NEWS LETTER

AUGUST-SEPTEMBER 2021

BULK DRUG MANUFACTURERS ASSOCIATION (INDIA) C-25, INDUSTRIAL ESTATE,
SANATHNAGAR,HYDERABAD-500018,

R K AGRAWAL ELECTED AS NEW NATIONAL PRESIDENT OF BDMA(INDIA)

The Bulk Drug Manufacturers Association (India), the apex body representing the Bulk Drug and API industry in the country, has elected its new office-bearers at its 30th Annual General Body Meeting of the Committee held through Virtual Meeting on September 25th, 2021..

ELECTED AS OFFICE BEARERS

SL.NO	NAME	COMPANY	POSITION
1	R K AGRAWAL	NAKODA CHEMICALS LTD	NATIONAL PRESIDENT
2	CHA.P.RAMESHWARA RAO	RAKSHIT DRUGS PVT LTD	SR VICE PRESIDENT
3	BR SIKRI	ABS MERCENTILES PVT LTD	VICE PRESIDENT (NORTH)
4	RAMESH SWAMINATHAN	LUPIN LTD	VICE PRESIDENT (WEST)
5	R. SRINIVASA RAJU	STANDRAD PRODUCTS MANUFACTURING CO	VICE PRESIDENT (SOUTH)
6	P.ANUPVEER	VEERCHEMIE & AROMOATICS PVT LTD	GENERAL SECRETARY
7	M.VIJAY KIRAN	COVALENT LABS PVT LTD	SECRETARY
8	L SUNIL LINGA REDDY	SARACA LABS LTD	TREASURER

- Sri M. Narayana Reddy, Virchow Labs Ltd will continue as President Emeritus of the Association
- Mr. V.V. Krishna Reddy shall be Immediate past National President.

R K Agrawal, National President, is the Managing Director of M/s Nakoda Chemicals Ltd ,a Chemical Engineer. Very active in various Professional associations. He is energetic, dynamic and very articulate in dealing with the core issues of the bulk drug and pharma industry. RK Agrawal said his priority would be to strongly pursue the important issues of the industry so that the industry gets the much-needed push to take the Indian API and Bulk Drug industry to the next level and make it a significant global player.

Other office Bearers are Ch A.P. Rameshwara Rao, Sr. Vice President is the Managing Director of M/s Rakshit Drugs Pvt Ltd. Rakshit is an integrated API manufacturing company. Established in 2000. Today Rakshit has emerged a dependable and strong manufacturer of key APIs & intermediates for global markets. Supplying its products to all over the globe from Unites States, Europe, Japan, Asia and to Latin America.

Mr. B. R. Sikri, Vice President (North Zone) is the Director ABS Mercantiles Pvt. Ltd. Mr. B.R. Sikri is also key promoter of following companies: Auro next Pharma Pvt Ltd, Next Wave (India),Aumento Pallinos Pvt Ltd, White Print- O-Pack, BRS Mercantiles Pvt Ltd
He is Vice President , Bulk Drug Manufacturers' Association (B.D.M.A) since long period; Secretary, Indian Drug Manufacturers' Association (I.D.M.A) (HP & UK) ; Advisor, Himachal Drug Manufacturers' Association ; President, Pharma Indenting Agents Association (P.I.A.A) ; Vice-Chairman, CIPI. Chairman CII committee of life sciences & biotech, northern region and Chairman FOPE.

Indian pharma group has eyes on Da Nang

A group of 30 pharmaceutical production companies from India plans to build the first Pharma Park in Vietnam, and Da Nang city's Hi-tech Park has been suggested as a prime location.

Factories are developing at the Da Nang IT Park. The city has been calling for investment from India to build the first pharmaceutical production centre in Da Nang. (Photo courtesy of Anh Huy)

Da Nang (VNS/VNA) - A group of 30 pharmaceutical production companies from India plans to build the first Pharma Park in Vietnam, and Da Nang city's Hi-tech Park has been suggested as a prime location.

The Indian business group, which accounts for a 30 percent share of Indian exports, expects to build a pharmaceutical production centre and fill the shortage of material and medicines supplying Vietnam's pharmaceutical production chains.

Vice-chairman of the municipal People's Committee Ho Ky Minh said the city's 1,184ha hi-tech park infrastructure has been flagged as a potential site for the first Pharma Park in Vietnam.

He said the park would be a magnet for Indian pharma firms and producers as it offers flexible land rent, land clearance, and favourable income tax and import tax policies including land rent exemption for the first three years of operation.

Under the Prime Minister's decision signed in 2018, investors in traffic, technical infrastructure and public works, or special investment projects will enjoy a land-rent exemption for the entire duration of their investment period in the park.

Investors will be given incentives as they benefit from a 10 percent tax rate for 15 years, a four-year tax exemption and a 50 percent cut in income tax for the following nine years, he said.

He added that projects valued at more than 133 million USD will get a 10 percent tax rate for 30 years, while businesses will have to pay no import tax on materials and equipment that are not available in Vietnam for the first five years of operation.

Minh said the city's education system with 106 universities, colleges and vocational centres supplies 25,000 students each year, while nearly 10,000 doctors, nurses and medical staff are working at 22 hospitals.

The Indian pharma producers group has its own manufacturing centre in Visakhapatnam, and a series of companies including Hospira healthcare, Hetero pharmaceutical company, Shasun pharmaceuticals, Natco Pharma and Eisai Pharmaceuticals.

Da Nang Hi-tech Park, which was designed as a 'green' hub in central Vietnam, offers a number of benefits to manufacturers.

This includes Lien Chieu seaport, Kim Lien railway station and logistics centre, an airport and national highway all within a radius of 20km.

It also smoothly connects with the Chan May Economic Zone in Thua Thien-Hue, the Chu Lai Economic Open Zone in Quang Nam and Dung Quat Economic Zone in Quang Ngai province, Minh said.

The park's authorities have granted an investment licence to the local Danapha Pharmaceutical Joint Stock Company for developing the first nano-technology and biotech project with an investment capital of 1.5 trillion VND (67 million USD).

Up-to-date, Da Nang has attracted 905 foreign direct investment (FDI) projects worth 3.85 billion USD, with the hi-tech park alone a destination for 24 of those projects with a total of 815 million USD./.

Source: en.vietnamplus

Fermenta Biotech Limited bags India's Best place to work in Biotechnology & Pharmaceuticals

New Delhi [India], July 28 (ANI/ThePRTree): Fermenta Biotech Limited ('Fermenta') today announced its recognition as one of India's Best Workplaces in Biotechnology & Pharmaceuticals for the year 2021.

After undergoing a rigorous evaluation of the quality of its employee experience and people practices, the company has emerged as one among just eight organizations in India to be recognized as the best places to work in its industry.

The company has received the Great Place to Work certification, April 2021 to March 2022, for the third year in a row. This year, Fermenta has graduated from being a mid-sized organization to a large-sized organization in the Great Place to Work category and is now in the august company of industry leaders that are recognized for their High-Trust, High-PerformanceTM

cultures. Additionally, Fermenta's Trust Index scores (based on the survey conducted internally across locations) have increased year on year during the last three surveys conducted by the Great Place to Work Institute.

Commenting on the initiative, Prashant Nagre, Managing Director, Fermenta Biotech Limited said:

Fermenta is extremely proud to be recognized as one of the best workplaces in our sector. An industry-wide accolade is proof of the trust we have inspired amongst our people by creating an environment that promotes camaraderie and instils a sense of belonging. At a time when we all have been physically far away from each other, this recognition proves that the Fermenta family stands united in spirit. This achievement is a hallmark of our associates' faith in the organization's ethos, and we remain committed towards providing an engaging, inspiring as well as challenging workplace for all."

Every year, more than 10,000 organizations from over 60 countries, partner with Great Place to Work Institute for assessment and benchmarking actions to strengthen their workplace culture. Great Place to Work Institute's methodology is considered as the gold standard for defining great workplaces across business, academia and government organizations.

Source: The PRtree

PM Gati Shakti may benefit 109 pharma and medical devices clusters across the country, says Centre

Our Bureau, New Delhi

Wednesday, October 13, 2021, 17:10 Hrs [IST]

The PM Gati Shakti, the Rs. 100 lakh crore National Master Plan for multi-modal connectivity, launched by Prime Minister Narendra Modi on Wednesday, is expected to benefit 109 pharma and medical devices clusters, apart from other industries.

"The National Infrastructure Master Plan targets 109 pharma and medical device clusters and 90 textiles clusters and mega textiles parks by 2024-25," said government officials.

The Master Plan is expected to reduce the logistic costs, cut turnaround time and improve the cargo handling capacity by reducing the clutter in the system and improving the infrastructure.

The Prime Minister said that due to the wide gap between macro planning and micro implementation problems of lack of coordination, lack of advance information, thinking and working in silos are leading to hampered construction and wastage of budget. Shakti gets divided instead of getting multiplied or enhanced, he said. PM Gati Shakti National Master Plan will address this as working on the basis of the master plan will lead to optimum utilisation of resources.

The PM Gati Shakti Master Plan not only brings together the government process and its various stakeholders but also helps to integrate different modes of transportation. "This is an extension of holistic governance," he said.

In the 5 years before 2014, only 1,900 km of railway lines underwent doubling. In the last 7

years, more than 9 thousand kilometres of railway lines have been doubled. In the 5 years before 2014, only 3,000 km of railways were electrified. In the last 7 years, more than 24,000 kilometres of railway tracks have been electrified, Shri Modi informed. The Prime Minister said before 2014, the metro rail was running on only about 250 km of track. Today the metro has been expanded up to 700 km and work is going on in the 1000 km new metro route. In the five years before 2014, only 60 panchayats could be connected with optical fibre. In the last 7 years, we have connected more than 1.5 lakh gram panchayats with optical fibre.

There were just 5 waterways in 2014, today India has 13 functional waterways. Turnaround time of the vessels at the ports has come down to 27 hours from 41 hours in 2014. He said that the country has realised the pledge of One Nation One Grid. Today India has 4.25 lakh circuit kilometre power transmission lines compared to 3 lakh circuit kilometers in 2014.

The Prime Minister expressed the hope that with the development of quality infrastructure, India can realize the dream of becoming the business capital of India. He said our goals are extraordinary and will require extraordinary efforts. In realizing these goals, PM Gati Shakti will be the most helpful factor. Just as JAM (Jan Dhan, Aadhar, Mobile) trinity revolutionized the access of government facilities to the people, PM Gati Shakti will do the same for the field of Infrastructure, he added.
Source: Chronicle Pharmabiz

Himachal drug units urge PM Modi to form task force to tame rising prices of APIs

Laxmi Yadav, Mumbai
Wednesday, October 13, 2021, 08:00 Hrs [IST]

Hit by steep rise in prices of raw materials including active pharmaceutical ingredients, excipients, solvents and packaging materials, the Himachal Drug Manufacturers Association (HDMA) has appealed to Prime Minister Narendra Modi to form a task force to streamline the prices of pharmaceutical raw and packaging materials.

MSME formulation units which are now struggling for survival in the current pandemic era have been worst hit by 25 per cent to 300 per cent rise in prices of APIs, excipients, solvents and packaging materials including aluminum, PVC, glass vials, mono carton, corrugated packing, said Himachal Drug Manufacturers Association president Dr Rajesh Gupta.

Himachal Pradesh has around 600 pharmaceutical units consisting of 80 per cent of MSMEs and 20 per cent large units.

India meets most of its API needs through imports from China. The increase in raw material costs in the wake of the Chinese power crisis will further add to the woes of the drug industry, especially MSMEs.

Prices of APIs such as paracetamol have gone upto Rs. 840 to Rs. 900/1,000 per kg whereas its pre Covid price was Rs. 300 per kg. Prices of excipients and solvents such as glycerin, propylene glycol, PVPK 30, isopropyl alcohol have also skyrocketed. Prices of packaging materials such as aluminium, printed, alu- alu foils have increased more than 30 per cent over the last three months and expected to cross 50 per cent in coming days, said Dr Gupta.

Similarly, prices of mono cartons and corrugated packing have risen by 25 per cent to 40 per cent and continue to go up while prices of PVC used for blistering of tablets and oral liquid PET bottles have witnessed a 25 per cent-30 per cent rise and trend still upwards. High prices of vials, ampoules, flip off seal, butyl seal parts have greatly affected the injectable products, he informed.

Besides this, freight rates of containers for import and export have zoomed up by 6 to 9 times compared to pre Covid-era due to shortage of containers amid pandemic.

On the other hand, hike in the prices of petrol, diesel and CNG has led to 10-20 per cent increase in logistics cost.

Last year Chief Minister Jairam Thakur had taken up the price rise issue with the Prime Minister's Office following a representation from the state pharma industry. Acting on the PMO's instruction, the Drugs Controller General of India (DCGI) had sought extensive data pertaining to price rise from state drug units. Despite submission of extensive data by the state drug units last year, hardly any preventive measures have been taken in this regard, he added.

The steep rise in prices of raw materials and packaging materials needs three times capital infusion which is impossible for MSMEs. If prices are not tamed, the production of several drugs would be stopped, he stated.

The task force having representation from various ministries including ministry of health and family welfare, ministry of chemicals and fertilizers, ministry of commerce and NITI Aayog would protect pharma MSME units and help avoid any shortfall of medicines in the country.

The task force would keep a watch on raw material import, its impact, bulk drug production in the country and their prices and devise a mechanism to check price rise so as to avoid the present situation, Dr Gupta stated.
Source: Chronicle Pharmabiz

Stringent regulations and high talent attrition hamper MSME growth: SN Rao

Nandita Vijay, Bengaluru, **Monday, October 18, 2021, 08:00 Hrs [IST]**

Micro Small and Medium Enterprises (MSMEs) will find it tough to follow the Union government's push to make India self-sufficient in pharmaceuticals by doing away with import dependence. This is because pharma is a big man's game. Regulations are stringent, international compliance requirements are intense on drug master file (DMF) submissions with demand for high quality expertise, said Sadanand Nagaraja Rao, chairman and managing director, Supreem Pharmaceuticals, Mysuru.

It is very difficult for the MSME sector to sustain as we encounter challenges while the Union government pushes for local manufacture. The only possible option for MSMEs would be to scout for joint ventures to gain new capacity, enter new geographies, have access to human resources expertise or through strategic mergers and acquisitions, he added.

China is known for its volume game and so India needs to gear up to build capacities to manufacture active pharmaceutical ingredients (APIs) on a large scale. But there are deterrents and obstacles, including rigid pollution control norms, which only big companies can meet with their investment capacity, Rao told Pharmabiz.

Of late, funding has not been an issue. Banks are willing to finance MSMEs that have healthy balance sheets and are willing to risks. Collaterals are things of the past and all that this industry needs is to have a good track record. Not all MSMEs can take up multi-billion projects but only medium sized projects, said the Supreem Pharma chief.

Yet another impediment for places like Mysuru is that they cannot attract good talent since freshers prefer to work for big companies. The sector is also trying its best to hire fresh pharmacy graduates and post graduates from across colleges. After we train them, we realize that most jump to bigger organizations after two to three years. This is because there is no mentoring. They should work for at least four to five years to get a grip of the pharma industry operations. With standards going up and rules getting more rigid, MSMEs need quality people. But this is very challenging. It is not the money or land but manpower is the most difficult

resource to access today, said Rao.

Owing to these challenges, several MSME pharma companies have diversified into nutraceuticals which offer promising prospects with a growth of 17 to 20 percent annually. There is demand for novel dosage forms like candies, gummies and ready-to-consume products providing the much needed health and immunity to fight the current pandemic.

Source: Pharmabiz

Parliamentary Standing Committee asks Centre to re-establish IPAB

Gireesh Babu, New Delhi

Monday, July 26, 2021, 08:00 Hrs [IST]

The Department related Parliamentary Standing Committee on Commerce has asked the Central government to re-establish the Intellectual Property Appellate Tribunal (IPAB), the appellate authority on patent related disputes and approvals, which was dissolved through a notification on April 22, 2021. The decision by the government was criticised by various stakeholders, alleging it would further delay disposal of litigations.

The Tribunals Reforms (Rationalisation and Conditions of Service) Ordinance, 2021 has abolished certain tribunals including IPAB wherein the pending cases of IPAB are to be transferred to the Commercial Courts and the High Courts for adjudication.

In a Review of the Intellectual Property Rights Regime in India, presented to the Rajya Sabha and laid on the table of Lok Sabha on July 23, 2021, the Committee said, "On being enquired about the impact of shifting of pending cases from IPAB to the Commercial Courts or the High Courts, the Department stated that transferring of such cases would have a negative impact on their speedy disposal and may further increase pendency. This would have an adverse effect on Commercial Courts and High Courts which are already overburdened with pending cases."

Observing that the Tribunal had a pivotal role in adjudication of IPR appeals and cases, it added that the overall scrapping of IPAB, which efficiently had been dealing with proceedings involving complex IPR issues, may create a void in appellate resolution of cases leading to their shift to Commercial or High Courts thereby increasing pendency of cases.

The inordinate delay in appointment of officials at higher level and the resultant pause in functioning of IPAB affected the optimal performance of IPAB.

"The Committee, therefore, recommends the Government that IPAB should be re-established, rather than being abolished and should be empowered and strengthened with more structural autonomy, infrastructural and administrative reforms, as well as ensuring timely appointment of officials and experienced manpower," said the report.

It also "noted with distress" the absence of any Judicial Impact Assessment, or active consultations with stakeholders, being conducted by the Government prior to the abolishing of tribunals under the Tribunals Reforms (Rationalisation and Conditions of Service) Ordinance, 2021. It also strongly recommended that the Government, before scrapping of significant tribunals through an ordinance, should undertake a Judicial Impact Assessment along with wide consultations with relevant stakeholders to ensure building a systemic perspective on abolishing an established system in the country.

In their response to a query of the Committee about the advantages in strengthening IPAB with requisite manpower and expertise rather than abolishing it altogether, the stakeholders stated that the IPAB, which has been a critical part of India’s IP eco-system, should be restructured and empowered and its abolition should be reconsidered.

The Committee was further informed by the stakeholders that IPAB has played a significant role in rendering decisions to complex issues involving IP Rights while contributing to speedy and effective hearing and disposal of IPR matters.

It was also stated that during the last decade or so, many landmark and path breaking judgements were delivered by IPAB. Hence, timely recruitment and augmentation of experienced officers and staff, improving its functioning by leveraging digital technologies and facilitating appeals and proceedings through digital media, and development of e-IPAB forums to improve the spread and outreach would enhance its present structure, it added.
Source: Chronicle Pharmabiz

Industry urges IPC to defer implementation of IP 2018 Addendum 2021 by six months

Laxmi Yadav, Mumbai
Friday, June 18, 2021, 08:00 Hrs [IST]

The drug industry has appealed to Indian Pharmacopoeia Commission (IPC) to defer the implementation of Indian Pharmacopoeia 2018 Addendum 2021 by six months in the wake of current situation of Covid-19 pandemic making it extremely difficult for the industry to release products in market complying with monographs of IP 2018 Addendum 2021.

The Addendum 2021 to IP 2018 is slated to be implemented from October 1, 2021. It contains a total of 66 new drug monographs (including 59 chemical, 5 herbal products, and 2 blood-related products) and 4 new general chapters. In addition, a total of 260 monograph amendments have also been included in IP Addendum 2021 that would further upgrade the quality of drug standards included in the IP. Accordingly, there is a huge impact on pharma industry with need of evaluation or reformulation for number of products which cannot be completed within the current timeline of October 1, 2021, said Indian Drug Manufacturers' Association (IDMA).

IDMA has recently submitted a representation to the Secretary-Cum-Scientific Director, IPC, the Drugs Controller General of India (DCGI), Directorate General of Health Services (DGHS) urging them to provide additional transition time of six months for implementation of Indian Pharmacopoeia 2018 Addendum 2021, that is March 1, 2022, as launch of products in market in compliance with monographs of IP 2018 Addendum 2021 is very challenging due to Covid-19 pandemic.

Before releasing a product in market with IP claim, lot of work is done by manufacturers within the organization and outside of it. Starting from procurement of required materials or equipments, testing as per monograph and in case needed, reformulation of product to make it compliant to monograph of IP. Then, printing of label which takes minimum 20 days. Also, in these struggling days, there will also be destruction of packaging inventory for products requiring revision in label claim, which will have financial and environmental impact and is not in national interest, stated Mahesh Doshi, national president, IDMA.

A number of drugmakers have already initiated the evaluation of monographs as appeared in this new edition. However, to evaluate, understand and then to implement the monographs of Indian Pharmacopoeia, will definitely take more efforts and time than usual in this difficult times. Accordingly, extension is very much required for smooth transition by pharma manufactures to maintain business continuity, ensure availability of safe and essential medicines in India market, he said.

India has been among the worst hit countries in terms of absolute Covid-19 numbers. All the companies are putting their efforts to fight and provide the medicines to save lives from Covid-19. While having the goal of providing sufficient quality medicines in market, all pharma companies are also facing the practical issue of working with limited manpower.

To overcome shortage of medicines in market, all pharma companies have shifted their focus to develop Covid-19 specific medicines at the earliest to meet the market demands. Additionally, the industry also needs to be prepared enough with medicines and supplies in case the next wave strikes the country. Hence in the interest of continuous availability of life-saving medicines to the Indian patients, the industry body appealed to IPC and DCGI to issue a notice with change in effective date of IP 2018 addendum 2021 as March 1, 2022 i.e., granting extension of

at least another six months.
Source: Chronicle Pharmabiz

DoP extends timeline to apply for PLI scheme, changes selection criteria for MSMEs

Gireesh Babu, New Delhi
Friday, July 23, 2021, 08:00 Hrs [IST]

The Department of Pharmaceuticals (DoP) has extended the deadline for submission of application for the production linked incentive (PLI) scheme for pharmaceuticals to August 15, 2021.

It has also changed the selection parameter for applicants, except in vitro diagnostics medical devices group, in which the weightage of 50 per cent for MSMEs would be based on the GMR from pharmaceutical goods in FY 2019-2020. In the operational guidelines issued on June 1, 2021, the 50 per cent weightage was on total investment committed by the applicant under the scheme, for MSMEs.

Global manufacturing revenue (GMR), according to the operational guideline, is the consolidated global revenues of the applicant and Group Company, if any, from the manufacturing of pharmaceutical goods and/or in vitro diagnostic medical devices. Revenues from any other source for instance R&D services, rental incomes, etc., shall be excluded for calculating the GMR.

The rest of the 50 per cent weightage will remain on the number of manufacturing plants in India owned by the applicant or group company and approved by foreign drug regulator with a compliance certification from a State Licensing Authority as on April 1, 2021.

"The application window shall be 75 days starting from June 2, 2021 to August 15, 2021 (inclusive)," says the government announcement. The previous application window was 60 days starting from June 2, 2021 to July 31, 2021, both dates inclusive

For applicants manufacturing only special empty capsules like HPMC, Pullulan, enteric etc., or complex excipients and not drugs, the selection parameter of number of Abbreviated New Drug Application/New Drug Application/Drug Master Filing/Certificate of Suitability (CEP) approvals is not relevant and the weightage for other relevant criteria will be increased prorata so that such applicants are not placed at a disadvantage, said the corrigendum.

Following the clause on the number of applicants to be selected, a new sub clause has been added stating that only one applicant, on behalf of its group companies (as defined in another clause of the guideline) shall be eligible for selection under the Scheme. The applicant and its group companies where the eligible products get manufactured will be considered collectively for the purpose of ascertaining threshold/committed investments, threshold/incremental sales and incentives under the scheme, it added.
Source:Pharmabiz

Pharma industry expected to clock in 12-15% growth this year: B R Sikri

Gireesh Babu, New Delhi
Wednesday, July 21, 2021, 08:00 Hrs [IST]

Shrugging off the Covid-19 challenges in its second wave through prudent planning and execution of manufacturing and distribution, the pharmaceutical industry in the country is expected to grow by 12-15 per cent this year, according to an industry expert. The availability and pricing of raw materials are also stabilising, thanks to the normalising supplies from China.

B R Sikri, chairman of Federation of Pharma Entrepreneurs (FOPE), chairman of CII Committee of Lifesciences and Biotech, Northern Region, and vice president (north zone) of Bulk Drug Manufacturers Association (BDMA), said that during the second wave of Covid-19, there was a sudden demand surge for lifesaving drugs, but the industry was able to cope with it unlike the first wave which was a little bit shaky for the industry because of some raw material shortage

and higher demand.

During the second wave, the manufacturers were not only able to supply to the domestic market, but also to fulfill the export demand. During the first wave the government has banned certain products like paracetamol from being exported. But in the second wave, there was no such measures considering that the industry planned in advance to avoid any shortage in the domestic market. There was a price increase, but it was beyond the control of the industry considering the raw material prices from China went up and there was a shortage.

Industry performed better during the second wave of Covid-19 pandemic. The supplies were good, products were available in the market and the sales also increased. "Overall it is a positive action taken by the industry," he said. The supply of raw material from China is now stable and the prices are also stablising now. It is improving day by day, price-wise and availability-wise.

"There is a potential of 12-15 per cent growth this year. Last year exports were stopped, which resulted in some adverse effects. We will be able to do better than last year," said Sikri.

The major challenge industry currently facing is the dependability on Chinese raw material. From a clearances and regulatory approvals point of view, the government is very serious and cooperating with the industry in reducing these imports. Environmental law has also been amended in favour of the industry. There is full support from the government and it is willing to give funding. Bulk drug parks are also expected to come up soon.

"We are confident that in four to five years the dependability on China will drastically come down. Not only will we be able to reduce Chinese imports, we will be able to export to other countries where China is exporting," he added. The production linked incentive (PLI) scheme will also support the industry to achieve this, including in terms of exports.

Currently China contributes to 68 per cent of the raw material requirement. The day it comes to 40 per cent, Indian industry will be in a commanding position, which will happen in next few years, he averred.

The industry is valued at $41.7 billion and is expected to reach $65 billion by 2024, according to the Government of India. This is expected to grow to $120-130 billion by 2030, it says. The market growth rate is expected at 10-12 per cent, it says.

The API industry is ranked third largest in the world and it has 57 per cent of APIs to prequalified list of the WHO. Incentives worth Rs. 21,940 crore (~$ 3 million) are approved for the sector.
Source:Pharbabiz.com

Frost & Sullivan sees investments into RNA therapeutics to spur faster returns in short span with better commercial success

Our Bureau, Bengaluru
Friday, July 23, 2021, 16:20 Hrs [IST]

Frost & Sullivan’s recent analysis, Global RNA Therapeutics: Technology Growth Opportunities, reveals that ribonucleic acid (RNA) therapeutics is poised to gain momentum in the next few years and can potentially be applied to a wide variety of disease interventions. Additionally, the growth opportunities exposed by the initial commercialization of mRNA vaccines, antisense oligonucleotides (ASOs) and short interfering RNA (siRNA)-based therapeutics are further attracting pharmaceutical and biotechnology companies to invest in this space and expedite research and development (R&D).

RNA therapeutics investment has a better chance of commercial success and enables better returns in less time for market participants. “Advances in RNA stability, manufacturing, chemical modification, and targeted delivery systems have led to the commercial translation of RNA therapeutics,” said Ruplekha Choudhurie, TechVision Industry Analyst at Frost & Sullivan.

“These are relatively easy to manufacture, cost-effective, and can act on undruggable targets. As a result, academic labs and small biotech companies are accelerating RNA therapeutics research, alongside Tier 1 biopharmaceutical companies. RNAs have certain advantages over deoxyribonucleic acid (DNA) and small molecule drugs, such as eliminating the risk of genomic integration, being relatively cost-effective, and having rapid development and production,” she added.

Specifically, for the development of vaccines for Covid-19 and other emerging infectious disease outbreaks, mRNA vaccines have an advantage over other types of vaccines as they can be rapidly developed and amenable to modifications to target evolving viral variants. The advantages of RNA therapeutics over conventional small molecule drugs and other biological drugs present immense growth opportunities for market players.

These cover Formulation and delivery of RNA therapeutics. Here Lipid-nanoparticles were used for delivery formulation in the previously approved RNA therapeutics, and similar (RNA-LNPs) formulations have been considered standard. Rapid formulation and delivery advances will improve the future of RNA delivery and help overcome the intrinsic stability issues of RNA.

Novel formulations that improve mRNA stability at ambient temperatures would facilitate the worldwide application of mRNA vaccines more rapidly and at a much lower cost. This will benefit mRNA vaccines and the entire RNA therapeutics field in general.

Currently, RNA therapeutics is one of the fastest and most promising approaches in biological therapeutics. Due to this, many stakeholders are investing heavily in mRNA vaccines, said Choudhurie.
Source: Chronicle Pharmabiz

Already approved drugs may be considered as new drug, if certain changes occur in active substance: DCGI

Our Bureau, New Delhi
Monday, July 26, 2021, 08:00 Hrs [IST]

The Drugs Controller General (India) has said that certain changes in the active substance of an approved drug may lead to change in drug specification and require validation of the manufacturing process.

In a circular, the DCGI has said that his office has received representation seeking clarification on if already approved drugs with change in (a) polymorphs, crystalline, amorphous, solvated or hydrate etc, (b) salt and (c) derivative, analogue, ester etc. are manufactured using the new manufacturing process, will be considered as old drug or new drug.

The circular clarifies that the change in these properties or already approved active substance may lead to change in drugs specification and may influence on the physiochemical properties particle size, hygroscopicity, solubility, density, flow ability and compatibility etc. It will also impact the dissolution, bioavailability and bioequivalence classifications, manufacturing of drug substance/drug product, and stability of drug substance/drug product.

Hence, changes mentioned above in already approved active substance may require validation of manufacturing process, stability studies, additional clinical and non-clinical studies, bioavailability/bioequivalence studies, to demonstrate its safety and efficacy, said the drug regulator.

“Therefore, any new (a) (b) & (c) of already approved active substance is considered as a new drug,” added the Circular.

However, applications of such new drug may be processed considering factories including that

in case (a), (b), & (c) of already approved active substance is significantly affecting physicochemical properties, manufacturing process, stability, safety and efficacy and bioavailability/bioequivalence etc., the new drug will be processed as new active substance and requirements will be the same as for any new active substance as prescribed in New Drugs and Clinical Trials Rules, 2019.

In case of any (a), (b) and (c) of already approved active substance, if there is no significant effect on physicochemical properties, manufacturing process, stability, safety and efficacy and bioavailability/bioequivalence etc., the new drug will be processes as subsequent new drug of already approved new drug and requirements will be the same as for new claim for any on already approved new drug, as prescribed in New Drugs and Clinical Trials Rules, 2019.

Accordingly, the applicant should submit an application as per the requirement prescribed in the said rules, added the Circular.

Prospects of pharma industry in SAARC nations

Sateesh Kulkarni

Wednesday, September 15, 2021, 08:00 Hrs [IST]

The South Asian Association for Regional Cooperation, or SAARC, is a geopolitical organization composed of eight countries - Afghanistan, Bangladesh, Bhutan, India, the Maldives, Nepal, Pakistan, and Sri Lanka. Almost a quarter of the world population lives in these eight countries.

According to estimates available, the world is already in an economic crisis as a result of the Covid-19 crises. South and Southeast Asian countries are no exception. They are heavily affected, in terms of health and on economic parameters. Countries are under full or partial lockdown for the last several months. Unlike the 2007-08 global financial crisis, the present situation is primarily a health crisis, which has further resulted in an economic shock.

The world is facing humanity’s biggest crisis since World War II. Almost every country has been affected by the devastating coronavirus disease. The cumulative number of cases reported globally now exceeds 183 million and the number of deaths is almost four million. Indirectly, billions of people have been suffering from the impact of the global pandemic, Covid-19. The global losses, according to some commentators, may exceed the World Wars I and II combined.

Pharma industry in major SAARC nations

India's domestic pharmaceutical market is estimated at US$ 42 billion in 2021 and likely to reach US$ 65 billion by 2024 and further expand to reach US$ 120-130 billion by 2030. The sector is expected to grow by 12 to 14 per cent in the next three years while the export market may grow by 8 to 14 per cent.

India ranks as the third-largest market globally by volume and 13th largest by value. India is one of the largest sources of generic drugs, supplying 50 per cent of global demand for a range of vaccines, 40 per cent of generic demand in the United States - where Indian firms are expanding - and 25 per cent of UK medicines. The fresh wave of Covid-19 in the country has pushed up sales of medicines and resulted in exponential growth for India’s pharmaceutical sector.

According to industry data, the Indian pharma market grew 59 per cent year-on-year in April, 2021 as against 16 per cent year-on-year in March, 2021 due to the low base effect in April, 2020 and sharp surge in Covid-19-related sales. In India, the epidemiological transition from communicable diseases to non-communicable diseases in the country is driving the pharma market. All major therapies posted high double-digit growth in April 2021. Cardiac therapy segment, anti-diabetic therapy, VMS (vitamins, minerals and supplements) and respiratory therapy segments have shown sharp rebounds in recent months. The industry is likely to see strong growth in the next few quarters driven by surging Covid-19-related sales.

Bangladesh is expected to have a US$ 6 billion plus pharma industry by 2025. Some of the growth drivers for Bangladesh’s pharma sector are – population growth, rise in life expectancy, growing per capita income, changing disease profile, changing lifestyle and thereby changing

disease profile. The share of imports is expected to be drastically cut and the local pharma companies would be commanding more than 90 per cent of the market. The share of generic drugs too is expected to cross 85 per cent by the 2025. All this would create an export opportunity of more than US$ 450 million for the industry by 2025.

Sri Lanka's pharmaceutical market is likely to touch US$ 625 million by 2024, growing at a compound annual growth rate (CAGR) of 1.6 per cent by 2024. This is expected to reach US$710 million by 2029. This growth will mainly be driven by the government's goal of localising pharmaceutical production to meet half of local medicine demand by 2024. In line with the decision, the Sri Lankan government has created a new State Ministry dedicated to pharmaceutical manufacturing. It has also established a number of new manufacturing zones with the pharmaceutical sector being a key focus. The government's emphasis on reducing imports thus poses a risk, particularly for low value treatments.

Pakistan's pharmaceutical market is valued around US$ 4.5 billion. The local manufactures comprise 70 per cent of this share and the multinationals account for the remaining. Over the recent years, the local industry has experienced impressive growth of around 15 per cent as compared to multinationals in the local market. Industry sources report that the potential in this market is huge. With an increase in health expenditure from the current one per cent of GDP and rising disposable incomes, this market is expected to exceed US$7 billion by 2021.

The industry is current struggling due to lack of chemical industry in the country, poor governance, electricity, inconsistence policies and absence of long-term drug policy. The local pharmaceutical industry in Pakistan is still predominantly large to medium scale. The reason is that the local industry is mostly financed by equity and none of the bigger groups in Pakistan have ventured into this industry due to the lack of technical knowhow. Also, the industry severely lacks trained human resources.

Pakistan's pharmaceutical exports in the first quarter of the fiscal year 2021 grew by 22.6 per cent year-on-year to US$ 68.1 million. In value terms, the country's pharmaceutical exports have grown by 22.6 per cent in Q1 of the fiscal year 2021 to US $ 68.1 million as compared to US $ 55.6 million in the corresponding period last year. Pakistan exports of pharmaceutical products to Afghanistan was US$73.84 million during 2020.

Challenges in post-Covid scenario

India has successfully controlled the transmission of Covid-19 till date, although given the size of population, challenges of vaccinating still remain. India's leadership position in pharmaceuticals and health science, mass public awareness with the help of digital systems and a combination of centralized as well as decentralised efforts helped in containing the spread so far.

South and Southeast Asian countries have been following a similar approach in containing Covid-19. In order to support the badly affected economies, all governments have introduced stimulus packages, particularly to support the heavily affected people, small and medium industrial units, agriculture, exports, health, rural community, etc. For example, Bangladesh has introduced an over US$ 8 billion stimulus package, India US$ 24 billion and Thailand US$ 58 billion.

While each of the South Asian countries has undertaken drastic measures to save its nation from Covid-19-driven pandemic, regional cooperation will be very important to effectively handle the common challenge. Towards this direction, the South Asian leaders have decided to launch a regional fund to deal with the crisis. An electronic platform with health experts has been launched and discussions are on for developing specific protocols dealing with the screening of goods and people at entry points and contact tracing to online training capsules for emergency response teams. Steps are also proposed to foster technical cooperation, training and capacity building, among others. While at the individual country-level, the immediate need will be to increase their healthcare spending, strengthen health infrastructure and support the economies come back to normalcy, there is also a need to revitalise regional effort not only to share the

responsibilities but also to reactive the SAARC process.

Instead of the normal FTAs, countries may opt for safe and secure trade than “free” trade. New “pandemic” related trade barriers may replace the traditional quota and other tariff and non-tariff barriers. The new global order will also create new jobs and skills. This presents an opportunity for India to design an export strategy moving away from reliance on China for the imports, particularly pharma APIs.

This is the time of a medical emergency calling for co-ordinated partnership. Countries have to work together while dealing with the crisis, particularly for the post-crisis recovery. India will have to play a decisive role in this and demonstrate that a stronger network between countries is vital to design a strategy for the entire Asian region.

(The author is a pharma consultant)
Source: Chronicle Pharmabiz

China’s dominance in CRAMS fades as India grabs global opportunities with talent & infrastructure

Nandita Vijay, Bengaluru September 27 , 2021

With China no longer dominating the CRAMs (contract manufacturing and research services) space, India has taken full advantage of the situation. Indian pharma has maximized this opportunity to prove its capabilities in CRAMS. Its 562 US FDA approved units have provided a headway in the stringent regulated regions of US and Europe for CRAMS’ orders. There is revenue generation, recognition of competence and cost advantage with high standards of quality and adherence to delivery timelines, said GG Gurudatta, CEO, Estima Pharma

Indian pharma has made strategic moves with acquisitions to propel expertise. It invested in infrastructure for advanced equipment and technology to cater to the requirements for research and manufacturing of APIs and specialty chemicals for global companies. There is no looking back but only going forward in CRAMS as the regulated regions of US and European Union look to Indian pharma as a reliable supplier, he added.

Capabilities of Indian pharma are justified with qualified English speaking workforce armed with technical skills in organic chemistry per se. This along with advanced infrastructure and instrumentation for analysis and accuracy of chemicals gives companies an edge in CRAMS, he added.

Though Indian pharma cannot be compared to China for its production volume, huge orders for API manufacture are coming through after China's slump following the pandemic. Our industry's strengths in reverse engineering have given adequate scope to gain in-depth knowledge about APIs in formulation development. This worked in favourably as global pharma opted for India as their best choice for CRAMS, Gurudatta told Pharmabiz.

In the last few years, Gurudatta noted that the large and medium sized pharma companies have gone in for backward integration to set up full-fledged R&D centres and upgrade manufacturing plants so that they need not outsource any service. Installing the latest analytical systems like gas chromatography-mass spectrometry (GC-MS), liquid chromatography-mass spectrometry (LC-MS), gas chromatography-infrared spectroscopy (GC-IR), and liquid chromatography-nuclear magnetic resonance spectroscopy (LC-NMR) have given them the recognition globally to be dependable for CRAMS.

In addition, Union government moves to encourage domestic manufacturing and reduce imports of key starting materials (KSMs), drug intermediates (DIs) and APIs brought in schemes like the production linked incentive (PLI) and promotion of bulk drug parks. This has considerably brought down dependence on China and in the next five years, India will be self-sufficient, he

noted.

States including Gujarat, Andhra Pradesh, Telangana, Karnataka and Maharashtra are looking at Bulk Drugs Parks to augment capacity in 2 years. There is no doubt India is the place for CRAMS. Particularly in Andhra Pradesh and Telangana CRAMs is happening on a big scale. From a global perspective there is no competition whatsoever. With China's dominance in CRAMS fading, India has taken full advantage of the situation, said Gurudatta.

Source: Ingredients SouthIndia.com

Telangana sees huge expansion in drug manufacturing

A Raju, Hyderabad

Tuesday, September 28, 2021, 08:00 Hrs [IST]

Telangana has witnessed a flurry of activities in its pharmaceutical sector after the onslaught of Covid pandemic.

The Covid-19 pandemic has in a way turned out to be a blessing in disguise for the pharma sector in Telangana as more than 93 firms from across India have expressed their intent to expand particularly in the bulk drug manufacturing and formulation segments. Most of these units are coming up in districts of Nalgonda, Siddipet, Kamareddy and Mahabubnagar which are located within the striking distance the capital city of Hyderabad.

According to Dr P V Appaji, former director general of Pharmexcil, the sharp surge in Covid-19 cases during the first and second wave in Telangana had increased the demand for medicines and this has prompted many pharma firms to expand their production lines. However, the main driving factor for the expansion of active pharmaceutical ingredients (API) and bulk drug manufacturing is the central government's production linked incentive scheme.

The strained border relations between India with China lead to a sudden stoppage of API imports from China. To overcome the shortage, the Indian government brought in the production linked incentives. This induced several pharma companies in and around Hyderabad to establish new bulk drug manufacturing units and a few of them decided to expand their existing production lines. With this the pharma sector in Telangana and in Andhra Pradesh witnessed a boom in the drug manufacturing business.

"As per the latest guidelines issued by the state government and the department of pollution control board, any new pharma unit will have to be set up outside the outer ring road (ORR) limits to check the environmental pollution. Even though many pharma firms are eager to set up their new units, the stringent environment regulations are becoming a major roadblock for the firms putting them in a hesitation mode. The recent green tribunal's verdict to deposit one per cent of the overall turnover of the firm as corpus fund toward environmental protection is becoming a major stumbling block for many firms," observed P Eshwar Reddy, executive director (ED) of Bulk Drug Manufacturers Association (BDMA).

As per the statics from the Pharmaceuticals Exports Promotion Council of India (Pharmexcil), the Indian pharma exports had increased by 15 per cent in 2020-21 compared to 2019-20. "Compared to last year the pharma exports have significantly improved during the pandemic. Out of top nine companies that supplied medicines to various parts across the globe, Dr Reddy's Laboratories and Aurobindo Pharma from Hyderabad excelled in global exports," informed Uday Bhaskar, director general of Pharmexcil.

In fact, during the Covid-19 pandemic in Telangana, after the agriculture sector, it is only the pharma sector that did brisk business in the state. Many industrial experts credited the performance of the pharma sector to the central government's product-linked incentive scheme. "The main objective of the scheme is to decrease API dependency on China. Formulations are also given incentives now," observed the Pharmexcil DG.

However, industry experts feel that even though the central government's production linked

incentive has helped a few companies to come and invest in the bulk drug manufacturing sector, the state government should also announce incentive schemes for capital markets to promote innovation.

With the pharma city and already existing pharma and bulk drug manufacturing base, Hyderabad has now emerged as global hub for finished dosage forms and bulk drugs in India.
Source: Chronicle Pharmabiz

Success strategies for Indian pharma industry in an uncertain world

The Indian pharmaceutical industry is going through a period of significant volatility and uncertainty, requiring companies to re-visit their traditional growth strategies to succeed

Fragmented Indian pharmaceutical market is facing high volatility and uncertainty. Increasing number of drugs in National List of Essential Medicines (NLEM) and price controls, changing FDI Policy, compulsory licensing, aggressive acquisition investments by MNCs, and declining global generic market opportunity is creating a new normal. Pharmaceutical companies need to re-visit their traditional growth strategies to succeed in a volatile world.

Indian pharmaceutical industry is valued at $ 12 billion in 2013. The market is primarily driven by exports to regulated as well as semi-regulated markets. Currently, India exports drugs to more than 200 countries and vaccines and biopharmaceutical products to about 151 countries. Globally, India ranks 3rd in terms of volume and 14th in terms of value.

Indian pharmaceutical industry is fairly fragmented with top 10 companies contributing to 41% of total sales. The next ten companies contribute to 22% of sales while the remaining companies contribute to 37% of the total sales. Urban regions (metros and tier I cities) contribute to about 60% of total sales while the remaining country contributes to the balance 40%. Tier I cities are growing at approximate 10% per annum (PA) while rural areas are growing at about 14.5% PA. The growth has been driven by increased access to healthcare, improved infrastructure and greater penetration of pharmaceutical companies into tier 1 cities and rural areas.

Changing market dynamics

The year 2013 has seen deceleration of industry growth rate from 16.6% in 2012 to 9.8% in 2013. During the year, the industry faced a different type of regulatory headwind; the patent office ruled against the intellectual property rights (IPRs) for several notable drugs, including Pfizer’s Sutent, Bayer’s Nexavar, etc. A still more daunting challenge for MNCs operating in India has been compulsory licensing and uncertainty about patent validity.

Source: Express Pharma