants, stricter regulations on agricultural antibiotics and higher water standards can help reduce the levels of waste in our waters.

Also there are various Government Organizations / Bodies which address the Pharma companies which helps reducing the various problems associated with disposition of Wastes.

Some of the Organizations include:

1. Central Pollution Control Board (CPCB) - Statutory organisation, was constituted in September, 1974 under the Water (Prevention and Control of Pollution) Act, 1974. Further, CPCB was entrusted with the powers and functions under the Air (Prevention and Control of Pollution) Act, 1981.It serves as a field formation and also provides technical services to the Ministry of Environment and Forests of the provisions of the Environment (Protection) Act, 1986. Principal Functions of the CPCB, as spelt out in the Water (Prevention and Control of Pollution) Act, 1974, and the Air (Prevention and Control of Pollution) Act, 1981.
   (i) To promote cleanliness of streams and wells in different areas of the States by prevention, control and abatement of water pollution, and
   (ii) To improve the quality of air and to prevent, control or abate air pollution in the country.

2. Maharashtra Pollution Control Board (MPCB) - Is implementing various environmental legislations in the state of Maharashtra, mainly including Water (Prevention /and Control of Pollution) Act, 1974, Air (Prevention and Control of Pollution) Act, 1981, Water (Cess) Act, 1977 and some of the provisions under Environmental (Protection) Act, 1986 and the rules framed there under like, Biomedical Waste (M&H) Rules, 1998, Hazardous Waste (M&H) Rules, 2000, Municipal Solid Waste Rules, 2000 etc. MPCB is functioning under the administrative control of Environment Department of Government of Maharashtra.

Some of the important functions of MPCB are:

- To plan comprehensive program for the prevention, control or abatement of pollution and secure executions thereof,
- To collect and disseminate information relating to pollution and the prevention, control or abatement thereof,
- To inspect sewage or trade effluent treatment and disposal facilities, and air pollution control systems and to review plans, specification or any other data relating to the treatment plants, disposal systems and air pollution control systems in connection with the consent granted,
- Supporting and encouraging the developments in the fields of pollution control, waste recycle reuse, eco-friendly practices etc.
- To educate and guide the entrepreneurs in improving environment by suggesting appropriate pollution control technologies and techniques
- Creation of public awareness about the clean and healthy environment and attending the public complaints regarding pollution.

3. Common Effluent Treatment Plants (CETP) - The concept of effluent treatment, by means, of a collective effort, has assumed reasonable gravity by being especially purposeful for cluster of small scale industrial units. Common effluent treatment plant (CETP) not only helps the industries in easier control of pollution, but also act as a step towards cleaner environment and service to the society at large. Small scale industries, by their very nature of job cannot benefit much from economies of scale and therefore the burden of installing pollution-control equipment, falls heavy on them. Realizing this practical problem, under the policy statement for abatement of pollution the Govt. Advantages of

CETP PLANTS :

- The Common treatment is always cheaper than small scattered treatment units.
- Availability of land which is difficult to be ensured by all individual units in the event they go for individual treatment plants.
- Contribution of nutrient and diluting potential, making the complex industrial waste more amenable to degradation.
- The neutralization and equalization of heterogeneous waste makes its treatment techno-economically viable.
- Professional and trained staff can be made available for operation of CETP which is not possible in case of individual plants.
- Disposal of treated wastewater & sludge becomes more organized.
- Reduced burden of various regulatory authorities in ensuring pollution control requirement.

Conclusion

On understanding the various processes followed by Pharmaceutical company, there were following observations:

1. There are instructional e – mails sent by the local government bodies to start / stop the effluent flow; from the companies.
2. The local authorities treat these effluents from the companies.
3. The companies have to abide by the guidelines given by the local government authorities.
4. As a result of which the rivers alongside the companies & industrial area are kept clean & maintained properly.
5. Thus Null Hypothesis proves to be wrong & Alternate Hypothesis proves to correct.

Discussion

On discussion with the panel it was concluded that this paper had to focus more on the wider aspects of the problem as in the area of research, research should be done on more companies instead of restricting to a single company.

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