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Pharma Hits Sweet Spot with Innovative Diabetes Drugs

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India has, unfortunately, turned into the diabetes capital of the world with even more patients being added every passing year. This is adding to the growing healthcare burden on the Indian economy and has become a major cause of concern for the Centre as well. The government is aware and seems to be taking steps to combat this by bringing down the cost price of a few, newly launched drugs used for diabetes. Pharma companies, too, are seeing a new growth opportunity by innovating new drugs and therapeutic combinations. As there are already numerous drug options available, is there a need to further add to the pool of newer, innovative drugs? Let's explore.

India, already known as the diabetes capital of the world, is adding new patients to its database each year. With 75 million diabetic patients, the country is galloping ahead to add another 200 million pre-diabetics. The diabetes care market, consequently, is expected to reach about $60 billion in the next 10 years, from approximately $17 billion in FY2021 according to a study conducted by Redcore, the research arm of Bengaluru-based Redseer Consulting. This does not bode well for the population and is a matter of tremendous concern. As is the case in most scenarios, one person's misery is the other's cause for joy; pharma companies could rake in big bucks by launching new drugs.

Looking at the growth potential of the diabetes market, Mumbai-based Glenmark Pharmaceuticals launched Thiazolidinedione Lobeglitazone (Lobeglitazone) in India for the treatment of type 2 diabetes in adults on October 6. Marketed under the brand name LOBG; it contains Lobeglitazone (0.5 mg) and to be taken once daily under prescription to improve glycemic control in adult diabetic patients. The company noted that LOBG, an innovative and affordable drug, will help in tackling insulin resistance among adult patients suffering from uncontrolled type 2 diabetes in the country.

To add to the list of launches of new drugs to address type 2 diabetes is Mumbai-based Alkem Laboratories Limited. The 5th largest Indian pharmaceutical company, Alkem has launched for the first time in India on October 6, triple drug fixed dose combination (FDC) of Dapagliflozin, Sitagliptin and Metformin under the brand name of Dapanorm Trio at an affordable price for adults with type 2 Diabetes in India. Dapanorm trio is priced at Rs 19.70 per tablet which is almost 70 per cent less compared to the combined cost of innovator drugs.

To support the diabetes patients, Ahmedabad-based Zydus Lifesciences Ltd launched the generic version of sitagliptin in India under the brand names Sitaglyn and Siglyn in July this year. Sitaglyn and Siglyn offer an oral solution to the patients providing ease of convenience and better compliance. These will add on to a comprehensive solution for the management of type 2 diabetes by "providing access to quality care to the patients at an affordable cost, approximately 60 per cent lesser than the originator", the company noted.

Zydus said India's oral anti-diabetic market is worth Rs 12,500 crore, of which DPP4i (Dipeptidyl peptidase 4 inhibitor) class of anti-diabetics has a share of more than Rs 4,000 crore. Sitagliptin is the gold standard in the DPP4i category with over 62 per cent market share in the global market, it added.

To fulfil the requirements of patients with chronic kidney disease (CKD) associated with type 2 diabetes, Bayer on August 25 announced the launch of Finerenone under the brand name Kerendia in India. Finerenone is a first-in-class non-steroidal, selective mineralocorticoid receptor antagonist to show a significant reduction in the risk of kidney and heart problems in CKD patients with type II diabetes. Kerendia, priced at Rs 97.5 per pill, and is to be taken once a day.

Talking about the risk factors associated with diabetes, **Manoj Saxena, Managing Director, Bayer Pharma** says, " Diabetes itself is a risk factor for many other chronic conditions such as CKD. 40 per cent of people with type 2 diabetes are at a risk of developing CKD."

Ahmedabad-based Cadila Pharmaceuticals has also made a foray into the diabetes care segment with the launch of Sitenali and Jankey, having cardio-safe gliptin sitagliptin. It has also launched a potent combination of Sitagliptin and Metformin and branded it as Jankey M. Sitagliptin is a drug from the class of DPP-4 inhibitors, and a one-of-its-kind drug for the treatment of high glucose levels in the blood, also known as hyperglycaemia.

During the beginning of this year Novo Nordisk India launched the world's first and only "peptide in a pill", oral semaglutide, a game changer in diabetes management. Semaglutide, a GLP-1 receptor analogue (GLP-1 RA) – one of the drug classes to treat diabetes, till now was available only in the form of injections. This is the first time a GLP-1 RA has been developed in an oral formulation.

Exactly a year ago (i.e. October 2021), Hyderabad-based MSN Laboratories launched empagliflozin tablets (SGLT2i), a promising drug in diabetic management, under the brand name 'EMPAONE'. The medicine will cost Rs 15.90 and Rs 18.90 for each 10 mg and 25 mg tablet respectively. 'EMPAONE' is intended to provide diabetes patients in need across India with an affordable and accessible therapeutic option. The interesting point to be noted is that MSN has developed the Active Pharmaceutical Ingredient (API) and the finished dosage formulation (FDF) of EMPAONE at its in-house state-of-the-art R&D centre. The development is fully indigenous right from conceptualization to API development and FDF.

Is there a need?

Though numerous drugs are being launched every year to treat diabetes, the question remains, 'Are we in a problem of plenty or is there, indeed, a requirement?' Experts have projected mixed opinions when it comes to launching new drugs in this segment.

All classes of antidiabetic drugs are well represented in India - namely. biguanides (metformin), thiazolidones (various glitazones), sulfonyl ureas (glipizide, glimepride), meglitinides (sulfonyl urea analogues such as repaglinide, nateglinide), GLP-1 receptor agonists (incretin mimetics such as liraglutide), DPP-4 inhibitors (gliptins such as sitagliptin & vildagliptin), SGLT2 inhibitors (dapagliflozin, etc.), Alpha glucosidase inhibitors (Acarbose).

Girdhar Balwani, Professional Mentor & Independent Director, Cadila Pharmaceuticals says, "The above classes of drugs represent all the different mechanisms for the physician to manage diabetes using pharmacotherapy (apart from diet & exercise). Also, many ayurvedic products are available in India to manage diabetes. Any further introductions on the global stage offer marginal benefits over existing drugs available in India."

However, he goes on to add that there is no need to launch new drugs unless the drugs offer significant benefits (in terms of efficacy, safety, cost and patient convenience) over existing drugs they need not be launched with marginal benefits.

Dr V Mohan, Chairman, Dr Mohan's Diabetes Specialities Centre says, "India is not certainly lagging behind the global counterparts when it comes to the launch of new drugs in diabetes. These drugs are almost launched simultaneously in India. India also participates in Phase 2 and Phase 3 trials, simultaneously along with other developed countries and hence there is no lag in the introduction of these drugs in India."

Disagreeing with Dr Mohan's views, D**r Parizad Elchidana, President, Controlled Release Society – Indian Chapter,** opines, "We are lagging not just in new drug development for the treatment of type 2 diabetes but also in developing better alternative dosage forms and novel delivery systems to the current injectable insulin for type 1 diabetes. The world has moved on to nasal delivery, and transdermal delivery using microneedles, and some oral delivery systems are also under trial. These systems will not require the product to be stored under refrigerated conditions, will do away with the syringe and needle requirement and thus the sterility management of the same and will also provide a huge saving on the supply chain front as the cold chain will no longer be required for transportation."

Indian scientists have only focussed on reverse engineering drugs and this has led them to neglect discovering new ones for what is one of the most prevalent diseases among Indians. The government should incentivise to find a cure or develop drug treatments that are affordable and accessible specifically for all Indians who suffer from this health condition.

According to **Dr S Kannan, CEO, Oncophenomics,** western peers keep releasing one innovative drug after another while we stand still. Indian pharma companies should be working on developing novel peptide-based drugs with previously unseen mechanisms of action. There is a need for first-in-class drugs to turn the tide on the growing threat of obesity, diabetes, and cardiovascular disease.

Says **Dr Sanjay Kalra, President-Elect of the South Asian Federation of Endocrine Societies,** "India is not lagging behind the world in new drug development. Thanks to our farsighted policy adoption and practices by our regulators, India is at the forefront of new drug development. More drugs are welcome."

Effective and affordable diabetic drugs are the need of the hour. With the pace with which the disease is spreading, the government needs to take proactive steps to ensure that the right drugs are launched in the market with ease in the regulatory process. Launching too many drugs is not going to solve the purpose and we will again go back to the drawing board analysing what went wrong.

Sanjiv Das

sanjiv.das@mmactiv.com