



Futuristic Role of Novel Drug Delivery Systems in Indian Pharmaceutical Market

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ABSTRACT

The domestic Indian Pharmaceutical Industry, once termed as the most progressive and highly growth oriented sector is witnessing a paradigm shift. The growth of the industry has slowed down due to various political, economic, social and environmental factors. The revenues have also dipped due to newer and more stringent governmental controls and better public awareness. The companies' profitability has taken a hit and the Industry is looking at newer avenues for driving the growth in both short and long term. One of the major such avenue is the development of Novel Drug Delivery Systems. Globally the market for NDDS has already taken off with more and more players jumping into the NDDS development and marketing. This article looks into current scenario of the Indian Pharmaceutical Market and the future of Novel Drug Delivery Systems as a tool to fuel the growth.

KEYWORDS : Indian Pharmaceutical market, NDDS, Efficacy, Safety, Compliance, Pill burden

Indian Pharmaceutical Industry – Current Scenario

The Indian pharmaceuticals market increased at a CAGR of 17.46 per cent in 2015 from US\$ 6 billion in 2005 and is expected to expand at a CAGR of 15.92 per cent to US\$ 55 billion by 2020. By 2020, India is likely to be among the top three pharmaceutical markets by incremental growth and sixth largest market globally in absolute size. India's cost of production is significantly lower than that of the US and almost half of that of Europe. It gives a competitive edge to India over others.^{1,3}

However, in the present scenario, the pace at which the Indian pharmaceutical industry was growing in the past few years, has slowed down. This slow down can be attributed to a number of factors, which include:

- Stringent UCPMP -The department of pharmaceuticals (DoP) has released the UCPMP (Uniform Code of Pharmaceuticals Marketing Practices). UCPMP is a voluntary code to be adopted by pharmaceutical industry to curb unethical practices in the healthcare sector. As per the UCPMP, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to persons qualified to prescribe or supply drugs, by a pharmaceutical company or any of its agents i.e. distributors, wholesalers, retailers, etc. Gifts for the personal benefit of healthcare professionals and family members (both immediate and extended) also are not to be offered or provided. Also, the free samples of drugs shall not be supplied to any person who is not qualified to prescribe such product. Where samples of products are distributed by a medical representative, the sample must be handed directly to a person qualified to prescribe such product or to a person authorised to receive the sample on their behalf.⁴
- Stricter implementation of MCI rules and regulations-The Medical Council of India (MCI) is set to notify the new ethical guidelines under the Indian Medical Council (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2015. For the first time, these guidelines will define punishment for errant doctors based on the value of favours or freebies received from pharma companies⁵.
- More than 300 formulations coming under NLEM (National List of Essential medicine) - The price controls on NLEM medications have retarded the segments such as cardio-diabetology and anti-infectives, which form a major chunk of Indian Pharmaceutical Business. The major Indian pharmaceutical companies as well as the MNCs-all have slowed down on growth and are looking at different innovative methods for boosting growth and fuelling profits. The MNCs especially have been hard hit in this scenario⁶.
- Ban on irrational fixed dose combinations - Health Ministry has banned about 344 fixed dose combination drugs, including cough syrups compositions, saying they involve "risk" to humans and safer alternatives were available⁷.

In addition to these factors, the number of newer molecules under research globally are very few and for Indian Companies, this new drug pipe line is drying up.

Apart from all above factors, the proliferation of regional and segmental players and the rise in awareness and usage of generic-generics market has played a key role in the paradigm shift being witnessed in the Indian Pharmaceutical industry.

The Indian companies are looking at various options to combat the slow down and are investing heavily in research and development, product improvements, sales force effectiveness, alternate modes to reach out to the end customers and creating loyal base of customers.

One of the most important routes being taken to come back to higher growth is the development and launch of Novel drug Delivery Systems (NDDS). Many of the traditional drugs are now being marketed with a novel delivery system.

Novel Drug Delivery Systems (NDDS)

Novel Drug delivery System (NDDS) refers to the approaches, formulations, technologies, and systems for transporting a pharmaceutical compound in the body as needed to safely achieve its desired therapeutic effects. It may involve scientific site-targeting within the body, or it might involve facilitating systemic pharmacokinetics; in any case, it is typically concerned with both quantity and duration of drug presence⁸.

The evolution of an existing drug from its traditional form to a novel delivery system may considerably improve its performance in aspects of efficacy, safety and patient compliance⁹.

Advantages of novel drug delivery systems¹⁰.

- Better quality of treatment of many chronic illnesses, thereby improving the quality of life of the patients. E.g. Cancer, Asthma, Arthritis.
- Equivalent efficacy and Increased Bio-availability.
- Reduction in the occurrence and badness of untoward systemic side effects related to high blood plasma drug concentration.
- Sustenance of the total amount of drug administered over the period dose periods.
- Reduction in the total amount drug administered over the period of drug treatment which reduce occurrence of systemic and local side effects.
- Prevention from first pass metabolism and gastrointestinal tract degradation.
- Better patient compliance effect from the reduction in the number and frequency of doses needed to maintain the want therapeutic responses.

- Targeting the drug molecule towards the affected tissue or organ make smaller the toxicity to the normal tissues.
- Versatile and pH dependent system release the drug whenever the body demands.
- Biocompatibility.

Global NDDS markets

Today even from the pharmaceutical marketing window, the companies are looking at brand and product differentiation. Most of the companies are caught between the dilemma of consolidating the existing, traditional brands or release new expensive moieties based on new product pipeline. The cost of the research and development of new drugs as well as the time period taken to develop and launch new drug is exorbitant. Here, also the development of novel drug delivery systems comes handy. The average cost and time for a new drug discovery and its development are much higher (approximately \$500 million and 10–12 years) than compared to development of novel drug delivery systems (NDDS) (\$20– 50 million and 3–4 years). The significant improvements in clinical efficacy, patient compliance, extension of product life through control release formulations as well as economic considerations such as reduced frequency and cost of the administering the drug are driving the demand for high performance, versatility and controlled-release systems. This made the novel drug delivery systems as one of the fastest growing segment in the pharmaceutical companies^{8, 11-15}.

Globally, Novel Drug Delivery Systems Market is Expected to Hit \$165.4 Billion By 2022. The key players involved in the novel drug delivery systems (NDDS) market are 3M Company, Abbott Laboratories Ltd., Amgen Inc., AstraZeneca Plc, Bausch & Lomb, Baxter International Inc., Bayer AG, Boehringer Ingelheim, Boston Scientific, Bristolmyers Squibb, Celgene Corporation, Cephalon, Inc., Genentech Inc., Genzyme Corporation, Glaxosmithkline Plc, Johnson & Johnson, Merck & Co., Novartis AG, Pfizer Inc., Roche Holding AG, Sanofi SA, and Teva Pharmaceutical Industries Ltd.¹⁶.

Projected market entry of several products and technologies during 2016 to 2022 in global novel drug delivery systems market are expected to provide an exceptional growth to the market. Novel drug delivery systems market is expected to intensify the market competition, ignition of price wars, and drive emphasis towards geographical expansion and penetration strategies to sustain in the competition¹⁶.

Way ahead:

The global market for the NDDS is growing at a phenomenal rate and is expected to increase rapidly. The reason being the advantages being offered by the NDDS formulations across the users and segments, and their potential to make it big.

The NDDS offer the following advantages from all the perspectives including:

- Medical fraternity - Optimum dose, at the right time, and in the right location which enhances the acceptance of NDDS at the level of prescribers.
- Industrial - Efficient use of expensive ingredients, thereby increasing the profitability of pharmaceutical companies.
- Economic- reduction in research cost as well as in production costs, leading to better sustainability of profits.
- Societal - Beneficial to patients, equivalent of better efficacy, enhanced safety profile, better therapy options, increased patient compliance, reduced pill burden and, improved comfort and quality of life.

Since, Indian Pharmaceutical market is witnessing looking at ways and means to increase both the revenues as well as the profitability, NDDS seem to be the future growth drivers. There are reasons to believe that NDDS acceptance in Indian market will increase in future, and so will be their usage. The usage and acceptance of NDDS is bound to increase. More and more Indian Companies are developing NDDS for the existing molecules and placing them in the market. The doctors find the NDDS beneficial from the point of view of efficacy, safety, patient compliance and reduced pill burden for the patients. The patients have a much better quality of life. The revenues and profitability of the companies increase in this scenario. So, it's a win-win situation for all stakeholders.

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