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CORONAVIRUS SPECIAL

Impact of coronavirus on pharmaceutical sector and government initiative to make self-reliant on API

Pharmaceutical sector though being a valuable sector at present coronavirus health crisis is facing tough threats and challenges for doing its business activities. As the novel coronavirus continues to spread across the countries, concern about the potential for disruption to the manufacture and distribution of pharmaceutical products has intensified. The government is recommending measures and steps to keep the situation under control and is contemplating many methods to encourage domestic manufacturing of pharmaceutical raw materials for formulations by creating a suitable ecosystem in the country.

Despite a nationwide lockdown that disrupted the distribution of drugs across the country and fresh prescription generation and pharmaceutical sales in March 2020 registered an 8.9 per cent growth. This was primarily on account of panic buying of medicines in the chronic disease categories.

According to reports respiratory therapy drugs witnessed the highest sales across the country in March 2020 compared to February 2020, recording a growth of nearly 25 per cent. This was due to the coronavirus epidemic and despite a nationwide lockdown that disrupted distribution of drugs and prescription medicines. Cardiac therapy drugs witnessed19.8 per cent growth in March 2020 compared to 11 per cent in February 2020, anti-diabetic therapy, also increased a strong growth of 18.2 per cent in March 2020, compared to 11 per cent in February 2020. On the other hand, segments such as dermatology, gastrointestinal, pain and analgesics, and vaccines categories showed a decline in sales during the same period of time.

Coronavirus outbreak and spreading have started to hit pharmaceutical sector of the country by rising the prices of key ingredients. Now the prices for vitamins and penicillin are double the price. The price of paracetamol has gone up. Another major impact is that pharmaceutical companies faces disruptions due to extended factory closures. If the pandemic continues then stock piles of pharmaceuticals, pharmaceutical raw materials and other chemicals may decrease, resulting in shortages.

Dr Sanjay Agrawal

Dr Agrawal founded PHARMA CONSULTANTS and INVENTOR to fulfill his passion, capabilities and desire to assist pharmaceutical companies around the globe. He has actively worked in pharmaceutical and related industries for more than 28 years and started this firm in 2005. He is **Editor-in-Chief** of renowned IJM Today and honorable member of the editorial board of **The Antiseptic**.

The government should take appropriate measures immediately to keep the situation under control. China supplies many of the critical intermediaries and pharmaceutical raw materials including high-burden disease categories such as cardiovascular diseases, diabetes and tuberculosis. These are also listed in the National List of Essential Medicines. In fact, the current market is largely dependent on China for antibiotic active pharmaceutical ingredients manufactured by the fermentation route such as penicillin, cephalosporins and macrolides.

Indian drug manufacturers rely heavily on imports of their active pharmaceutical ingredients from China. As a result of the lockdowns and closures, slowed production of active pharmaceutical ingredients resulted in less availability and higher costs for the materials required for generic drug production. As per the current report, the prices of vitamins and penicillin have also been hiked tremendously.

Initiative by government

Indian government is encouraging more start-ups companies for production of pharmaceutical raw materials such as APIs, additives, fillers, etc to make the economy self-reliant, reduce over dependency on China. Also, multiple non-pharma and non-healthcare entrepreneurs would enter the sector and invest in manufacturing of active pharmaceutical ingredients, generic drugs, medical equipment and wearables. It is the right time for Indian medical start-ups to make wonders in the global healthcare arena.

Aiming for self-reliant, the government has come out with draft guidelines for the Rs. 6,940 crore production linked incentive scheme for promotion of domestic manufacturing of identified critical key starting materials/drug intermediates/active pharmaceutical ingredients in the country.

The guidelines were prepared by a technical expert committee, headed by the joint drugs controller (I) of CDSCO, constituted by DOP on April 17, 2020 after detailed consultations with industry, experts and other relevant stakeholders.

Objective of the production linked incentive scheme is to reduce import dependency and boost the domestic production of bulk drugs. Currently, India imports about 70 per cent of active pharmaceutical ingredients, by value, from China.

The import of active pharmaceutical ingredients has risen at a CAGR of 8.3 per cent from 2012 to 2019 and API import reached a value of Rs. 249 billion in 2019, according to reports. From forty-one eligible products for production linked incentive scheme, there are four fermentation based key starting materials/drug intermediates, ten fermentation based key starting materials/drug intermediates/active pharmaceutical ingredients, four chemical synthesis based key starting materials/drug intermediates (with backward integration) and twenty-three chemical synthesis based key starting materials/drug intermediates (with backward integration). Rs. 20 crore is threshold investment for twenty-three chemical syntheses based key starting materials/drug intermediates. These include meropenem, atorvastatin, olmesartan, valsartan, losartan, levofloxacin, sulfadiazine, ciprofloxacin, ofloxacin, norfloxacin, artesunate, telmisartan, aspirin, diclofenac sodium, levetiracetam, carbidopa, acyclovir, carbamazepine, oxcarbazepine, vitamin B6, levodopa, ritonavir and lopinavir.

The ten fermentation based niche key starting materials/drug intermediates/ active pharmaceutical ingredients are such as neomycin, gentamycin, betamethasone, dexamethasone, prednisolone, rifampicin, vitamin B1, clindamycin phosphate/clindamycin HCL, streptomycin, tetracycline/ oxytetracycline/ doxycycline.

As per the draft guidelines issued by the government, it should be a Greenfield project and the threshold investment ranges from Rs. 20 crore to Rs. 400 crore as per project. Investment made for the purchase of land shall not be considered as threshold investment. Building, plant and machinery may constitute about 45 per cent of the threshold investment.

Start-up companies or applicants need to make threshold investment to manufacture the eligible product post approval to make themselves eligible for the scheme. There is no upper limit cap on the investment.

The start-ups using novel technologies such as flow chemistry or continuous manufacturing known for safety, low environment and solvent burden; biocatalysts/novel enzymes; substitution of noble metals with cheaper metals; green chemistry/zero discharge or low polluting technologies with in-process recoveries will be given preference.

Adoption of Pharma Apps

Pharmaceutical manufacturing companies across the globe now have commenced introducing Pharma Apps to educate doctors, healthcare workers and hospital staff about new drugs launched in the market and for promoting these drugs in the absence of medical representatives who are kept at bay by medical professionals due to the present coronavirus pandemic crisis.

It is learnt that the new strategy is implemented to market company products through e-promotion activities. Products will be sent to the doctor, primary healthcare centres and the hospitals clinics directly by the manufacturing companies on placing of orders through online.

According to reports from various healthcare industry sources, using mobile technology hundreds of multinational and other pharma majors in India are resorting to digital routes to reach out to physicians and hospitals directly to share information on new products. The Pharma Apps rolled out by manufacturers contain information on new products, their efficacy and side-effects related matters and commission offers to doctors and hospitals. This digital form of marketing strategy is adopted by many companies for boosting their marketing in the wake of inability of sales representatives to visit doctors in clinics and hospitals. Manufacturing companies with various therapeutic segments bring out separate Apps on each product and share it with doctors who become their prospective direct clients without field staff.

Adoption of data analysis

There will be increased adoption of data analysis to understand disease patterns, patient responses and drug development would be based on that.

More plans and methods will be developed for better patient engagement, better accessibility to doctors and medicines, and increased patient adherence. There would be use of more evidence-based, therapeutic tools. The ongoing situation will accelerate the digital transformation of healthcare or e-healthcare. It will lead to more e-health usage and accessibility in the country - be it in the area of telemedicine, electronic health records, medical billing software, hospital management systems, telemedicine, patient management programmes, healthcare wearables. There will be more usage of video-conferencing through zoom and skype calls.

Challenges ahead

As coronavirus pandemic continues to drive up the count of those affected on a daily basis across the globe, businesses and people are exposed to new risks and the corona virus outbreak is disrupting and challenging across the globe.

Pharmaceutical sector, it is turbulent times as recognition and demand for pharma products are higher than ever before. At the same time, they have to come to terms with the harsher realities of this pandemic, supply shortage of active pharmaceutical ingredients and higher demand.

The human race is witnessing an unprecedented health crisis brought by coronavirus across the globe. The market is falling, the production units are standing still, and millions of people are suffering because of jobless.

According to reports the economic impact of the coronavirus crisis will be worse than the financial crisis of 2007-08. Every business activity is seeing a downturn. Even the pharmaceutical industry is not an exception.

Import of raw materials is restricted, which will affect the manufacturing activity and in turn will lead to lower sales. Insufficient ancillary supplies such as bottles, caps and packaging material for medicine will affect the output, the impact of which is expected to be felt over a period of next three to four quarters. This supply shortage may also lead to pricing volatility in future. Companies will try to maintain inventories for longer duration, buffer capacity will be increased which may affect the inventory cycles.

This crisis may also force few companies to think about new business models. E-pharmacy business may show higher growth. Companies may focus on backward integration for active pharmaceutical ingredients and intermediates. The thing worth looking for in the future is whether the pre-pandemic scenario in trade will be restored or new countries will emerge as export leaders in next few years as governments will try to become self-sufficient in medical supplies.

~Dr Sanjay Agrawal