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EXPRESS PHARMA

INDIA'S FOREMOST PHARMA & BIOTECH MAGAZINE 16-31 MARCH 2020, ₹ 40

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INDIA'S FOREMOST PHARMA & BIOTECH MAGAZINE
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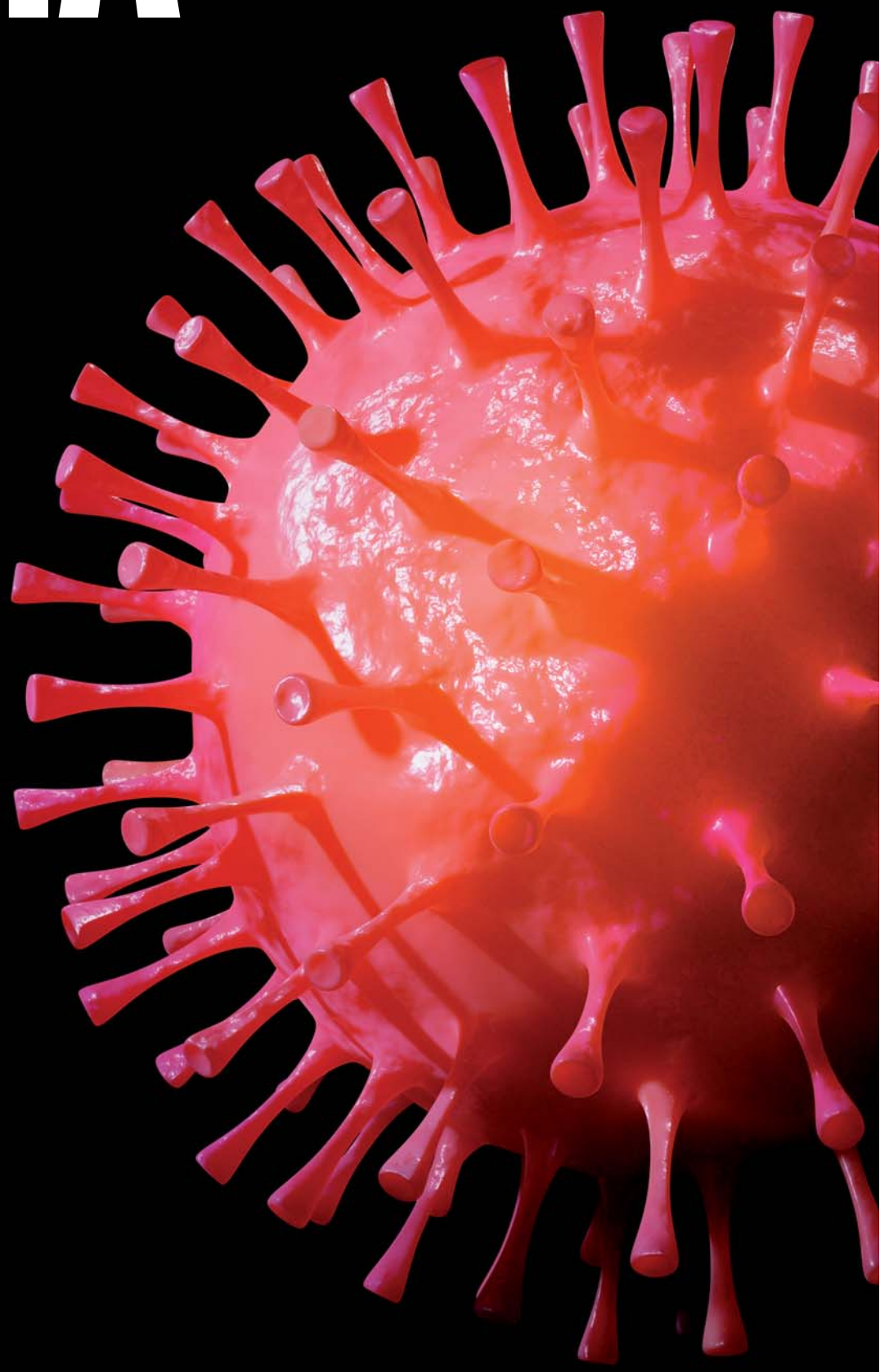
Deal tracker
Healthcare industry reports 56 deals worth $2.3-bn

HR
Sharad Tyagi appointed as President of OPPI

FINDING THE SILVER LINING OF CORONAVIRUS PANDEMIC

As India Pharma Inc reels under the far-reaching impact of the coronavirus epidemic, industry experts suggest policy reforms to insulate the sector and improve its emergency-preparedness



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Project Types	Numbers
Manuscript	57
Review Articles/Meta-analysis	30
Posters	70
Slide Decks	110
Abstracts	90
Case Reports	23
Protocols	95
Consensus Guidelines	11
Advisory Board Meetings	4

Project Types	Numbers
Book Chapters	10
Whitepapers	5
Newsletters	3
Video Animations	3
Clinical Study Reports	80
Module 2.7 of CTD	2
Module 2.5 of CTD	3
Investigator Brochures (IB)	29

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CONTENTS

INDIAN PHARMA INDUSTRY LIKELY TO REACH $100-BN AND MEDICAL DEVICES SECTOR TO $50-BN BY 2025 : D V SADANANDA GOWDA

Gowda spoke at the India Pharma and India Medical Device 2020 event where FICCI-EY report 'Reshaping India into a life sciences innovation hub' was also released | P10

PRE EVENT

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Lessons from COVID-19

On March 11, the WHO characterised COVID-19 as a pandemic. While this sounds scary, WHO Director-General Dr Tedros Adhanom Ghebreyesus took pains to point out that the epidemic seems to have stabilised in China and the Republic of Korea, which are two of the four countries with more than 90 per cent of the cases. While China was the origin, secondary disease hot-spots have now emerged in South Korea, Italy and Iran.

The infection in India seems to be reaching its peak, with the first death on March 12, and the total number of positive COVID-19 cases standing at 75 as on March 13. This includes 17 foreign nationals currently in the country who have tested positive. The number of new cases being confirmed per day across various states, currently in the high teens, is predicted to rise, following the trend observed in China.

The ripple effect of COVID-19 continues. Individual states are shutting down cinemas, gyms and asking schools to shut except for conducting examinations. Industry events are also being postponed. For instance, iPHEX-2020 scheduled over May 6-8, has been postponed. Those that are being held, like the PharmaTech Expo & LabTech Expo 2020, organised from March 4-6 at Bombay Exhibition Centre, Mumbai, gave away free hand sanitisers to visitors as a reminder to take precautions.

On the other hand, alarm over the spread of COVID-19 has resulted in a spike in sales of medicines in February. According to data from AIOCD AWACS, sales of medicines at the retail level increased by more than 4 per cent in February, and a volume growth of 3.8 per cent over the previous month. Eight of the top 10 therapies registered a double digit growth. The top three therapies in terms of growth were respiratory (17.9 per cent), anti-infectives (14.1 per cent), and cardiac (13.3 per cent). In the respiratory section, 18 sub-groups grew by an average of 16.8 per cent growth, while among anti-infectives, the top 8 sub-groups had an 18.7 per cent average growth.

The reason for this growth is obvious: panic buying and stocking medicines for the next few months in anticipation of shortages due to the shutdown of API factories in China. Business intelligence agency AIOCD AWACS also attributes this growth to February generally seeing an increase in viral infections, which explains the higher growth in both respiratory and anti-infectives sections. Given these factors, this growth may not sustain.

Policymakers will have to balance incentives for the pharma sector to scale up production with strict monitoring on environmental controls and retail prices

The situation has also seen e-commerce platforms step up to meet shortages. While stock levels have been increased to meet demand, there is no doubt that inventory levels are being tracked more closely. COVID-19 has thus been a tough lesson in inventory management across the pharma supply chain.

The cover story in the March 16-31, 2020 edition of *Express Pharma* suggests that similar silver linings can result in the COVID-19 cloud. For instance, policies to incentivise the setting up of bulk drug and API manufacturing plants can be fast-tracked. However, setting up new facilities will take time. A better solution seems to be the upgrading/revamp of older existing facilities, either as PPPs, etc.

But have we missed the bus already? China is already revving up. While ground-zero Wuhan city might need eight weeks or so to get back to some normalcy, other regions are due to start dispatching KSMs and APIs in about two to three weeks.

There are already reports that Chinese authorities are holding back exports of some APIs and KSMs. This could be for two reasons. Once, since this is a new virus, nothing much is known about the chances of a recurrence of COVID-19 infection, even in patients who have recovered. Secondly, the Chinese authorities might be creating an artificial scarcity so that prices can be hiked to make up for the lost time.

Even as we need to scale up the manufacture of APIs and KSMs, it is right that the government takes time to frame these policies. Pharma manufacturing is one of the most polluting industries worldwide and the government will have to ensure that no short cuts are taken with regards to impact on the environment, effluent treatment and discharge. As WHO Director-General Dr Tedros Adhanom Ghebreyesus cautioned in his March 11 address declaring COVID-19 as a pandemic, "All countries must strike a fine balance between protecting health, minimising economic and social disruption, and respecting human rights."

VIVEKA ROYCHOWDHURY *Editor*
viveka.r@expressindia.com

VAV to hold a seminar on drug delivery systems in Mumbai

The event will also offer participating students an opportunity to present their phospholipids based research papers followed by a special felicitation ceremony for their outstanding research work

VAV will be organising a one-day seminar on drug delivery systems in Mumbai on March 27. The theme of the seminar will be 'Phospholipids: New Horizon for Drug Delivery'.

"This one-day seminar will be an excellent opportunity for industry professionals and scientists from formulation, analytical or process development who understand the opportunities in NDDS and liposomal delivery including the 505(B)(2) pathway presents and yet see challenges in formulating or analyzing novel delivery systems," a press release issued by the company stated.

Lecithins and Phospholipids can significantly improve solubility, stability and bioavailability of drugs, enhance the drug design and speed up the drug development process. The event participants will get focused sessions on all relevant topics connected to Lipidic drug delivery.

The conference will also consist of presentations by subject experts and guest speakers, talks, real-time case studies and plenty of networking opportunities. Attendees will be able to directly apply their learnings from this seminar to their daily formulation development work.

The event will also offer participating students an opportunity to present their phospholipids based research papers followed by a special felicitation ceremony for their outstanding research work.

Focus topics will be:

1. Application of Phospholipids in different types of drug delivery systems
2. Regulatory advantages of phospholipids based formulations
3. Tailored release profiles
4. Journey to the unexplored

Contact for more information:

Tanvi Gavankar – Scientific Communication
tanvi@vav.in
+91 22 22836802 ext.33

Indian pharma industry likely to reach $100-bn and medical devices sector to $50-bn by 2025 : D V Sadananda Gowda

Gowda spoke at the India Pharma and India Medical Device 2020 event where FICCI-EY report 'Reshaping India into a life sciences innovation hub' was also released

'India Pharma and India Medical Device 2020', organised by FICCI, jointly with the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India is currently undergoing in Ahmedabad. The three-day event will witness a conglomeration of policymakers, national and international leaders from medical technology industries, academic and research fraternity.

DV Sadananda Gowda, Minister of Chemicals and Fertilizers, said that the Indian pharmaceuticals and medical devices sector has the potential to become the world leader and government will provide all necessary support. According to him, India today is a major hub for medical devices and diagnostics. There have to be certain interventions by the government as far as polices are concerned.

He said that affordability of the medicines is one of the prime concerns of society. "In developing countries where a large section of the population is poor and out of pocket expenses are very high, affordability of the medicines is one of the prime concerns of the society," he added.

Gowda emphasised that the government is making all efforts to boost the Indian pharma and medical devices sector. He said, "In countries where R&D are taken care of, where academia and industry collaborate in order to build a strong R&D ecosystem. In India, we need to follow this. The government has initiated various steps for strengthening the Indian pharma and medical devices sector."

Speaking on the COVID-19, Gowda said that it is challenging times and we should all stand together at this time. Govt has and is taking all necessary steps in this direction. "There is no shortage of medicines. We have sufficient medicines and sufficient APIs so that for another three months to ensure there is no shortage in producing medicines," he said.

Vijay Rupani, Chief Minister, Gujarat while highlighting the state's contribution to the national GDP said that Gujarat is one of the few states in the country to provide all necessary support to strengthen the pharma and medical devices companies. He said that the state government is planning to come up with two dedicated parks, one for bulk drugs manufacturing and other for medical devices.

"In India, pharma and medical devices sector are growing rapidly. Gujarat has become a hub in the manufacturing sector, agriculture and social sector. Now, Gujarat is ready to take the lead n pharmaceuticals and medical devices sector," added Rupani.

Mansukh Mandaviya, Minister of State (I/C) for Shipping and Chemicals & Fertilizers, Government of India said that today when the world is in recession, the Indian pharma sector is growing at 10 per cent and Indian medical devices sector is growing at 20-25 per cent. "India has a lot of opportunities and this is not only encashed by Indian companies but also global players are also investing in these sectors," he added.

He further added that the government is working on bringing the new policy to strengthen the Indian API market.

Dr PD Vaghela, Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India, said that government will be setting up a 'Pharma Bureau', which will help facilitate both foreign as well as domestic investment in the pharma and medical devices industry in India. "Pharma Bureau will act as a policy think tank to support the Government as well as the Industry," he said.

MK Das, Principal Secretary, Industries & Mines Department, Government of Gujarat highlighted the growth of Gujarat's economy and enumerated various policy initiatives which enabled the state to attract 51 per cent of the country's FDI.

Pankaj R Patel, Past President, FICCI and Chairman, Zydus Cadila while highlighting the current challenges of the sector said that this is a wake-up call for the sector. "The pharma industry in India is today the pharmacy of the world," he added.

Badri Iyengar, Chairman, FICCI Medical Device Forum said that India contributes to 1.2 per cent of the global medical device market and about 6 per cent of the total healthcare market globally.

FICCI-EY report 'Reshaping India into a life sciences innovation hub' was also released during the event.

Report on the 18th International Symposium of the Controlled Release Society Indian Chapter (CRS IC)

Gowda spoke at the India Pharma and India Medical Device 2020 event where FICCI-EY report 'Reshaping India into a life sciences innovation hub' was also released

THE INDIAN chapter of Controlled Release Society (CRS IC), one of the 15 global chapters of CRS USA, organised its 18th International Symposium on the theme 'Advances in Technology and Business Potential of New Drug Delivery Systems' on February 28 and 29, 2020 at Hotel Sahara Star, Mumbai, India. The symposium provided an interdisciplinary forum to discuss the latest innovations in the arena of pharmaceutical drug delivery research and offered an impetus to the research aptitude and collaborations among the attendees. This year's symposium attracted over 400 delegates from the industry and academia.

The conference started with the welcome and opening remarks from the President of CRS IC, Dr Parizad Elchidana, followed by the inaugural address by Ajit Singh, President ACG Worldwide and Chairman of the Local Organizing Committee, CRS IC. The honorable Drug Controller General of India (DCGI), Dr V G Somani, the Guest of Honor for the symposium, urged for extensive research in novel drug delivery systems that aligns the efforts of academia and industry with those of the government, which is improving access to quality and affordable medicines. Prof Clive Wilson addressed the gathering by sharing insights on the commercialisation of formulations and further went on to release the 11th edition of CRS IC Newsletter along with the other members of the organising committee. This was followed by the unveiling of the online abstract book, which comprised more than 150 poster abstracts presented during the symposium. Prof. Vandana Patravale, Vice President, CRS IC then delivered her vote of thanks concluding the inaugural session.

Lamp Lighting at the inaugural session by Dr. Clive Wilson, Chief Guest and Mr. Ajit Singh Chairman ACG along with the Executive Committee Members of CRSIC

> The power-packed two-day experience at the International Symposium expanded the delegates' scientific and business acumen towards excellence and innovation with a singular agenda of furthering public health

Serial entrepreneur and inventor, Prof Samir Mitragotri from Harvard University, USA was the keynote speaker for Day One. During his talk on 'Understanding and overcoming biological barriers for drug delivery', he shared valuable insights on various challenges and solutions to improve drug absorption and his research strategy on utilising "cells as drugs".

The keynote address was followed by the first technical session by Dr Joyce Macwan from Simulations Plus team, US in which critical points on physiology-based biopharmaceutics modeling and virtual bioequivalence assessment to support formulation development were discussed. The post-lunch session commenced with the technology showcase podium presentations. Dr Sameer Padhya from Arihant Innochem, India elaborated on various excipients for hot melt extrusion, while Nilesh Mahajan, Shin-Etsu, India gave an interesting talk on L-HPC, a novel multifunctional excipient in formulation development. Christian Schneider, Celanese Corporation, Germany delivered the third technology showcase presentation on novel EVA excipients for the upcoming long-acting dosage forms. The next session of the

symposium included three invited lectures, the first of which was delivered by Prof Karl Wagner from University of Bonn, Germany. He explained in detail the characterisation and applicability of solid-state modification for life cycle modification of a drug product by sharing case studies on real-world issues and ways to mitigate them. This was followed by a captivating talk by Prof Matthias G Wacker from National University of Singapore, who gave a broad perspective on the importance and applicability of performance assays for next-gen translational nanotechnology. The last talk of the day was by Suhas Yewale from Sotax India, India who elucidated the dissolution testing of novel drug delivery systems giving case studies from almost three decades of experience in analytical R&D.

The second day of the symposium had a great start with the keynote address by the stalwart of drug delivery research, Prof Clive Wilson from the University of Strathclyde, UK. He presented a very unconventional view on the barriers that are still observed while developing well-studied regional gut delivery. The momentum set by Prof Wilson was further elevated by Prof Vinod Labhasetwar from the Cleveland Clinic Lerner College of Medicine, USA. His session delved through the severe catastrophic spinal cord injury that mainly affects the younger population. Dr Siddharth Jhunjhunwala from the Indian Institute of Science, India presented a scintillating talk on the current strategies employed in tertiary healthcare centres and his research group's efforts to address the unmet needs in diabetic foot ulcers treatment by immunomodulation followed by regenerative medicine. In the following talk, Dr Kailas Thakker, the Co-founder Emeritus of Tergus Pharma, USA stressed upon the importance of Quality by Design in topical drug delivery.

Next, Dr Josedas Neves from University of Porto, Portgual went on to share insights on the global pandemic - HIV and the women-centric strategies using nanotechnology based microbicides for topical pre-exposure prophylaxis. In the post lunch session, the delegates also benefitted from the tech-showcase speakers of Day two. Sanjay Negi from Ideal Cures, India presented details on innovative coating technology for sugar coating and was followed by Dr Smita Rajput from Merck Life Sciences, India who spoke about Merck's new line of tailor-made excipients for high-risk formulations. The last invited speaker for this two day symposium was Gargi Nadkarni from Sun Pharma, India. She gave a utilitarian business perspective to the 505(b)(2) US FDA regulatory pathway using case studies of successful and unsuccessful approved 505(b)(2) products.

Dr. V. G. Somani – Drugs Controller General of India being felicitated as Guest of Honor by Mr.Ajit Singh, Chairman ACG and Dr. Parizad Elchidana, President CRSIC

Dr. V. G. Somani – Drugs Controller General of India addressing the Participants

Release of CRSIC News letter by Dr. Clive Wilson, Chief Guest at the Symposium

Another highlight of the event was a poster presentation competition in which over 150 selected abstracts were evaluated over the two days of the symposium. In the concluding session, CRS IC announced three best poster awards and a special mention award selected by an esteemed panel of independent judges.

Preeti Sharma from the Centre of BioSystems Science and Engineering, Indian Institute of Science, Bengaluru, India bagged the first place for the poster titled “Interactions of Nano- and Micro- Drug Delivery Systems with Phagocytic Immune Cells”. The second and third best poster awards were presented to Shruti Singh from Faculty of Pharmacy, The Maharaja Sayajirao University of Baroda, Vadodara, India and Tushar Malakar from the Department of Pharmaceutics, National Institute of Pharmaceutical Education and Research (NIPER), Guwahati, India, respectively. Dr Nilesh Mahajan from the Department of Pharmaceutics, Dadasaheb Balpande College of Pharmacy, Nagpur, India received the special mention award.

The power-packed two-day experience at the International Symposium expanded the delegates' scientific and business acumen towards excellence and innovation with a singular agenda of furthering public health.

Healthcare industry reports 56 deals worth $2.3-bn in Feb'20

The healthcare industry reported 62 VC deals worth US$0.9-bn in February 2020, compared to the last 12-month average (February 2019 to January 2020) of 105 deals worth US$1.8-bn

In February 2020, the healthcare industry reported 56 deals worth $2.3 billion as compared to the last 12-month average (February 2019 to January 2020) of 60 deals worth $21.8 billion.

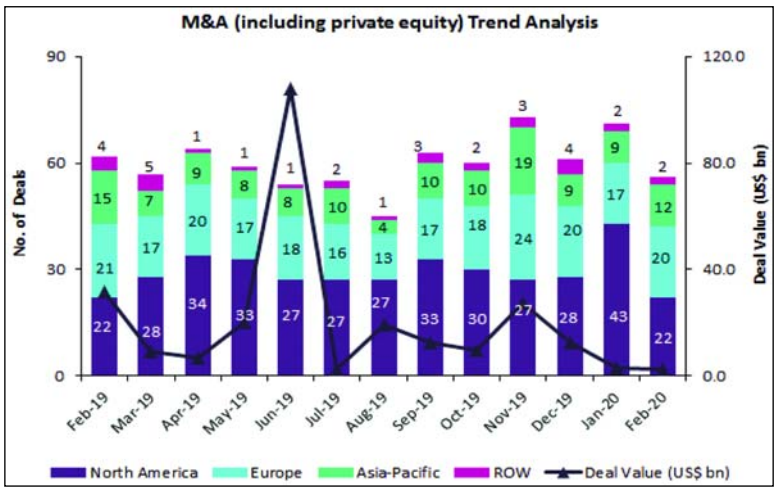
Collegium Pharmaceutical's acquisition of NUCYNTA Franchise of Products from Assertio Therapeutics for $375 million; Hillhouse Capital investing $331 million in Asymchem Laboratories (Tianjin); Takeda Pharmaceutical acquiring PvP Biologics for $330 million; and Catalent acquiring cell therapy company MaSTherCell Global for $315 million were some of the deals which contributed 58 per cent to the total deal value in February 2020.

The healthcare industry reported 62 venture capital (VC) deals worth $0.9 billion in February 2020, compared to the last 12-month average (February 2019 to January 2020) of 105 deals worth $1.8 billion. ALX Oncology raising US$105 million in series C round of financing; Canbridge Pharmaceuticals raising $98 million in series D funding; and Spruce Biosciences raising US$88 million in series B financing are some of the major VC deals reported in February 2020.

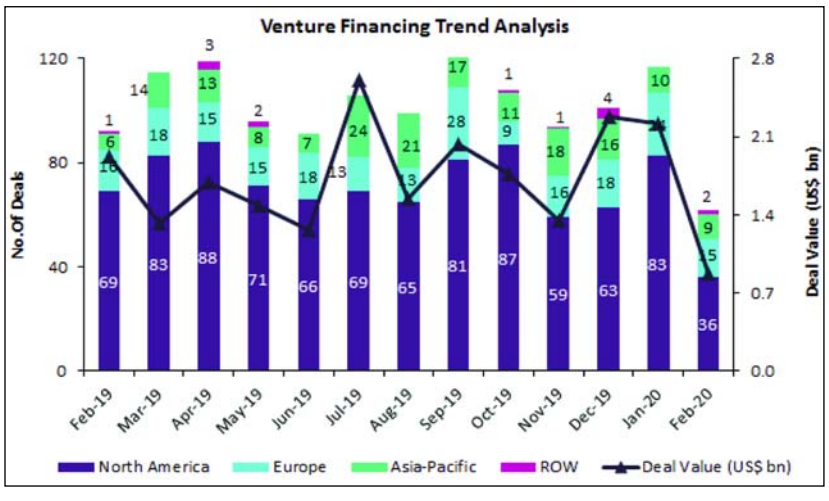
Deal Date	Acquirer (s)	Target	Deal Value (US$ m)
6-Feb-20	Collegium Pharmaceutical Inc (US)	NUCYNTA Franchise of Products (US)	375.0
17-Feb-20	Hillhouse Capital Group (China)	Asymchem Laboratories (Tianjin) Co Ltd (China)	330.5
26-Feb-20	Takeda Pharmaceutical Co Ltd (Japan)	PVP Biologics Inc (US)	330.0
2-Feb-20	Catalent Inc (US)	MaSTherCell Global, Inc.(Belgium)	315.0
12-Feb-20	Dr. Reddy's Laboratories Ltd (India)	Business Division of Wockhardt in India (India)	259.5

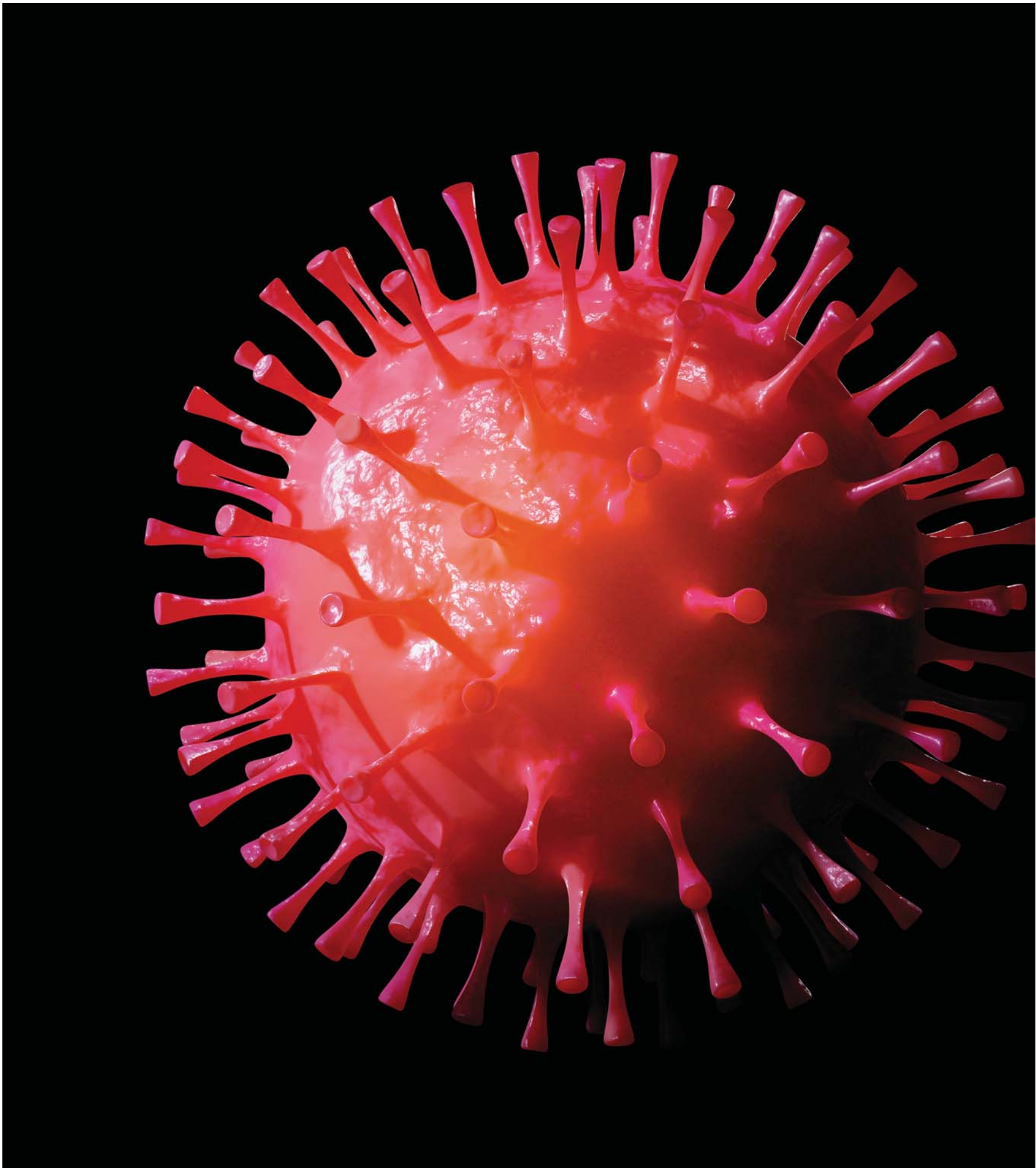
Deal Date	Acquirer (s)	Target	Deal Value (US$ m)
12-Feb-20	Janus Henderson Group Plc; venBio Partners LLC; LSV Capital Management LLC; Foresite Capital Management LLC; Cormorant Asset Management LLC; HBM Healthcare Investments AG; BVF Partners LP; Vivo Capital LLC; Logos Global Management LLC	ALX Oncology Inc (US)	105.0
18-Feb-20	General Atlantic LLC; RA Capital Management LLC; Hudson Bay Capital Management LP; WuXi AppTec Co Ltd; Tigermed Investment; YuanMing Prudence Fund	Canbridge Pharmaceuticals Inc. (China)	98.0
19-Feb-20	Omega Fund Management LLC; Sands Capital Management LLC; Aisling Capital; RiverVest Venture Partners LLC; Abingworth LLP; HealthCap LLC; Rock Springs Capital Management LP; Novo Holdings AS; Surveyor Capital Ltd	Spruce Biosciences Inc (US)	88.0
20-Feb-20	Undisclosed Investor(s); Gurnet Point Capital Limited; Equilibra Partners Management LLC	Alladapt Immunotherapeutics Inc (US)	60.0
19-Feb-20	Undisclosed Investor(s)	NeoTX Therapeutics Ltd (Israel)	45.0

DEAL VALUE DECLINED BY 27% IN FEB 2020 COMPARED TO DEAL VALUE IN JAN 2020



VENTURE CAPITAL INVESTMENTS DECLINED BY 62% IN FEB 2020 COMPARED TO VALUE IN JAN 2020





FINDING THE SILVER LINING OF CORONAVIRUS PANDEMIC

As India Pharma Inc reels under the far-reaching impact of the coronavirus epidemic, industry experts suggest policy reforms to insulate the sector and improve its emergency-preparedness

By Usha Sharma

The novel coronavirus pandemic (COVID-19), which began with an outbreak in China, has killed over 4,990 people worldwide and the death toll is increasing constantly. With over 120 countries affected by the virus, this threat has put a dent on the global economy as well. The COVID-19 pandemic's impact on India Pharma Inc too will be mammoth in stature.

One of the most signifcant impact will be the lack of availability of key raw materials for the pharma industry. Presently, the Indian pharma companies who lead the global generic business markets are largely dependent on China for up to 90 per cent of their APIs imports, and they stock a maximum six months worth market requirements. The Indian regulatory agency anticipates that 50 plus APIs of crucial antibiotics, vitamins, and hormones or steroids could go out of stock in case of a prolonged lockdown in China. Also, the sector is already witnessing a rise in prices of several key ingredients which will certainly disturb product availability in the market.

According to Pharmaceutical Export Promotion Council (Pharmexcil) reports, there has been a rise of nearly 40 per cent in the cost of paracetamol from Rs 250-300 kg to 400-450 kg. 'Montelukast sodium' (an anti-asthma drug) is now trading between Rs 52,000 - 58,000 per kg, compared to Rs 33,000-38,000 per kg a few months ago. Similarly, the prices of vitamins and penicillin have increased by 40-50 per cent and the majority of the vitamins are trading at double or triple the original price. The cost of azithromycin - an antibiotic used for curing various bacterial infections - increased by 70 per cent. The companies may end up exhausting most of their stock of active ingredients for high-demand drugs like paracetamol and ibuprofen in another two to three months. There are also fears that an artificial shortage of essential drugs might get created in the market.

All these factors have pushed regulators and government authorities to hold several brainstorming meetings with pharma stakeholders. For instance, last month the central government formed a committee to monitor the availability of drugs in India. The committee, led by Joint Drugs Controller Eswara Reddy subsequently asked drug-makers across India to inform the government if they required urgent 'pick-ups' from China. To this, Cipla wrote back with a requirement of six tonnes of raw material primarily comprising of active pharmaceutical ingredients (APIs) and key starting materials. Following this request, the central government promised to help Cipla import cargo weighing six tonnes from China, most likely by a flight run by Cathay Pacific from Hong Kong at the earliest.

Thus, the authorities are trying to tackle these challenges but the situation has reiterated how important it is for India to become more self-reliant. Though 2015 was declared by the Government as 'Year of Bulk Drugs', unfortunately nothing concrete happened on that ground. After that too, several attempts have been made by the pharma industry to make India self-reliant at the API front. There were also concerns that political relations between India and China and the trade wars between US and China could affect the pharma industry adversely.

However, there are hopes that this crisis will offer some silver linings in the form of learning opportunities and expedition of policy reforms. This, in turn, can eventually boost the process of India becoming more self-sustainable.

In this light, industry stakeholders share their views on how COVID-19 may prove to be a turning point in the Indian pharma industry.

'Need to adopt a strategy to make India self-sufficient in KSMs, intermediates and APIs'

In terms of imports from China, India is vulnerably dependent for imports of key starting raw materials (KSMs) like Penicillin G, 6APA, 7ACA and lot of APIs. In all 600 such molecules are being imported in India out of which 58 are imported from China only and out of 58, 12 are imported from Hubei province where Wuhan Coronavirus affected city is located. We're confident through our suppliers and sources in China that areas in access of 500 km from Wuhan City will start dispatching KSMs and APIs in two to three weeks. Wuhan city might take eight weeks or thereabouts to bring about a semblance of normalcy to some extent. Therefore, 16 molecules will be affected to a larger extent such as certain antibiotics like Chloramphenicol, Erythromycin, Azithromycin, Clarithromycin, Amoxicillin, Vitamins A B, E & C & E, hormones like Progesterone, Metronidazole etc. India may have to go slow on exports of formulations based on these molecules so as to ensure adequate supplies for India irrespective of other international commitments. In case of such commitments to the foreign suppliers, *force majeure* clause can be initiated.

COVID-19 is a wake-up call for India and we need to adopt short, medium and long term strategy to make India self-sufficient in KSMs, intermediates and APIs. As a short term measure, GoI may incentivise MSMEs and certain large companies which were earlier API producers but stopped producing on account of Chinese companies dumping at the below

Dr Dinesh Dua, Chairman, Pharmexcil, Chairman, Entrepreneurship & Startups, CII North India, CEO and Director, Nectar Lifesciences

variable cost. With new scenario, they can be incentivised to restart old plants which were shut down. Assessments can be made through DoP and Ministry of Commerce, Pharmexcil, IDMA and other recognised bodies to ensure that genuine manufacturers are incentivised.

As midterm measures, existing clusters in states like Telangana, Andhra Pradesh, Maharashtra and Gujarat should be fast-tracked in terms of manufacturing KSMs, intermediates and API's on SOS priority basis on China parity both in terms of financing at Libor + 1.5 per cent and non WTO conflicting incentives to promote manufacturing for APIs at reasonable profit and RoI approximately 10 per cent or thereabouts. Clusters may be expanded from current size 100-200 acres to 500 acres wherein in China clusters are in region 4000 to 5000 acres with complete assistance from the Chinese government both in terms of moratorium on interest for five years, as well as various incentives to promote exports andself-sufficiency for the domestic market.

A suitable work plan can be provided to GoI for this purpose as a long term measure.

Keeping in mind the long term objectives, a moratorium period for the first five years should be provided on principal and interest. With significant volumes and ascendancy over China all over the world, both interest and principal can be paid off and became larger suppliers of all these three verticals not only for domestic sufficiency but also for current exports $22 billion estimated in 2021 can go to $50 billion or more in the next four to five years.

"We have a chance to improve the Indian API sector in the coming years"

Although the Indian pharma industry has an edge over China in production of pharma formulations for domestic and international markets, India still needs the support of China for the supply of a good number of APIs and intermediates for making the formulations.

Due to coronavirus impact in China, there have been delays/suspension of supply of APIs to India, which are very important for our formulations, particularly, antibiotics, hormones and vitamins. At this point of time, it has become difficult to estimate how long this situation is going to continue.

All along, the Indian pharma industry has been requesting the government for providing supportive measures for the development of API sector in India to compete with China. Although the intention of the Government has been positive, the response has been slow. The year 2015 was declared by the government as 'Year of Bulk Drugs', but nothing concrete happened on the ground. Now, due to the impact of coronavirus, leading to a possible shortage of medicines, the Government has come into full gear to look at the possibilities of boosting the Indian API sector.

The government is also considering clearing of bottlenecks for getting quicker environmental clearances. If the

S V Veeramani, Chairman & Managing Director, Fourrts (India) Laboratories and Past President, IDMA

We need to consider imports of raw materials from non-affected areas of China

government is able to announce a package quickly for the existing as well as the new API industries, in the form of soft loans, capital subsidy, power subsidy, interest subsidy and other support, besides speedy environmental clearance, we have a chance to improve the Indian API sector in the coming years, although it may not meet the immediate requirement due to paucity of time. To meet the immediate requirements, we need to consider imports of raw materials from non-affected areas of China as well as doing any short term measures to increase the production of APIs in India.

A short term measure for API production can be in the form of lifting environmental restrictions and allowing Indian manufacturers to produce any raw material if they are within the the approved pollution load.

"Old PSUs should be revived to produce antibiotics like Pen G"

These are challenging times for the Indian pharma industry and the Government of India,and they need to do an analysis about the sudden shortage of APIs and intermediates due to the Coronavirus pandemic. We normally wake up when there is a fire in the system and that is what has happened this time. The industry, as well as people at large, have been expressing concern for a number of years to reduce the dependability on one particular country for Key Starting Materials(KSM), Intermediates, and many of the APIs but nothing concrete has happened over a period of more than a decade or so.

A ray of hope was seen in 2015 when the Government of India declared that particular year as 'Year of API' and to that extent. Many interactive sessions and workshops were also conducted by Department of Pharma with BDMA as well as with IDMA but the unfortunate part is that during those sessions, nothing happened. Now it is a blessing in disguise that the government and industry have realised the importance of strengthening domestic API industry and DOP as well as Ministry of Commerce and NITI Ayog has felt the pain and took immediate action.

The main concern is the availability of the products whether it comes from abroad or within the country. As everyone is aware, India is the capital of diabetes and around 10 per cent population is suffering from this illness. Metformin is a well-known dose for the treatment of diabetes and hundred per cent of its intermediates are depended on China.

Similarly, most of the antibiotics, vitamins, hormones and steroids salt also are sourced from China alone. The issue which we all have to understand is the Question of National Security. If suddenly, due to any reason, supplies are stopped, then what is going to be the fate of patients of the Indian population? It is high time for the industry and the Government to sit together and start reducing dependability on China, category wise. It is practically not possible for the government to suddenly develop the production of such molecules locally but category wise product range can be short-listed and dependability can be slowly and gradually be reduced. The second option is that old PSUs should be revived to produce antibiotics like Pen G etc. It may not be viable for those units to produce the product at the cost on which China is producing because of technology, because of tariff of power and because of the economy of school. However, our country can afford to subsidise the product to some extent.

B R Sikri, Chairman, Federation of Pharma Entrepreneur (FOPE)

Another method is to have a PPP model. Government, PSUs and the private sector can join hands and start production of sensitive items. An ordinary product like paracetamol cannot be manufactured in India without its intermediates which are hundred per cent being sourced from China. Another solution to this problem is to allow an increase in the existing capacity of all the APIs if the pollution load is not going to increase. At present, the Environmental Ministry has allowed 50 per cent increase in the production but why to have such a cap on percentage. It should be limitless. Such a decision will give a breather to the industry. Secondly, permission is granted by EC product-wise whereas industry demand is to give permission category wise. This will also give a sigh of relief to the nation. Industry- academia collaboration is also lacking. Academia is capable to develop new technology but some agency has to arrange their tie-up with the industry with budget allocation. To sum up, we need the following action plan immediately to reduce the risk factor:

1.Industry Academia collaboration

2.Revive PSUs

3.To have PPP model of Govt, Pvt and PSU

4.To allow increase in the existing production to any extent if pollution level is same.

5.To grant permission category wise and not product wise.

6.To arrange tie up with other countries like Italy etc. instead of keeping all eggs in one basket.

7.To accept some of the recommendations of Dr Katoch committee to start with.

Nation first, National security second and profit or loss at the last should be the motive of the Government and Industry.

"Domestic competition should be encouraged in case of fairly improved technology implementation"

"I trust enough time has already been lost discussing the dependence on intermediates and APIs, on China. Instead, it's time to execute the well-framed policies and investments in this area as it's fructification shall take time.

Being capital intensive and because of delayed economic returns, the companies need protection against unfair domestic and international competition. At least domestic competition must be fair and allowed while ensuring comparative compliances including EHS, before providing product-specific clearances for manufacture. In other words, domestic competition should be encouraged in case of fairly improved technology implementation and respect for IP. Many manufacturers of the same API/ Intermediate in small capacities will never do good for the industry as a whole.

The support for current manufacturers and encouragement to expand should yield quicker results. The operating organisations carrying skills and need shall be in the best position to upscale/ expand.

An intelligent balance of regulatory expectations of audit agencies can be equally important, to either loose economics or business. Most of the time, companies either want to be over safe (defensive environment and less attractive economic returns) or lack control to demonstrate compliances as expected (risk of observations/ warning letters by audit agencies).

Dr Ashutosh Agarwal, Ex-CSO, Jubilant Life Sciences

> At least domestic competition must be fair and allowed while ensuring comparative compliances including EHS

Smart manufacturing solutions, leading to reduced plant costs, and containment of operational costs, are critical for the sustainability of economics and businesses. "

"We should look at reviving the plants which have shut down"

Corona Virus Pandemic and resultant lockdown in China has exposed the vulnerability of India Pharma. Over the years, dependency on China of APIs and KSM has become such that we have forgotten the simple management principle of spreading out our vendors geographically. More than 70 per cent of our requirements were met by a single country with whom we do not have very friendly relations. It is always known that it is going to be a strategic risk but the country chose to ignore it for the simple reason that we are getting APIs and KSM at relatively low cost. India used to be a powerhouse in APIs but many plants shut down due to non-viability in the face of Chinese competition. Whatever is already running are dependent on China for KSM and Intermediates. China does not have a great formulation Industry but off late it has changed gears. Formulation Industry in China is on overdrive and they have got their act together. It will be a great Strategic Risk not only for Indian Pharma Industry as well health economy of more than 1300 million Indian population if China decides to stop the export of APIs and KSM to support their formulation industry.

At this moment in a short term we cannot do much but watch the situation unfolding in china and how they revive the production to meet the global shortfall of API. At the most what we can do is airlift the supplies from China, but this will be unviable for low-value items like Paracetamol, Metformin, Aspirin, Diclofenac etc. Supplies need to get normalised in the next couple of weeks, which looks highly unlikely as per the present scenario. If not, we are heading for tough times. Already prices of key APIs have skyrocketed. Supplies to government institutions have the potential to be badly hit depriving poor patients of medicines.

Harish K Jain, Director, Embiotic Laboratories

As a formulator, we cannot increase our MRP due to DPCO restrictions. Formulations supplied for government supplies are bound by rate contracts. It is an unprecedented situation. In medium term, we should look at reviving the plants which have shut down and are lying idle. The existing players should expand their capacities. We could also look at countries other than China to source APIs, registration for which should be done on fast-track. However, what we need is a long term planning to become self-reliant. It is unsustainable to have a third-largest by volume US $40 bn world-class formulation industry exporting products to all nook and corner of the world dependent on imported APIs. Corona Virus is a wake-up call and I hope all the stake holders work together to build a robust world-class home grown API industry. The Government should also pitch in with some proactive approach. Some of the measures I feel should be taken are:

1. Ease of doing business with respect to implementation of environmental laws. Currently, environment clearance for a bulk drug plant takes anywhere between 12-24 months. This needs to be within a reasonable time of say 60-90 days. If the quantity of effluent remains same, product-wise NOC needs to be done away with.

2. Department of Pharmaceuticals has the scheme to assist Bulk drug park offering up to Rs 100 crore in grants. But this is available only to parks developed by State Govt Agencies. The scheme needs to be extended to Private Parks as well those on PPP model.

3. Special encouragement should be given for ZLD plants.

4. Bulk drug industry is capital intensive and so we are at a disadvantage since comparatively, our interest costs are high. Liberal Capital Investment Subsidy scheme is needed since bulk drug manufacturing is going to be an import substitute.

5. Electricity tariff subsidy of Rs 2 per unit should be introduced.

6. Export credit at libor rate of interest

7. Anti dumping duty should be imposed where it is findings that there are hidden subsidies violating WTO norms.

1. Setting up of R&D and Innovation Centres to help start-ups to carry out their work before investing in the plants.

"Government should support in setting up mega API SEZs"

India is facing a difficult situation in the importing API from China due to the Coronavirus impact. In this tough situation, not just the government, but all stakeholders including industry, hospitals and healthcare professional must come together to face this challenge. CDSCO office is playing an essential role in overseeing our country's medical products as part of its vibrant mission to protect and promote public health in India.

As a short-term solution to immediately address this challenge, the following could be implemented:

Product Supply Chain Surveillance: The Coronavirus outbreak may further impact the product supply chain, including potential disruptions to supply or shortages of critical medical products in the country. This could be due to reason of shortage of API or finished product. Before situation worsens, the regulatory office could reach out to manufacturers as part of a proactive approach to identify severe shortages of API or products. This would help to monitor the situation and take actions as per the current situation in consultation with manufacturers. This can also be achieved through networking with manufacturer trade associations.

In addition to manufacturers, it would also be advisable to keep in touch with other country regulators like US FDA, EMA, Health Canada etc. to assess and monitor for indications and early warning signs of potential manufacturing discontinuances or interruptions due to the outbreak in respective countries.

Expedited route for development and approval: This is important to find a drug which can diagnose, treat and prevent this disease. There should be an abbreviated pathway for the development and approval of this drug in the country. There should be technical assistance, regulatory advice, and guidance to advance the development and availability of vaccines, therapies, and diagnostic tests for this novel virus.

Parveen Jain, Head- Regulatory and Government Affairs, Fresenius Medical Care

Evaluate API and finished product export: To prevent a shortage of API and product in future, the government should continuously monitor the situation for export.

Long term solution: Local manufacturing plants to increase production capacity for these lifesaving drugs. On consultation with CDSCO office, local manufacturing plant can increase production capacity for these lifesaving drugs. As situation requires, it's advisable to use all available tools i.e. increase batch size, increase production shift and alternate supply to react swiftly and mitigate the impact to Indian patients.

Abbreviated pathway for API import registration and license fees: Currently in India, for API Registration Certificate registration (RC), it's the same registration pathway as the finished product. So, it becomes difficult for small scale industries to register API for import because of extensive documents requirements and finance issues. Hence there are limited companies/vendor apply for Registration application of API. If there would be an abbreviated pathway for API, there would be more companies who would register and then it would less likely to have API shortages.

Capacity building for government PSU's: It would be important to do capacity building of government PSU's for these critical APIs. Set up of SEZs and tax favourable environment for local API manufacturing. The government should support and create an enabling environment to set up mega API SEZ's having common facilities for pollution control, effluent treatment, single window clearance and giving tax favourable environment.

We need to introduce policy measures which will enable local manufacture of APIs

According to estimates by the WHO, China boasts 20 per cent of the global API output. The Medicines and Healthcare Products Regulatory Agency of the United Kingdom estimates the figure to be twice that. They vary because there is no reliable registry of APIs. However, there is no denying that China dominates the market by a significant margin.

They export to over 70 countries in North America, Europe, Asia, and Latin America. In the event of global trade disruption, as is the case with the coronavirus outbreak, it would be extremely difficult for foreign suppliers to replace Chinese APIs. Pharmaceutical producers, buyers and traders should be preparing themselves for potentially far reaching supply disruptions. The delay in production could end up affecting deliveries in the second quarter of 2020. We are talking about life-saving antibiotics and surgical drugs. Manufacturers of generic drugs in India have built a sizeable pharma industry that has been instrumental in lowering the cost of many life-saving drugs. In the process, we also ended up becoming the largest importer of Chinese APIs. We depend on them for 80 per cent of APIs and other chemical intermediaries. So unless they make provisions for alternate sourcing, there is going to be a considerable shortage in supply. In the long run, we also need to introduce policy measures that will enable local manufacturing of medicines and their key ingredients. They are a strategic asset to our healthcare industry and we cannot rely on China for a lion's share of our supply.

Sanjay Jha, Director, ColMed

> Pharmaceutical producers, buyers and traders should be preparing themselves for potentially far reaching supply disruptions

u.sharma@expressindia.com

INTERVIEW

‘Vaccination is about providing children with a lifetime of benefits’

Over three million children die every year, which could easily be prevented by vaccination, informs **Neeraj Mehta**, CEO, ImmunifyMe during an interaction with **Akanki Sharma**

What is the current scenario of immunisation in India? Compared to other countries in the world, where does India stand?
Immunisation helps half-a-billion children against a range of deadly diseases, preventing seven million future deaths in the process. The bottom line is that vaccination is about providing children with a lifetime of benefits. However, India has the largest number of unimmunised children which is 7.4 million, and the country also has the largest number of births per year (26 million). Nearly 90 per cent of children in India are born in government or private facilities. According to the latest statistics released by NSO for immunisation, 98 per cent of the children born in the urban setting get at least one vaccine between the age group of zero to five years, but the number goes down to about 61 per cent when it comes to the children being fully vaccinated. Similarly, when it comes to the rural setting, 97 per cent of the children between the age group of zero to five years get at least one vaccine but the number again goes down to 58 per cent, who were fully vaccinated.

What was the idea behind setting up ImmunifyMe? When was it found?
Over three million children die every year, which could easily be prevented by vaccination. Yet, one in every five children remains unimmunised. ImmunifyMe leverages technology to monitor vaccination and bridges the immunisation gap. With a team of diverse background from a Virologist to a Cloud solution architect and a business development professional, who are bound by a single commitment and vision of reducing the immunisation gap, ImmunifyMe was born. The journey began in 2018 and till now ImmunifyMe has been recognised by many national and international bodies and won many grants and awards. It is currently launching its operations in India.

How does ImmunifyMe offer the framework to close the existing immunisation gap?
One of the main reasons for the low immunisation rate in India and many developing countries is that an increasing number of people live under the radar. With the current vaccination record keeping, they are invisible. Further, with outdated, paper-based methods being used, it’s impossible to find unvaccinated children. ImmunifyMe will streamline analytics of vaccination monitoring, record keeping and outreach without adding significant complexity to the workflow; provide accurate and verifiable proof, aggregate data that can easily interoperate with other existing identity management systems, negating the need for each organisation to independently identify beneficiaries, taking timely interventions in outbreak situations, disease surveillance and making policies to bridge the immunisation gap.

In what ways does ImmunifyMe help the organisations that work on vaccination? Name some of these.
Digital record-keeping makes it convenient to track a child’s immunisation and eliminate unnecessary paperwork. ImmunifyMe is convenient for connecting and confidentiality is easier to preserve. It helps forecast the demand and availability of vaccines. Besides, information can be easily and securely shared with medical practitioners, schools and wherever it is necessary. High-quality relevant data produced by immunisation information systems can be used by global and national-level decision-makers to drive resource allocation and other strategic decisions. In case of an adverse effect, ImmunifyMe will also help pharmaceutical companies trace the batch and finally the single vaccine, saving them precious time and millions of dollars in an investigation.

What kind of innovative technology solutions and services do you provide to the children and their caregivers?
While reducing mortality is already reason enough to want to have every child on this planet vaccinated, now we have the added motivation that we are not just saving lives, but also helping to improve many more lives in the process. We are making sure that every child receives all the necessary vaccines and they reach the vaccination clinics on time by sending reminders. Not only that, but we also monitor the growth of the child, social-emotional development, physical, cognitive, communication development and making sure they have a healthy childhood.

How can hospitals, pharma companies and governments benefit through ImmunifyMe?
Government organisations working on vaccination - the data created by ImmunifyMe can be used for decision making and provide proper vaccination to children. The government can easily introduce new vaccines to the existing vaccination schedule just by a request. Information can be easily sent to parents about upcoming vaccination campaigns organised by the Government or NGOs. Instead of umbrella campaigns, they can do targetted campaigns and save money and efforts and make sure children will follow up and complete vaccination. The network created through ImmunifyMe will be huge and the knowledge and information can be easily delivered to end-users by SMS or email.

Apart from it, if there is any adverse effect of the vaccines, it can be traced back

to the lot and finally to a single vaccine, saving them precious time and millions of dollars in an investigation.

In terms of financial growth, where do you see yourself in the next five years?
More than 350,000 children are born daily worldwide. Introducing our innovative product for five per cent of the newborns will make us support eight million children. Introducing ImmunifyMe to countries which have a low rate of immunisation and higher non-compliance will drastically improve the immunisation gap and improve the quality of care.

ImmunifyMe is country agnostic and can be replicated worldwide or in any particular region/country with ease. There are over 128 million children being born every year worldwide or 353,000 children every day. There are about 49,500 children being born every day in India alone.

We are looking to make a foothold in the Indian market in the coming two years with around three million children on board. Our plan is to grow beyond India in other SAARC countries in the third year of our operation.

Who are your investors? How are you funding your operations?
We have been fortunate enough to receive grants early in our journey. The first grant of $80,000 we received was from the Government of Chile through its programme Startup Chile. The second grant of $180,000 came from the Government of Luxembourg.

We are also fortunate enough to be invested in, by the largest vaccine manufacturer in the world which is Serum Institute of India, a Cyrun Poonawalla group company. They took equity of 25 per cent in ImmunifyMe. At this moment, when we are launching our operations in India, we are running our finances through the seed funding we received from Serum.

What is your business model?
We have two kinds of business models – the first being B2B2C, in which we tie-up with private paediatricians, hospitals and other child healthcare providers to promote ImmunifyMe application to the parents of children aged between zero to five years.

The second is B2G in which we tie-up with various central and state governments. The world has moved to being digital. Why should our vaccination record still remain on paper?

How many hospitals have you tied up with for vaccine record-keeping? Kindly name/list them.
Since we are in the process of launching in India, we are concentrated mainly in the north. This includes independent practitioners, doctors and few hospitals. We have also tied-up with Bihar's largest private medical college, Narayan Medical College and Hospital, and are also working in two blocks in the Rohtas district of Bihar.

akanki.sharma@expressindia.com

Cleveland Clinic researchers discover a new diet-associated gut-microbe metabolite linked to cardiovascular disease

Discovery could help explain why beta-blockers are effective in treating heart disease patients

Cleveland Clinic researchers in the US have identified a gut microbe-generated byproduct – phenylacetylglutamine (PAG) –- that is linked to the development of cardiovascular diseases, including heart attack, stroke and death. The study was published in Cell on Thursday [March 5].

Phenylalanine is an amino acid found in many foods, including plant- and animal-based protein sources like meat, beans and soy. The researchers – led by Stanley Hazen, MD, PhD, chair of the Department of Cardiovascular & Metabolic Sciences in Lerner Research Institute and co-section head of Preventive Cardiology & Rehabilitation in the Miller Family Heart, Vascular & Thoracic Institute – found that when phenylalanine is broken down by microbes in the gut, it produces a byproduct (metabolite) that ultimately shows up in blood called phenylacetylglutamine (PAG) that contributes to heart disease.

"Over the past decade there has been an increasing amount of data to suggest that gut microbes play a role in health, especially as it relates to heart disease," said Dr Hazen, who also directs the Cleveland Clinic Center for Microbiome and Human Health. "We found that blood levels of PAG contribute to cardiovascular disease risk in a couple of different ways."

Analyzing samples from more than 5,000 patients over three years revealed that elevated PAGln levels predicted subjects who went on to experience adverse cardiac events like heart attack and stroke in the future, and also in those with type 2 diabetes (an independent risk factor for cardiovascular disease). Animal model and microbe transplantation studies suggest the gut microbe-produced PAG can play an important role in driving cardiovascular diseases.

Phenylacetylglutamine(PAG) enhanced platelet reactivity and clotting potential, which increases the likelihood of blood clots

The researchers also analysed whole blood, platelet-rich plasma and isolated platelets from patient samples to understand how PAG affects cell processes. They then analyzed animal models of arterial injury to see how PAG induced cellular changes manifest into disease. Dr Hazen and his team found that PAG enhanced platelet reactivity and clotting potential, which increases the likelihood of blood clots, a major cause of adverse cardiac events like heart attack and stroke.

"Part of the reason we were so interested to have made this discovery is that we found that PAG binds to the same receptors as beta-blockers, which are drugs commonly prescribed to help treat cardiac diseases," said Hazen.

Administering beta-blockers to animal models with elevated PAG was shown to reverse cardiovascular endpoints driven by PAG. Additionally, researchers found that using gene-editing technology or drugs to block PAG-receptor signalling significantly reduced clotting activity.

"We believe our findings suggest that some of the benefits of beta-blockers may be attributed to preventing PAG-related activity," said Hazen. "Beta-blockers have been widely studied and are prescribed to many cardiac patients, but, to our knowledge, this is the first time that this mechanism has been suggested as an explanation for some of their benefits."

Ina Nemet, PhD; Prasenjit Saha, PhD; and Nilaksh Gupta, PhD, are co-first authors of the present study, which was supported by the National Heart, Lung, and Blood Institute (part of the National Institutes of Health) and the Leducq Foundation.

Mutations in plasma cells play a key role in light-chain amyloidosis

The research was conducted by Technical University of Munich and Heidelberg University

BONE MARROW plasma cells produce antibodies. These comprise two long and two short protein chains. The pathological proliferation of plasma cells can lead to an overproduction of the short chains. These associate to fibrils and deposit in organs. The result is fatal organ failure. A research team from the Technical University of Munich (TUM) and Heidelberg University have now identified the mutation behind the disease in a patient.

In people suffering from light chain amyloidosis (AL amyloidosis), these light chains are deposited as extremely fine fibres, so-called amyloid fibrils, in tissue or in organs. The disease is often recognised only after the deposits already compromise the function of organs. In many cases AL amyloidosis is fatal.

"Depending on the organ affected, the symptoms vary considerably. Furthermore, each patient produces different types of antibodies. The disease is thus difficult to diagnose at an early stage," said Johannes Buchner, Professor of Biotechnology, Technical University of Munich.

The team of scientists succeeded in identifying eleven mutations caused by the disease in the antibodies of a patient with advanced AL amyloidosis.

Exactly one mutation was responsible for the destabilisation and formation of the disease-causing amyloid fibrils. This mutation causes the unstable light chain to lose its structure after breaking into fragments, which then form the deadly amyloid fibrils.

"Mutations that lead to unstable light chains are an important factor in the occurrence of amyloidosis," says Pamina Kazman.

VENDOR NEWS

Ami Polymer recognised as the best MSME of 2019 by ASSOCHEM

The award was presented by Nitin Gadkari, Minister for Road Transport & Highways of India and Shipping Ministry of Micro, Small and Medium Enterprises

Ami Polymer received the Best MSME of the Year Award, 2019 by ASSOCHEM (The Associated Chambers of Commerce and Industry of India) at the 7th MSME National Excellence Awards organised by ASSOCHEM. The award was presented by Nitin Gadkari, Minister for Road Transport and Highways of India and Shipping Ministry of Micro, Small and Medium Enterprises.

Since 1996, Ami polymer has been working dedicatedly for innovative product development for Food, Pharma and heavy engineering industry and having world-class cleanroom facility in compliance with ISO 9001, ISO 14001, OHSAS 18001 and ISO 27001.

> PPL's Motto is to develop import substitute products with solution giving approach and make sure that the customer gets a delightful experience

At present Company enjoys more than 3000 customers from various industries, business with more than 40 countries worldwide with having 5000+ product portfolio.

APPL is a leader in Polymer solutions with high-quality product offerings like Pharma tubings, Reinforced hoses, Inflatable seals, Sieves/screens and customized product varieties. Quality Products are registered in US FDA for 7 DMF Registrations along with NSF 51 Registration in USA.

Reputed pharma and Biopharma giants are now very keen to join the hands with Ami polymer for new product research and development support. APPL's Motto is to develop import substitute products with solution giving approach and make sure that the customer gets a delightful experience. APPL believes in doing business with ethics and never compromised on the core values.

PRODUCTS

Create a secure seal around trailers when they dock when you combine a dock seal and shelter solution

IF YOU think about it, each loading dock door opening represents a giant hole in the wall of your facility. Strung together, these dock openings present an enormous opportunity for bad things to enter your facility – think bugs, dust, wind, rain and rodents – and for good things, like expensive heating and cooling energy, to escape.

Weather-related product damage and contamination, employee comfort and safety, facility hygiene and cleanliness, air quality, maintenance of product quality characteristics and passing inspections are all concerns related to protecting and controlling the environment at the loading dock. Anything a company can do to seal up these holes in the wall, ensuring a complete seal at every dock door, can have an immediate positive effect. Fortunately, highly effective dock sealing products from Gandhi Automations exist that can be

designed and installed quickly to make sure docks are sealed up tight and your people, products, processes and profits are protected.

Dock Seals and Shelters improve energy conservation, help preserve internal temperatures and protect products from outside contaminants. Dock Seals provide an effective barrier against the elements, keeping loading docks safe and productive. A loading dock seal can also be a critical component in containing cooled air inside climate-controlled and cold storage facilities for superior energy efficiency.

Loading dock seals and loading dock shelters play a primary role in keeping out dust, dirt and insects as well as protecting against the elements. If your facility is air-conditioned or refrigerated, dock seals and dock shelters will pay for themselves in no time with energy savings. They

come in many different sizes and have several options including material type and colours.

Creating a tight seal between the building and the back of the vehicle, dock shelters help maintain a steady temperature in climate-controlled areas, which significantly reduces energy bills. They also keep loading docks productive, regardless of the weather.

What is the difference between Dock Seals and Dock Shelters?

Dock seals are soft-sided pads covered with a durable fabric that allows the trailer to compress into and seal up the dock door. With several fabric options, we can find you the right product for your needs and budget.

Dock Shelters are typically rigid structures with fabric curtains that hug the back of a truck as it backs into the dock door. Several options are available to customize the fit of this product to your dock door.

Dock Seals

Dock seals create an airtight fit. If your warehouse requires a climate-controlled environment, or if you frequently handle delicate loads that cannot be exposed to outside conditions, dock seals are ideal because they provide a perfect seal between a loading dock and the truck.

Dock Shelters

Dock Shelters are more flexible in terms of application use. If you have a variety of different trailer sizes that use the same loading area, or a larger size door opening a dock shelter is the better choice because they are adjustable. Both are great ways to save on energy costs and protect delicate loads.

Gandhi Automations can provide a customised solution to meet any specific requirements you have including:

- Temperature Control
- Weather Protection
- Manual or Automated Control

Which dock seal or shelter is best suited to your loading dock? Dock applications, site criteria and facility operations vary and may require one feature more than the others. Many configurations are available from basic types of compression dock seals, standard dock shelters, inflatable seals to hybrid dock seal / shelter /inflatable designs.

Key Benefits

- Energy saving
- Enhanced vehicle seal
- Weather protection
- Temperature management
- Bespoke design available
- Low maintenance

RETRACTABLE DOCK SHELTER

Retractable dock shelter is best suited for facilities with large doors and where the entire truck/trailer door opening must be unobstructed. Retractable dock shelters with inclined roofs are formed by a perimeter structure that holds a series of canvases which adapt to the truck's bodywork.

This structure is retractable so that if any incorrect manoeuvre is performed by the truck, the shelter returns to its initial position. The aim is to provide a perfect seal when loading and unloading to achieve considerable energy savings and the resulting protection of the goods.

Retractable Dock Shelters are commonly used on ambient unheated or part heated warehouses where weathering of the opening and protection of the goods are the main criteria.

CUSHION DOCK SHELTER

Cushion seals are also known as dock pads. They provide a better seal than dock shelters but are less tolerant of a varying vehicle fleet. The cushion seal height can be varied by using a deeper head pad or curtain, Gandhi Automations also make wedge shaped pads that are wider at the front than they are at the back thus closing a door opening that is slightly too wide.

A cushion dock shelter from Loading Systems offers the best insulation when a dedicated vehicle fleet is used to ship goods. When swap-trailers and mobile containers are often loaded at your loading bay our cushion dock shelter is the best solution.

Cushion seals are mainly used on temperature-controlled stores where the compression of the pad gives a tighter seal and maintains the tight control of temperature and energy losses that this type of facility demands.

Inflatable dock shelter

Improve dock energy efficiency and loading dock environmental control all at once with Serco inflatable dock seals and shelters. Ideal for climate-controlled loading docks, inflatable dock seals and shelters offer flexibility and convenience, as they create the ultimate energy seal for your dock without putting pressure on your building walls. And best of all, they can easily be interlocked with Serco restraints and other dock equipment for improved efficiency and safety.

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Waters drives materials sciences innovation forward at Pittcon 2020 with new instrument introductions

WATERS CORPORATION introduced new products that bring greater productivity and efficiency to materials science research. The new Discovery X3 Differential Scanning Calorimeter, Discovery Hybrid Rheometers and TAM IV Micro XL isothermal microcalorimeter support the development of next-generation, high performance materials and products and are being introduced to the world's analytical scientists at Pittcon 2020, March 1 – 5 in Chicago.

"These new products emphasize our commitment to materials sciences," said Jonathan Pratt, Senior Vice President of Waters Corporation and President, TA Instruments. "For scientists exploring the relationship between the structure and property of materials, these technologies enable efficiencies in both streamlining laboratory operations and accelerating new product innovation."

Discovery X3 Differential Scanning Calorimeter for three times greater throughput

Uniquely engineered to eliminate multiple testing steps, the new Discovery X3 Differential Scanning Calorimeter (DSC) generates three times the amount of experimental data as a standard DSC, effectively consolidating three instruments into one. The data quality and sensitivity of the instrument allows researchers to compare various formulations or competitive materials side-by-side under the exact same test conditions. It is the most versatile, highest-throughput DSC available to scientists.

Discovery Hybrid Rheometers with enhanced measurement sensitivity

This new trio of high-performance rheometers are five times more sensitive than previous versions and offer class-leading versatility in a platform that makes it easier for users of all experience levels to obtain accurate rheological data. Scientists are now empowered to measure weak intermolecular structures, lower viscosities, and obtain results on smaller volumes of low viscosity or weakly structured fluids than previously possible - a critical consideration when working with scarce or novel materials.

The unique dynamic mechanical analysis feature enables the characterization of solid samples in dynamic tension, bending, or compression mode. Researchers can get both dynamic mechanical and rheological measurements from a single instrument and thereby obtain more information more efficiently.

TAM IV Micro XL Microcalorimeter for next-generation battery development

Light, compact batteries power much of today's world and they hold the key to the transition away from fossil fuel dependence. Cost and performance improvements in battery technology continue to drive the need for better, more sensitive measurements.

The new TAM IV Micro XL is a powerful isothermal microcalorimeter (IMC) specifically designed to give researchers a better understanding of battery discharging and charging dynamics, including the precise mechanisms of "parasitic reactions" that shorten battery life.

It is the only sub-microwatt calorimeter capable of addressing a wide range of battery types for use in medical devices, consumer electronics, automobiles and aircraft/spacecraft. Researchers will now be able to access critical information for an array of applications, and develop safer, more powerful and longer-lasting batteries.

VALUE ADD

Novel excipient regulation in China

Cloris Tian, Senior Regulatory Manager, APAC, Shanghai, China **Yuwei Heinzel**, Head of Pharma Registration Germany, Merck KGaA, Darmstadt, Germany writes about the opportunities and challenges for the pharmaceutical industry in the face of new excipient regulations in China

CHINA IS currently one of the most promising pharmaceutical markets. However, the outstanding opportunities are accompanied by substantial challenges for companies who want to manufacture, import or sell drugs in China. New regulatory requirements are leading to important changes, especially regarding excipients used in drug manufacturing. In fact, Chinese excipient regulation is a globally unique situation.

With a population of 1.4 billion and an ageing society, China is a highly attractive market for pharmaceutical companies. To keep pace with the demographic developments and the ever-growing needs in the healthcare sector, the Chinese authorities have issued major reforms over the past decades. The most recent ones have already significantly increased regulatory efficiency and transparency, while to some extent also resulting in better alignment with international standards.

Cloris Tian, Senior Regulatory Manager, APAC, Shanghai, China

Yuwei Heinzel, Head of Pharma Registration Germany, Merck KGaA, Darmstadt, Germany

A globally unique situation for excipients

In August 2019, the China Drug Administration Law was revised; the changes went into effect on 1st December 2019. This law aims at enhancing drug safety and improving public health. Although it includes most of the previous reform outcomes, keeping pace with the constantly evolving regulatory requirements remains an enormous challenge, and efficiently planning and implementing all necessary steps is a major undertaking.

As far as excipients for the use in drug manufacturing are concerned, the situation in China is unique: no other country has higher regulatory requirements for excipients. Every single excipient used in drugs sold on the Chinese market, including those used in imported goods, must be registered – a huge challenge, especially for players who are not familiar with the Chinese regulatory system. Whoever wants to manufacture and market pharmaceutical products in China, needs a partner with long-standing expertise in regulatory affairs and experience with Chinese authorities and business practices. This said, it is helpful to cast a glance at the milestones of the current regulations.

The evolution of excipient regulation in China

2001 marked the starting point of the regulatory focus on excipients. Article 11 of the Pharmaceutical Administration Law stipulated that excipients used for pharmaceutical production should meet the requirements for medicinal use. This very general wording led to quite inconsistent approaches. Some Chinese provinces regulated excipients as APIs, while others did not regulate them at all. In 2005, the China Food and Drug Administration (CFDA) issued the Pharma Excipient Dossier Requirements for industry, proposing excipient registration according to the same process as APIs with a standalone review by the Centre of Drug Evaluation (CDE) for import and novel excipients, and by the local FDA for excipients described in the Chinese Pharmacopeia (ChP).

In the following years, China's pharmaceutical industry developed rapidly, resulting in a broad range of new, improved medical products. However, the approval process could not keep pace and had to be supplemented and improved on numerous occasions. Prompted by a substantial backlog in drug review, the Chinese State Council initiated reforms to enhance transparency and efficiency of both the drug and the excipient approval process. Apart from increasing the number of reviewers from the previous 100 to approx 800, the review scheme for excipients was revised substantially, changing from the stand-alone review to a bundling review scheme first, which was followed by the current co-review process.

In addition to these developments, the Chinese regulatory authorities also engaged in an intensive exchange with the US Food and Drug Administration (FDA), the respective EU authorities and the European Directorate for the Quality of Medicines & HealthCare (EDQM). Moreover, China has been a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) since 2017. The implementation of the ICH guidelines in China is an ongoing process.

The co-review process for excipients

The co-review process went into law in December 2017. According to CFDA announcement No. 146, all pharmaceutical excipient manufacturers or owners, domestic or foreign, must submit their dossiers to the CDE. After a successful completeness check, a registration number is created on the CDE registration platform. The registrant can then issue a Letter of Authorization (LOA) to its customers, i.e. the drug manufacturers, for their respective drug application. In fact, the drug manufacturer or owner can only submit an application if it provides valid registration numbers for all excipients used.

After successful submission by the drug manufacturer, the CDE starts the assessment process. The applicant must answer questions regarding the product and is informed if there is a deficiency letter for the API, excipient or packaging material. If so, the CDE contacts the respective excipient registration owner. Once this assessment has been finalised, the drug manufacturer receives approval. At the same time, the status of the co-reviewed excipients is changed to 'Active' on the CDE platform.

In the first quarter of each year, pharmaceutical excipient manufacturers must submit annual reports to the CDE in order to keep their registration number active. If certain excipients have already been successfully registered in the context of previous drug reviews and have maintained their registration number, there may be no need for a new review and the NMPA (previously CFDA) can use the excipient registration data directly. However, another technical review may be necessary if the CDE decides that the use of the excipient has changed.

Dossier requirements and pharmacopoeia compliance

Just like the individual process steps, the content of the dossier must fulfil very specific requirements. General information on the company and the excipient itself, such as its

name, structure, characteristics, approval and usage information, must be included in the registration dossier. Detailed information on the manufacturing process is also required, together with a list of equipment and process validation data. Finally, the dossier must comprise quality control specifications with descriptions of the analytical and validation methods.

The level of detail required for the registration dossier is based on the excipient classification as revised by the NMPA in July 2019. Excipients are classified into products with or without a history of use in approved drugs. The latter includes completely new molecules, as well as molecules with simple changes to their structure or a changed route of administration. Products with a history of use are in turn divided into two groups: excipients that are included or not included in the Chinese Pharmacopeia (ChP) or the pharmacopoeias of the European Union, the United States, Great Britain or Japan.

As confirmed in announcement No 56, which went into effect on 15th August 2019, the NMPA has also identified low-risk excipients that are exempted from mandatory registration. Among these exemptions are corrigents, like sweetening agents, colourants or pH adjusters. However, the final decision on whether a certain excipient needs to be registered must be confirmed by the CDE and depends on its use in a given drug formulation. In general, all excipients used in drugs for the Chinese market must be compliant with the ChP, as stipulated in the Chinese Pharmaceutical Administration Law issued in 2019. The current ChP edition includes 270 excipient monographs. The goal for the 2020 edition is to add another 100 excipient monographs and to promote the harmonisation with other national pharmacopoeias in the European Union, the United States and Japan.

Seizing the Opportunities

The reforms made over the past years have led to a much more efficient and transparent excipient registration process. In addition, the recent regulations have started to harmonise the registration procedure with international standards. Now both domestic and foreign companies are subject to the same registration requirements. And, most importantly, all companies have an equal opportunity to tap the potential of the Chinese pharmaceutical market. However, some challenges remain: as there was no transition time, many excipient manufacturers now lack the technical dossiers they need for successful registration. As a result, many drug manufacturers cannot yet register their products in China. Finally, the ChP has not yet been fully harmonised with other international compendia, which forces global pharmaceutical companies to perform additional comparisons of methods and cross-validation checks.

The co-review process requires a firm command of the Chinese language and familiarity with Chinese business practices. It is therefore highly recommended to work with an agent in China, as the relevant dossiers and the registration platform are only available in Chinese. In addition, close cooperation and clear communication between the excipient manufacturer, the drug applicant and the CDE are essential to understand the complex requirements and foster an efficient process. Nevertheless, the fast-growing Chinese pharmaceutical market is highly attractive and holds tremendous potential. Together with an experienced partner, these challenges can be overcome. The results are both rewarding and achievable.

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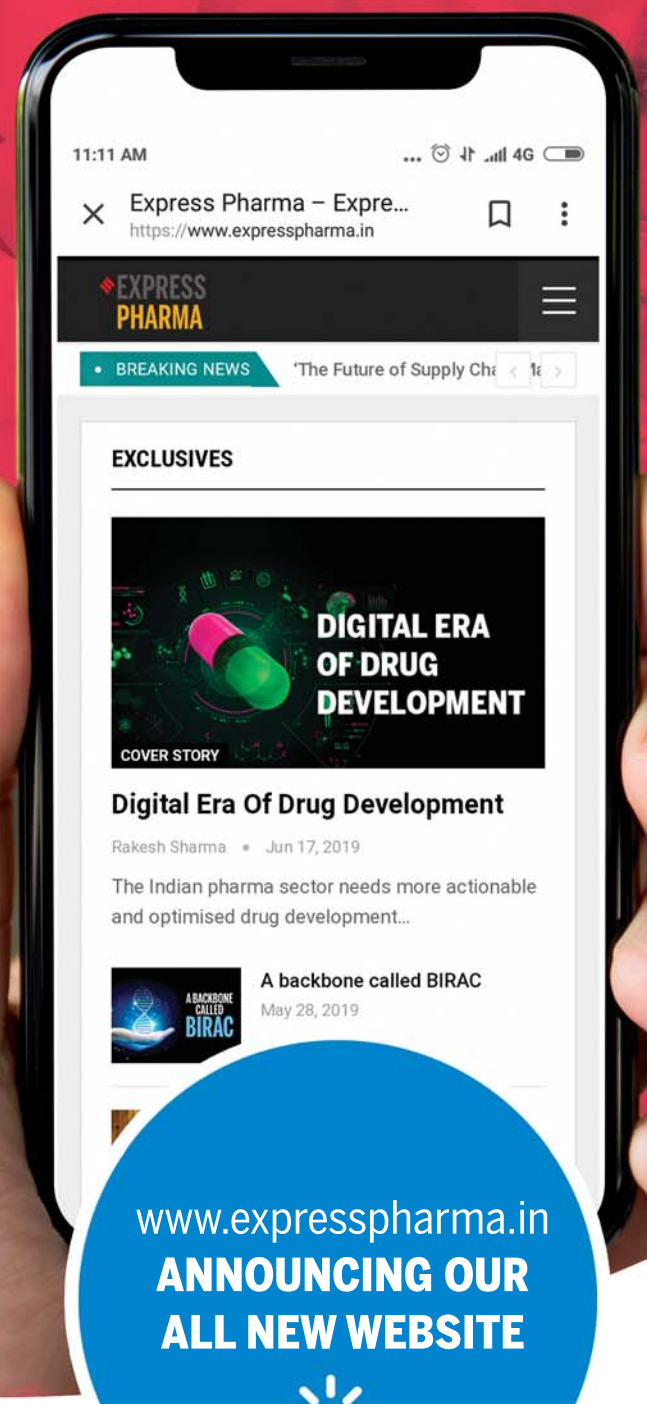

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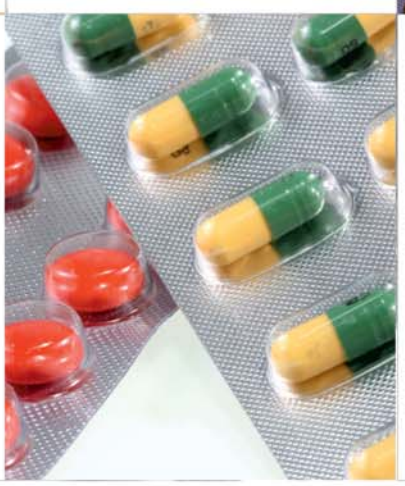

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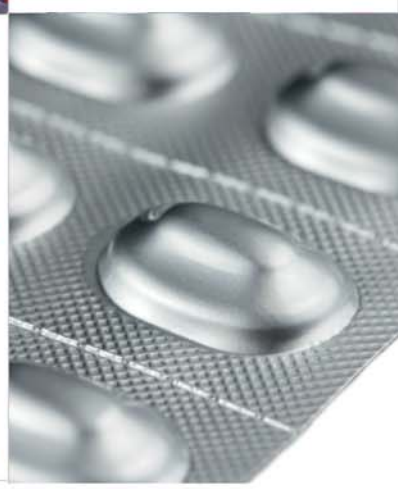

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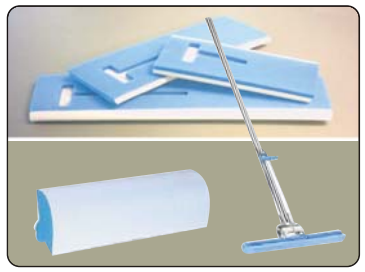

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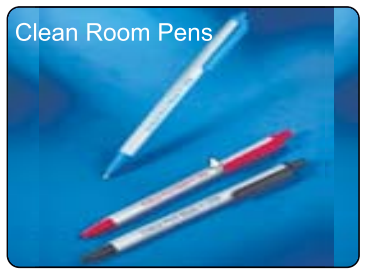

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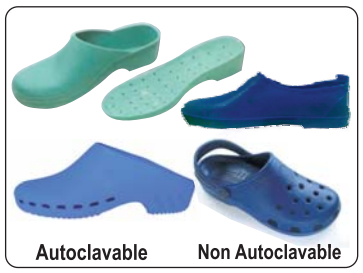

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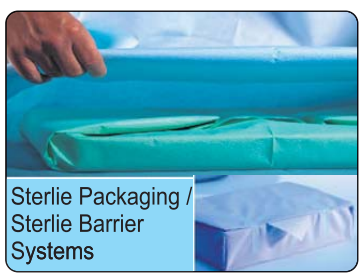

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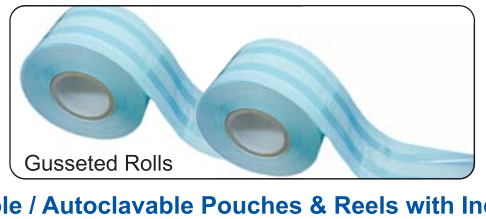

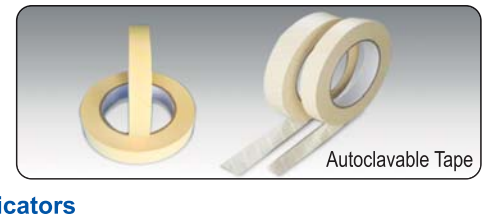

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Sharad Tyagi appointed as President of OPPI

Sharad Tyagi is the Managing Director of Boehringer Ingelheim India and has also been a Vice President and Executive Committee of OPPI for the last ten years, heading important Work Groups & Committees for OPPI

The Organisation of Pharmaceutical Producers of India (OPPI), which represents the research-based pharmaceutical companies, has appointed Sharad Tyagi as President for a period of three years, with effect from April 01, 2020. Sharad Tyagi is Managing Director, Boehringer Ingelheim India and has also been a Vice President and Executive Committee of OPPI for the last ten years, heading important Work Groups & Committees for OPPI. He takes over from A Vaidheesh, Managing Director, India, Glaxo SmithKline Pharmaceuticals, who has been OPPI President for the past three years.

Welcoming Sharad Tyagi as President, A Vaidheesh the outgoing President, said, "While I continue to be a part of the industry that positively impacts human lives, it is time to pass on the baton. I welcome Sharad as the new President and under his leadership I am confident that OPPI will continue to advocate for patient-centred policies that are focused towards building a healthier India through access to Innovation. Spending three decades of my life in this industry, I feel privileged to be associated with an industry that truly transforms human lives. The pharmaceutical industry, with its share of challenges, also provides several opportunities for economic, social and healthcare reforms. Over the past three years, we at OPPI have worked towards building a patient-driven healthcare ecosystem while advocating for innovative healthcare financing

models; robust OTC guidelines; collaborative PPP models with States and several other initiatives that aim to improve access to medicines in the country. I will continue to be part of this ecosystem and will be always available for guidance to my colleagues and friends at the OPPI."

Speaking on his appointment, Tyagi, President- OPPI said, "I would like to thank Vaidheesh and my colleagues on the Executive Committee and I am excited to be a part of this transformational healthcare journey. Expanding healthcare access; fostering research and innovation and leveraging health data are the three emerging patient-centred themes. The research-based pharmaceutical industry continues to play our role in reimaging India's healthcare landscape as we remain committed to our purpose which is to bring newer and better medicines to every citizen of the country. I believe we at the OPPI have clear priorities and along with the OPPI Secretariat led by KG Ananthakrishnan, Director General, OPPI, we will together work towards serving our patients and strengthening our approach of Health meeting Hope."

Sridhar Venkatesh appointed as MD and VP of GSK India

Venkatesh is a senior business leader with more than 24 years of diverse experience in pharmaceuticals and healthcare and has a strong track record of success in multiple roles within GSK

SRIDHAR VENKATESH has been appointed as Managing Director and Vice President of GSK India effective April 1, 2020. He succeeds Annaswamy Vaidheesh who will retire from the Company effective March 31 2020.

Venkatesh is a senior business leader with more than 24 years of diverse experience in pharmaceuticals and healthcare and has a strong track record of success in multiple roles within GSK.

He joined GSK in 2011 as Head of Commercial, Established Products, Branded Generics, and moved as General Manager, Singapore before taking up the role of Commercial Head, India from 2014 to 2016. He was then promoted as VP of Central America & Caribbean before taking the current role as Vice President, Emerging Markets East with direct management of six markets (Philippines, Vietnam, Thailand, Malaysia, Indonesia, and Sri Lanka). Venkatesh is a Registered Pharmacist, with a Master's in Pharmacy (Pharmaceutical Marketing).

Commenting on the appointment Renu Karnad, Chairperson of the Company said, "I warmly welcome Sridhar to lead GSK in our next phase of growth to serve the patients of India. I would also like to take this opportunity to thank Vaidheesh for his leadership during the last five years. Vaidheesh has represented the company with great skill and has helped GSK India become a positive force for change on many important matters. I am grateful for the excellent counsel and support he has provided to the Board. I wish him success in all his future endeavours."

Takeda appoints new Area Head for India, CIS, Middle East, Turkey, and Africa

Dr Mahender Nayak will lead the company's operations from Dubai, United Arab Emirates (UAE), where he will be based

TAKEDA Pharmaceutical announced the appointment of Dr Mahender Nayak as Area Head for the Company's ICMEA (India, CIS, Middle East, Turkey, and Africa) Area. In his current capacity, Dr Nayak will lead the company's operations from Dubai, United Arab Emirates (UAE), where he will be based.

Dr Nayak has more than 20 years of performance-driven leadership experience in the biopharmaceutical industry, having worked in multinational and regional companies. Before this role, he oversaw Portfolio Management for Takeda's Growth and Emerging Markets Business Unit based in Singapore (2018 to 2020). Prior to that, Dr Nayak was the General Manager of Takeda's operations in Korea.

Commenting on his new role, Dr Nayak said, "This is an exciting time to move to a part of the world that is teeming with great opportunities to increase patient access to Takeda's highly innovative medicines. We aim to do this through our commercial activities and commitments around our approaches to Access to Medicines across rare diseases, oncology, neuroscience, and gastroenterology."

Across ICMEA, Takeda collaborates with governments and regulators, to ensure that its diverse portfolio of innovative medicines is made available to patients as quickly and safely as possible.

"These countries are open to innovation and partnering with world-leading R&D-led organisations like Takeda. Our diverse talent across the company's presence in over 82 geographies bring many different experiences, backgrounds, cultures, and perspectives that help drive health innovation and ultimately benefit patients. This can only be done by nurturing and developing the best talents and ultimately becoming an employer of choice", added Dr Nayak.

Dr Nayak started his career as a physician in Bangalore, India and has an MBA in Marketing. He joined Takeda in 2011 and, since then, grew within the company to hold various senior international and regional roles.

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COREL House, Opp. Bhagwat Petrol Pump, Gota, S.G. Highway, Ahmedabad - 382 481, Gujarat, INDIA
Tele: +91-8000880011 / 22 / 33 | **E-mail:** corel@corelpharmachem.com,
marketing@corelpharmachem.com | **Website:** www.corelpharmachem.com

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