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Contents

The Old Order Changeth: Women CEOs at Foreign Firms In India Chart New Course

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Executive Summary

Foreign firms including Merck KGaA, Boehringer Ingelheim, Takeda and Sanofi's vaccines business are being led by women in India, a fiercely competitive, largely out-of-pocket market. There's a lot riding on these female leaders as they seek to drive business growth and potentially change the paradigm around the gender gap in pharma at the top.

More women are moving into the corner office in pharma in India, with Merck Specialities Pvt. Ltd, the healthcare business of Merck KGaA emerging as the latest foreign firm that will be steered by a female executive in the country.

Company long-timer Pratima Reddy was appointed as managing director of Merck Specialities effective 1 August, emerging as the first woman CEO for the group's healthcare business in India.

Reddy's elevation comes after a relatively "rough year" amid the COVID-19 pandemic, with the company deciding on a strategy "refresh" to sharpen the focus of its teams and drive sustainable growth across its franchises.

"Four global strategic priorities underpin our refreshed approach: growing our core business, maximizing launches, leveraging digital to drive growth and harnessing the power of our people and culture," Reddy told Scrip.

Last year Merck launched in India its advanced infertility treatment Pergoveris Pen, a ready-to-use combination treatment option for women with severe follicle-stimulating hormone and luteinizing hormone deficiency, as also the Pfizer Inc.-partnered checkpoint inhibitor Bavencio (avelumab).

On Sustaining Oncology Momentum, Product Launch Plans

Merck's Pratima Reddy: The Indian market focus is slowly leaning more towards other sectors, and one such extension is oncology.

With multiple lifestyle changes, the cancer diagnosis rate in the country today is exceptionally high compared to previous years' data. With an increased cancer burden on health systems and high unmet medical needs, Asia Pacific sees considerably high cancer mortality rates.

As early innovators in immuno-oncology and precision medicine, Merck continues to take a biology-focused approach as we develop our portfolio and pipeline.

Our newest drug Bavencio launched last year in our oncology therapy unit, is already making a difference in patients' lives. Bavencio is co-marketed by Merck and Pfizer in India and globally. We are building conviction through in-market activities - global expert meets, peer-to-peer meets reached an all-time high this year (engaging more than 2,000 doctors). With the increasing unmet need of Indian cancer patients, the launch of Bavencio is a beacon of hope for many patients in India.

This gives us the confidence to look at indications that require globally successful therapies. We are always looking for opportunities to bring global brands to India. We focus on enhancing access to our portfolio of medicines across the country. With a renewed mission post-COVID, we are now designed to amplify each therapy area's strengths. There are ongoing conversations around bringing some immunotherapy drugs to India because there is such a need that stands out in the country.

Within the fertility portfolio, Merck was also working in India to develop a new "digital health ecosystem" that can help patients "feel more involved, and better taken care of, throughout their fertility journey," Reddy's predecessor Anandram Narasimhan had told Scrip at the time. (Also see "Merck KGaA Stepping Up In India, Eyes On Bavencio Trajectory" - Scrip, 6 Sep, 2021.) (Also see "Interview: German Merck Set For Big "Leap" In India" - Scrip, 26 Sep, 2016.)

Reddy indicated that several organizational changes and a new operating model to support the life science business sector's long-term growth strategy better serve its customers' evolving needs are being implemented.

"Science and technology are advancing at an unprecedented speed, and with that are the needs and expectations of our customers worldwide. A suitable operating model will accelerate the ability to provide customers with the best products and services," she added. Reddy had in a previous stint led the turnaround of the oncology business in the country by demonstrating the opportunity to drive strong growth via focused access strategies.

Within the German group, Reddy's new role perhaps isn't viewed as too unusual. Merck KGaA has been an industry outlier of sorts and is led by CEO Belen Garijo, who is also chair of the executive board. At the time of her moving to the helm last year, Garijo was reported as being the only solo woman chief of a company that's a constituent of the DAX, the German blue chip stock market index. Jennifer Morgan, co-CEO of software company SAP was the other woman chief, but had a short stint at the helm. (Also see "Changing Of The Guard At Merck KGaA With Garijo Succeeding Oschmann As CEO" - Scrip, 29 Sep, 2020.) Garijo is among the few female pharma CEOs at big pharma alongside GSK plc's Emma Walmsley.

Other Women Leaders In India

Back in India, though, Reddy isn't the only female chief to helm a foreign biopharma firm. German peer Boehringer Ingelheim, Takeda. and Sanofi's vaccines business all have women at the helm. Several Indian pharma firms too have women leaders who have proved their mettle over the years. (see chart - not an exhaustive list).

Women At Pharma's Helm In India

Company	Executive	Leadership Role
Merck Specialties	Pratima Reddy	Managing Director
Boehringer Ingelheim	Vani Manja	Country Managing Director for India
Takeda	Serina Fischer	General Manager India
Sanofi	Annapurna Das	Head of Vaccines, Asia
Sanofi India	Preeti Futnani	General Manager – Vaccines*
Roche India	Lara Bezerra	Managing Director#
Cipla	Samina Hamied	Executive Vice Chairperson
Lupin	Vinita Gupta	CEO
Biocon	Kiran Mazumdar -Shaw	Executive Chairperson
Indoco Remedies	Aditi Kare Panandikar	Managing Director
Piramal Group	Swati Piramal	Vice-Chairperson
Piramal Pharma/Piramal Enterprises	Nandini Piramal	Chairperson/Executive Director

*Futnani succeeded Annapurna Das, who was elevated as Sanofi's Head of Vaccines, Asia

#Bezerra led Roche India from Nov 2017 to 1 Dec 2019; V Simpson Emmanuel now heads Roche Pharma India as CEO & MD

Boehringer Ingelheim's country managing director for India, Vani Manja, who took over the reins amid pandemic turbulence in 2021, had to hit the road running, steering the group's growth efforts while fending off patent challenges to Jardiance (empagliflozin) and Trajenta (linagliptin) alongside. (Also see "Boehringer Ingelheim Primes For Top Five Multinational Slot In India" - Scrip, 28 Mar, 2021.)

Takeda's general manager (India), Serina Fischer, too likely has a lot on her plate as she strives to build momentum with a mix of new products like the gut-selective biologic, vedolizumab (available as Entyvio internationally) as also drawing on the ex-Shire PLC range of therapies in the largely out-of-pocket Indian market. (Also see "Takeda Expands Hemophilia Play In India But Hemlibra

Has Made Inroads" - Scrip, 20 Jun, 2022.) (Also see "Takeda Introduces Vedolizumab In India Amid Signs Of Gear Shift" - Scrip, 13 Jul, 2020.)

2022 also saw Sanofi transition Preeti Futnani, its franchise head for Dupixent dermatology in the Greater Gulf MCO (a cluster of six countries including Saudi Arabia, UAE, and Kuwait), as general manager, vaccines, in India.

Futnani, who moved into the top India position in June, began her tenure in Sanofi over six years ago in Specialty Care Gulf, after stints of increasing responsibility at Novartis in marketing and commercial operations across Switzerland, the UK, and India. She succeeded another female leader, Annapurna Das, who was elevated to Head of Vaccines, Asia, at Sanofi.

Diversity in the Biotech Industry

Ideally, women moving up to helm pharma in India or elsewhere shouldn't really make headlines – talent should not to be determined by gender, color, race or ethnic background.

But biopharma as a whole, still has considerable ground to cover to improve gender representation and ensure that women have a truly level playing field when it comes to top jobs. The gender pay gap is another key area that warrants more efforts across the board. (Also see "Mind The Gap: UK Gender Pay Report Is Time Bomb For Pharma" - Pink Sheet, 12 Mar, 2018.)

For instance, BIO's third annual report "Measuring Diversity in the Biotech Industry: Tracking Progress in Small and Large Companies" noted that gender representation of employees in the latest sample achieved near parity — companies reported that 49% of their total employees are women versus 51% men. (Also see "BIO 2022 Notebook: Future Directions For R&D" - Scrip, 16 Jun, 2022.) (Also see "Gender Diversity In Pharma: Caught Between Desire And Reality" - In Vivo, 11 Dec, 2019.)

However, the representation of women continued to decrease at higher levels of an organization — only 34% of executive teams and 20% of CEOs were reported to be women, the findings from the voluntary survey of 99 BIO member companies from November 2021 to January 2022 indicated. In the 2020 sample, closer to one in four CEOs (23%) were women.

The report also affirmed that a key policy that continually emerges as vital to diversity, equity and inclusion progress is pay equity; undertaking a pay equity analysis helps "correct for past bias in compensation decisions", as pay gaps often show up for women and employees who are not white, it noted. In terms of actually moving to action, 77% of large companies and 44% of small companies had taken steps to ensure pay equity, the report noted.

But most large companies now appear to be making earnest efforts to bridge the gender gap. In India, multinational companies such as GlaxoSmithKline Pharmaceuticals Ltd. have made notable strides in nurturing women leaders.

GSK told Scrip that the pandemic allowed it to "pause for purpose" and re-imagine the charter to draft a roadmap for women in India.

The company's Women's Leadership Initiative Employee Resource Group, now in its new avatar, plays a pivotal role to strengthen inclusive culture and increase leadership accountability by focusing on three pillars: culture, capability and careers. "Through KPI-led periodic reviews, leadership-led interventions and a rapid feedback loop, the team aspires to elevate the experience of women at GSK," it explained.

GSK's Women's Leadership Initiative (WLI), which is chaired by Dr Rashmi Hegde, executive vice president – medical affairs, is working to amplify the firm's efforts to be a "disruptive

innovator, trustworthy employer and happier workplace" through strengthening an inclusive culture and increased leadership accountability; 66% of the WLI team is represented by women across all levels and functions.

Some of the key milestones achieved over these years include the elevation of two India women leadership team members to critical regional and global roles in GSK, while current gender representation stands at 12% with a slight increase observed amongst commercial teams in the Indian arm of the UK multinational.

More widely, 21% of the India leadership team in GSK Pharmaceuticals are women, while in senior manager and above positions 23% are women; 18% of the new hires in the company are women (year-to-date July 2022).

On whether the WLI also looks into gender pay gap issues, GSK said that human resources team does this exercise annually to analyze and addresses any gaps with support from the chief human resources officer and business leaders. "The consolidated outcome is reviewed at the leadership team level."

Indian firms too are acting in the area and some have laid out ambitious plans. For instance Dr. Reddy's Laboratories Ltd., the only Indian pharma company to be featured on the Bloomberg Gender-Equality Index 2022, aims to have at least 35% women in senior leadership (3X from current levels) by 2030 and achieve gender parity for the organization by 2035. Of the firm's 20,122 permanent employees, 2,327 are currently women.

Women Leaders Demonstrate Game-Changing Ideas

While most of the gender partity plans are work in progress, the arrival of leaders like Reddy, Manja, Fischer, Futnani and Das reinforce that "the times they are a-changin", if one were to borrow from legendary folk singer and writer Bob Dylan's iconic title track.

Merck's Reddy stated that women today are altering "traditional practices" by introducing a diverse approach to face challenges head-on and promote growth and as a result, they are proving to be the "game changers" in reinventing leadership globally.

"Today I see my peers demonstrating game-changing ideas and services in some of India's top pharma and healthcare companies," she told Scrip.

She encourages women aspiring to move up the corporate ladder to take risks by focusing on their strengths, "staying their authentic self" and also rallying to create an impact that would matter to the community and future generations.

"We will hopefully see more women emerge in this sector and make a difference in the lives of millions," she declared.

BI's Manja had similarly noted that the gender gap issue is not just an India or pharma challenge but a truly global one and while progress had been made in the last couple of decades, it is "woefully short" of the balance that is needed to harness the full potential of talented women in the workforce and in society.

"Much work needs to be done and this is a conversation that we need to keep going," she told Scrip in an interview in October last year. (Also see "B-Ingelheim India Chief On Strategy, Jardiance Challenge, Gender Balance In Pharma" - Scrip, 27 Oct, 2021.)

Manja urged women leaders to be their best advocate and not limit possibilities because of "how others may perceive you".

"Don't ever sell yourself short. Seek, take and own your seat at the table with confidence, not

apology," she underscored at the time.

While these words of advise augur well and several firms are making concerted efforts to increase the gender diversity of senior ranks, COVID-19 has thrown up new challenges in retaining women in the workforce as they struggle to balance work/life arrangements and shoulder additional responsibilities in the new normal way of life.

A McKinsey study indicated that pre-COVID-19, women in corporate America had slowly been making some progress in the workplace across industries. Between January 2015 and December 2019, the number of women in senior-vice-president positions rose from 23 to 28 percent, and in the C-suite from 17 to 21 percent.

But the pandemic has dealt a huge blow with one in four women considering exiting the workforce or downshifting their careers versus one in five men. "While all women have been impacted, three major groups have experienced some of the largest challenges: working mothers, women in senior management positions, and Black women," McKinsey said in an article last year.

Hopefully as the pandemic recedes, more women will opt to rejoin the workforce and progress their careers, traditional and new barriers notwithstanding.

India Physician Conduct Rules Want Them Off Pharma-Sponsored Symposia

Joseph Haas
01 Dec 2022

Executive Summary

Wider-ranging new draft rules suggest that physicians in India should not engage in educational activity sponsored by pharma and urges them to declare financial earnings and benefits received from industry via an affidavit. The Pink Sheet discusses with industry experts some of the nuances and seeming loopholes in the rules, currently in self-regulatory mode but with penalties proposed for violation.

India's new rules pertaining to the professional conduct of Registered Medical Practitioners (RMPs) puts a question mark on the participation of physicians in pharma-sponsored conferences and urges them to come clean about their relationship with industry. The wide-ranging rules cover a gamut of areas including guidelines on social media conduct of RMPs and telemedicine, and also prohibits endorsement of products.

The National Medical Commission (NMC) Registered Medical Practitioner (Professional Conduct) Regulations, 2022, currently in draft form, specify that RMPs should not be involved in any third-party educational activity like continuing professional development (CPD) programs, seminars, workshops, symposia or conferences which involve "direct or indirect sponsorships" from pharmaceutical companies or the allied health sector.

The rules maintain that physicians should be "aware of the conflict of interest situations that may arise" and that the nature of these relationships should be in the public domain and not contravene any law, rule or regulation in force.

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Social Media Conduct

The National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2022 also provide guidelines on social media dos and don'ts.

Among a range of suggestions, the guidelines say that while RMPs can provide information and announcements on social media, this should be factual and such that it can be verified. The information should not be "misleading or deceptive, nor should it exploit the patient's vulnerability or lack of knowledge."

In what's probably a reflection of the far-reaching impact and tactics on social media, the guidelines also underscore that RMPs should not directly or indirectly purchase "likes, followers" or pay money so that search algorithms "lead to their name being listed at the top" or registering on software programs (apps) that charge fees for higher rating or soliciting patients.

Physicians also should not share patient testimonials or recommendations/ reviews/endorsements on social media, the regulations add. RMPs also need to distinguish between social media and telemedicine consultation, the rules specified, setting out a range of norms for the practice of telemedicine in India.

"An RMP himself or as part of any society, organization, association, trust, etc. should be transparent regarding the relationship with the pharmaceutical and allied health sector industry," state the rules, which are open for comments until 22 June.

Delinking Pharma From Conferences Unrealistic?

While the transparency requirement is clearly the way forward, industry experts maintain that keeping pharma out of the medical conferences equation is impractical.

Ranjit Shahani, ex-vice chairman and managing director of Novartis India Ltd., said that "reasonable" efforts are made on RMP capacity-building, awareness and educational initiatives, and also highlighted the rapid pace at which innovations happened over the past two years itself – mainly attributed to COVID-19.

"Therefore, restricting RMPs from being involved in educational seminars, symposia, CPDs etc. will significantly impact the ecosystem. Also, how do you expect these programs to run/ sustain without the support of pharmaceutical companies or allied sectors?" Shahani said in comments to the Pink Sheet.

The industry veteran noted that India doesn't really have independent, "financially well-backed-up" associations, R&D set-ups or academia to sponsor such programs.

"It's unrealistic to delink participation of pharma companies/ allied sectors from such programs. In fact, it's the sector's responsibility to operate such programs on a larger scale and RMPs be involved in these activities," he declared.

Others mirrored similar views, but also pointed out that the NMC guidelines are essentially meant to be "self-regulatory and strictly ethical" in nature.

"It is quite difficult to believe that medical conferences and meetings will happen without sponsorship from pharma or allied health sector. This will mean that the associations will have to raise the money from their members," said Salil Kallianpur, a former executive vice-president at GlaxoSmithKline plc in India.

But Kallianpur believes that the fact the guidelines are not meant to be legal - and therefore not law and cannot be binding - provides a "neat little loophole" that can be used.

"I hate to be pessimistic but this is unlikely to happen in the near term as the transactional nature of relationship between pharma and doctors is quite strongly embedded," Kallianpur, who now runs a digital health consultancy, told the Pink Sheet. The National Medical Council's code of ethics is framed as a self-regulatory set of guidelines reflecting professional and social expectations.

Probably keeping that in mind, the guidelines in parallel recommend transparency and a declaration of lack of conflict of interest by physicians "as an option", the executive noted, adding that it is not a completely new section and has existed since the Indian Medical Council Regulations of 2002, which was then hailed as India's "Sunshine Act."

No Gifts, Travel Facilities

The draft rules also touch on the infamous gifts and hospitality component of the physician-pharma relationship. It specifies that RMPs and their families should not receive "gifts, travel facilities, hospitality, cash or monetary grants, consultancy fee or honorariums, or access to entertainment or recreation" from pharmaceutical companies, commercial healthcare establishments, medical device companies or corporate hospitals.

However, the norms specify that this does not include "salaries and benefits" that RMPs may receive as "employees" of these organizations – again seemingly a window for the consultant physician or then the medical associate role in pharma, which potentially can then be assumed to be beyond the purview of the rules.

Kallianpur believes that this is definitely a loophole, where a healthcare professional (HCP) may be "hired" as an advisor or consultant and a payment may be made by pharma or the allied health sector at "fair market value."

Ex-Novartis India chief Shahani maintained that if RMPs are involved in scaling up capacity building/educational efforts, then there should not be any restriction on "adequate" compensation.

"There could be some fair value guidelines which can be designed to ensure that companies or RMPs are not using such contracts to unfair advantage," he suggested.

Industry veteran and president and CEO of Danssen Consulting, Dr Ajit Dangi, noted that, as is seen in most pharma companies in India and in developed countries, it is a common practice to have doctors and disease specialists in a company's full-time employment as a part of its "medico marketing" team.

"One presumes that such professionals are exempted from these ethics guidelines, although appointing part-time consultants to play an advisory role is a grey area and needs to be specifically defined," Dangi, a former president and executive director of Johnson & Johnson in India, told the Pink Sheet.

Dangi also underscored that much depends on the "intent" when it comes to gifts, travel facilities and monetary grants to RMPs by pharma. For instance, if a KOL (key opinion leader) is invited to present a research paper on a particular new drug at a conference, as long as they present the data in an "objective manner" without mentioning the brand name and are compensated "modestly" for this professional service, "there should not be any problem."

"One way of solving this problem is to give funding to the conference organizers and the

organizing committee decides how to allocate the funds equitably to the presenters," the executive suggested.

However, it's unclear if such funding may be construed as indirect support, some industry observers said.

Affidavit On RMPs' Financial Earnings From Pharma

Strikingly, the rules also suggest that RMPs may be required to file an affidavit regarding their financial earnings and benefits received in the past five past years from pharmaceutical companies or the allied health sector.

While it's unlikely that the medical community will, in totality, be keen to fall in line with these suggestions, Shahani said that the norms are indeed a fair expectation.

"If rules regarding participation, engagement and consulting contracts are clear – then RMPs should be encouraged to be transparent regarding their financial earnings. Issue creeps in when there are restrictions on everything and people find alternatives to bend those rules."

For instance, the seasoned executive noted that if an RMP is engaged with a pharma company for a patient registry program or supports a CME (continuing medical education)/ educational activity for which they are being trained and can then be compensated for training a larger network of RMPs, "then what is there to hide?"

With the "right rules," expectations of transparency can be maintained and this will not be a "big operational hazard," he declared.

Kallianpur said that the affidavit requirement is perhaps the most important part of the guidelines from an implementation point of view and provided a distinct dimension on a potential snag.

He explained that the whole idea is about avoiding tax evasion and as long as doctors declare "what they receive from pharma and others, as taxable income [as proposed in the Finance Bill]," the government should have no problem with them.

"Filing an affidavit [to anyone other than tax authorities] will probably be seen as an additional activity and unless there is a sound reason in doing so, complying to this could be a problem," he added.

Dangi similarly believes the affidavit requirement for RMPs is a classic case of "over regulation" and is not only unlikely to pass muster with the medical community but is also "oblivious of the ground realities."

Endorsement Prohibition

Another part of the draft regulations calls for the prohibition of endorsement of "the product or a person" by a RMP, raising questions on whether this could imply that physicians aren't supposed to be talking about the benefits of a particular new drug/molecule.

Specifically, the rules suggest that RMPs shouldn't provide any "approval, recommendation, endorsement, certificate, report, or statement concerning any drug, medicine, nostrum remedy, surgical, or therapeutic article, apparatus or appliance or any commercial product or article with respect of any property, quality or use thereof or any test, demonstration or trial thereof, for use in connection with his name, signature, or photograph in any form or manner of advertising through any mode."

Nor should the RMP "boast of cases, operations, cures or remedies or permit the publication of report thereof through any mode."

Shahani believes such prohibition could pose a "risk" to the industry and the overall healthcare

ecosystem in general. “The issue is on drawing lines and understanding how ‘recommendation’ is different from ‘promotion/ endorsement,’ he commented.

He explained that most R&D-led companies do significant clinical, real-world evidence studies for their molecules and these are led by KOLs and physicians to understand safety and efficacy profiles - these are not only for new drugs but also mature molecules/fixed-dose combinations to understand different aspects.

“Physicians, RMPs should have the flexibility of analyzing such outcomes and publish them as part of research work undertaken by them, which is validated by external entities,” he asserted.

Such outcomes become part of broader practice network and help RMPs drive awareness-building across larger community of RMPs, practice improvement based on clinical evidence amongst different patient profiles and also share clinical case studies which form the basis of CME.

“Most patented drugs were successful in India over the past decade because companies and HCPs, KOLs put in effort and understand clinical cases to drive wider adoption amongst a broader set of generalist physicians,” the former Novartis India head pointed out.

Ex-GSK executive Kallianpur, however, said that the RMP guidelines could essentially mean that RMPs do not offer a testimonial like they do in a local advert for Sensodyne toothpaste - hence GSK clarifies that the said HCP practises in the UK.

“In India, doctors stay away from such endorsements anyway. I do not think that it will change how pharma engages with them because doctors can still talk about the benefits of a molecule as witnessed in their clinical practice. The sharing with other doctors via a CME or in a medical conference is done as a discussion about how the doctor treated a particular patient,” he observed.

He believes that as long as doctors stick to discussing the “disease, the molecule, the science and the general role in therapy and treatment,” they will not violate the NMC guidelines. Other industry experts said the guidelines need to clarify or come up with a kind of addendum on some of the nuances to avoid confusion.

Disciplinary Action

Breach of the guidelines could attract disciplinary action, which is structured into levels ranging from “reformation” at level one, all the way to debarring a physician permanently from practice under level 5, if they have committed wilful/intentional harm and an unlawful, prohibited action.

Levels 2, 3 and 4 could entail reformation or suspension of license to practice for specified periods.

The Ethics and Medical Registration Board has the power to draft guidelines on penalties for misconduct, including a monetary penalty among others, details in the rules suggest.

Needs Wider Consensus?

Meanwhile, Ex-Novartis India chief Shahani underscored that the new guidelines still require wider consensus amongst all stakeholder groups – including pharma companies and allied healthcare sectors - for them to be effective in implementation.

“In its current form, it restricts capability and awareness-building initiatives for RMPs/HCPs, platforms and forums of how the ecosystem can work more effectively; and therefore does not solve far larger issues around accessibility of appropriate treatment,” he asserted.

India Physician Conduct Rules Want Them Off Pharma-Sponsored Symposia

Parts of the guideline have also been mentioned in other rules such as the Uniform Code of Pharmaceutical Marketing Practices (UCPMP) guidelines that were released by the India's Department of Pharmaceuticals in 2015 and is currently voluntary in nature. (Also see "AdvaMed Launches Ethics Code To Meet 'Business And Market Realities' In India" - Medtech Insight, 28 Oct, 2021.)

‘Constantly Being Chased’: Cutting-Edge Gene Therapy Developers Moving Fast In China

Half US Price Still Too Costly?

Brian Yang
04 Mar 2022

Executive Summary

Plagued by a scandal which gained global attention a few years go, the gene therapy sector has recovered and is now thriving in China. But a drive for innovation, combined with ready cash for aspiring start-ups, may not translate into leaps and bounds in the field due to challenges unique to these latest treatments, including manufacturing, durability and coverage.

Eager to get ahead, gene therapy and gene-editing companies in China are now racing to secure funding and get their treatments in front of patients.

Given the promise these modalities potentially offer, it’s not surprising to see such a rush into the field. But China has its own challenges in the wake of a total ban on such experimental therapies in the country just three years ago.

In November 2018, He Jiankui, a researcher at China Southern University of Technology in Shenzhen, shocked the world with an announcement of the birth of the world’s first babies using gene-edited embryos. Such germline editing had long been considered a taboo no-go area for fear that such so-called “designer babies” would trigger a Pandora’s box of ethics concerns.

Three baby girls were born as a result of the experiment and, amid worldwide criticism and an ethics investigation, He was eventually sentenced to three years in prison.

Yet gene-editing technology has many scientists excited about its potential, especially the use of such tools as CRISPR Cas9 to treat rare and gene mutation-related conditions such as sickle cell disease and beta thalassemia.

Three years after the scandal, China’s gene-editing and gene therapy sector has rebounded and is now thriving. The speed of the recovery has been mesmerizing, even to industry insiders who observe developments daily. “I feel constantly chased,” noted Li Yun, head of research and development at EdiGene Inc, a leading gene-editing developer in the country.

Speaking at a conference on gene and cell therapy development in Shanghai on 24-25 February, Li said the general speed of progress had prompted the Beijing-based company to keep innovating around product development.

The Beijing Zhongguancun Hitech Park-based venture has teamed up with MIT and Broad Institute’s Feng Zhang and Zhang’s startup Arbor Biotechnologies to access Arbor’s CRISPR-based cell therapy targeting cancer. A additional deal with domestic cell therapy startup Neukio Biotherapeutics, founded by veteran Richard Wang, will explore allogeneic induced pluripotent stem cell (iPS) and chimeric antigen natural killer (CAR-NK) cell therapies.

Besides pipeline enhancement, developers are also looking to quickly build up clinical trials via a somewhat reluctant partner - physicians.

IIT: Same Bed, Different Dreams

Investigator-initiated studies have emerged in China as the best way to quickly provide much needed clinical data, but the practice in the country is still somewhat murky and can be a double-edged sword.

While China allows trials for experimental cell and gene therapies to be started by physicians or developers, regulatory agencies over health facilities the National Health Commission tightened its oversight after a controversial tragedy. Wei Zexi, a 21 year-old college student, died in 2016 after receiving an experimental DC-CIK treatment for his sarcoma at No.2 Armed Police Hospital, and the administration of such treatments was thereafter only allowed in qualified hospitals and physicians. (Also see “China Surprises With First CRISPR Trial Despite Regulatory Lag, Concerns” - Scrip, 25 Jul, 2016.)

Compared to novice start-ups, physicians at these nationally-recognized hospitals have easier access to patient pools and can start studies quickly. But one potential downside is also evident, in that some physicians have developed their own in-house cell therapies and so may not give equal attention to studies from these these developers.

Shanghai-based gene therapy company Belief Biomed Inc., founded by Xiao Xiao, a professor at North Carolina University in the US, become the first developer to obtain an investigational new drug approval for BBM-H901, a hemophilia B treatment in China, using a modified version of an adeno-associated virus (AAV) vector. The Shanghai firm has so far collected data from 10 patients over one to two years in an investigator-initiated study conducted at the China Hospital of Hematology under the China Academy of Medical Science. Only one participant has had any bleeding episodes.

These positive findings in turn helped Belief secure the IND and series B funding, after an initial financing round from leading venture capital partners including Qiming Capital.

But the Tianjin-based hospital was also conducting a trial with its own gene therapy for the same indication, disclosed Xue Feng, a hematologist who spoke at the Shanghai meeting. The physician-led study achieved similar, although not quite as good, results as Belief’s BBM-H901, Xue noted.

‘Constantly Being Chased’: Cutting-Edge Gene Therapy Developers Moving Fast In China

Ready Funding, Regulatory Support

With new gene developers now popping up quickly in China, funding is following. Belief’s Xiao told Scrip that the company, established only around five years ago, is now moving onto a series C financing.

The rush towards gene therapy in China is now so pronounced that even academics are leaping into the fray. Rao Yi, a renowned neuroscientist who graduated from the University of California San Francisco, founded a start-up, Grit Science, in September 2019 and has already secured CNY100m ($15.8m) in initial funding. Lead investors include the major domestic investment bank Renaissance Capital.

Meanwhile, more established gene therapy firms are speeding up their development pace to enter the clinic. Wuhan-based Neurophth Therapeutics, Inc. is leading the pack in developing a gene-based treatment for the rare eye disorder leber hereditary optic neuropathy, one among a range of ophthalmology conditions that have seen many companies flocking in following the approval of Roche Holding AG/Spark Therapeutics, Inc.’s Luxturna (voretigene neparvovec) for biallelic RPE65 mutation-associated retinal dystrophy.

Founded by Wuhan-based physician Li Bin, Neurophth secured CNY400m in a B round and soon afterwards obtained a further $60m in a series C funding, led by Sequoia Capital China.

Meanwhile, to accelerate the development of promising gene and cell therapies, Chinese regulators are moving to grant the green light to clinical studies. Swiss giant Novartis AG, for instance, has obtained approval to start a study with Zolgensma (onasemnogene abeparvovec) for spinal muscular atrophy in China. Already approved and marketed in the US and Japan, it is the first gene therapy for the devastating progressive neuromuscular condition.

Despite facing potential formidable competitors such as BioMarin Pharmaceutical Inc. and uniQure N.V., Belief’s Xiao is not deterred. China has a large population with rare bleeding disorders and the cost of standard treatments such as Factor XI and the routine infusions required to prevent bleeding episodes can cause a heavy financial burden on many hemophilia B patients.

Manufacturing, Durability Issues

Despite the favorable regulatory tailwinds, one potential lingering concern is the still strict controls in China over the collection, storage, import and export of genetic material samples. Extensive administrative approvals are required, which has delayed the inclusion of China in some multinationals’ global clinical studies.

The sweeping Chinese biosecurity law enacted in 2021 poses generally higher hurdles for overseas gene and cell therapy developers eyeing the market. (Also see “China Tightens Clinical Study Grip In Sweeping Biosecurity Law Proposal” - Pink Sheet, 26 May, 2020.)

On top of this and unlike small molecule drugs and biologics, individualized treatments such as gene and cell therapies also have one distinctive extra layer to take into consideration - manufacturing complexity.

Li Zonghai started his pursuit of a cell therapy for solid tumors such as liver cancer in China back in 2015, the chairman and CEO of CARsgen Therapeutics, which now has two cell therapies in clinical development in the US, said during the Shanghai meeting’s panel discussion, noting that China still lacks clinical data and practice in the field.

Only armed with long-term clinical data can patterns be identified, he stressed. While gene therapy is considered a one-time cure, there is still a lack of long-term efficacy, safety and durability results, the longest of which so far cover only a five-year span.

‘Constantly Being Chased’: Cutting-Edge Gene Therapy Developers Moving Fast In China

Deeming the “process is the product,” many Chinese gene developers say there is still a long way to go before catching up with their US counterparts, despite China now catching up quickly in terms of number of trials.

Even so, “don’t look at the figures, you have to look at the quality,” advised Richard Wang, founder of Neukio Biotherapeutics and former CEO of Fosun Kite Biotechnology Co Ltd told the audience. Many Chinese developers are still concentrating on single therapeutic targets such as CD19 and there is also a lack of an industry ecosystem.

Who Foots The Bill?

Although having two marketed cell therapies, China is nowhere near offering reimbursement to pricey gene-based treatments, even if these sail through the regulatory process in the next year or so.

The currently approved therapies, Yescarta (axicabtagene ciloleucel) from Fosun-Kite and Carteyva (relmacabtagene autoleucel) from JW Therapeutics Co., Ltd, are priced at CNY1.2m and CNY1.29m, respectively. This is still hefty for patients in China, despite these levels being around 50% cheaper than gene therapies in the US, underscoring a large reimbursement challenge ahead.

While similarly expensive treatments such as immuno-oncology antibodies have been covered by China’s vast but basic national health insurance scheme, cell and gene therapies won’t fit the same bill, stressed Wang. One distinguishing aspect is one-time use, which leaves no need for re-dosing or lifetime treatment, and so “pay-for-performance” should be incorporated into any coverage of such therapies in China.

“Values dictate the prices,” said another cell therapy development executive, JW Therapeutics CEO James Li.

Citing hemophilia as an example, Belief’s founder and chief scientific officer Xiao said gene therapies for rares diseases should be priced on their broader value. Many hemophilia patients in China are effectively handicapped due to the lack of timely treatment, he observed.

A one-time “cure” would offer long-term protection from bleeding episodes and reduce the need for blood factor infusions, he added.

Bayer’s Koenen: Decentralized Trials For Pivotal Studies Not ‘Black Or White Scenario’

Anju Ghangurde
31 Mar 2022

Executive Summary

A cross-section of biopharma experts including senior executives of Bayer, Boehringer Ingelheim and Accenture and US FDA Director at the India Office deliberate digitization and evolving trends in clinical research, including the potential of decentralized trials and metadata-driven automation.

High-profile industry experts and regulatory officials discussed, at a recent summit, a range of issues around trends in clinical trials including the role of digital technologies, metadata-driven automation and also real world data and predictive evidence in insight generation.

Addressing the annual summit of the Organization of Pharmaceutical Producers of India (OPPI), Dr Christoph Koenen, global head of clinical development and operations, Bayer AG indicated that clinical trials will remain a “cornerstone” of evidence generation of the future but with a shift to decentralized clinical trial (DCT) approaches.

“The whole idea of DCT as a concept is not going to change, but the technology you can use to successfully collect data in DCT is constantly going to evolve, and therefore going to change the pace of DCTs over the next coming years,” Koenen said at the virtual event.

Koenen also observed that while currently the acceptance of DCT-collected data for pivotal studies varies depending on “which regulator you talk to”, there is some skepticism around whether the data/end points collected using DCT has the same degree of quality as the traditional brick and mortar approach.

Bayer's Koenen: Decentralized Trials For Pivotal Studies Not 'Black Or White Scenario'

"That is the reason why you do not see right now completely DCT-run pivotal studies yet," declared Koenen, who took charge in his role at Bayer in January this year moving from Otsuka Pharmaceutical Co. Ltd., where he held the position of Chief Medical Officer.

Regulators have, on their part, urged industry to talk to them or others with experience with DCTs, and ensure that such dialogue occurs early.

Not A 'Black Or White Scenario'

Nonetheless the Bayer executive believes that as industry's experience and confidence with DCTs grow and evolve, their acceptance for pivotal studies will also increase.

"However, it might not be a black or white scenario where you will have a study that is done 100% brick and mortar and 100% DCT; we might find ourselves in a situation where we have a certain percentage of patients participating in the study by a DCT approach and then you might have certain percentage of patients that will participate in the study by a brick and mortar site," Koenen explained.

The advantage of having this flexible approach, he said, is that you can make the participation in the DCT approach dependent on a specific patient's "living situation - how is the access to technology/ data connection/home care - and you can take a very flexible approach."

Earlier McKinsey & Co noted that the shift of trial activities closer to patients has been enabled by a constellation of evolving technologies and services including tools such as electronic consent, tele-healthcare, remote patient monitoring, and electronic clinical-outcome assessments which enable investigators to maintain links to trial participants without in-person visits.

Digital Heath Technology - "Fit For Purpose"

Dr Sarah McMullen, director, US FDA India Office, touched upon aspects of leveraging different types of digital health technology (DHT) tools in the conduct of clinical trials.

McMullen urged sponsors to ensure that a DHT is "fit for purpose".

"This can mean asking and answering questions such as is the tool reliable and appropriate to that context? Is the data to be captured valid to the intended research question? Is the consent process adequate for describing the risks of the use of this technology to the participant? And can it also be ensured for traceability from end-to-end usage and its main consideration for data integrity," McMullen explained in the panel discussion at the OPPI summit.

In addition, the regulatory official also referred to cyber security risk, noting that most people have been probably impacted in some way in their lives by "some sort of cyber security risk or malfeasance in that area as well".

In December last year the FDA had introduced a draft guidance "Digital Health Technologies for Remote Data Acquisition in Clinical Investigations" ; it provides recommendations to sponsors, investigators, and other stakeholders on the use of DHTs to acquire data remotely from participants in clinical investigations evaluating medical products.

The guidance suggests that sponsors should ensure that the level of validation associated with the DHT is sufficient to support its use and interpretability in the clinical investigation. (Also see "FDA Draft Guidance Paves Way For Collecting Clinical Study Data Via Digital Health Technologies" - Medtech Insight, 22 Dec, 2021.)

Bayer's Koenen: Decentralized Trials For Pivotal Studies Not 'Black Or White Scenario'

The management consulting firm also indicated that the fully virtual model is gradually migrating from smaller, early-phase and post-approval studies towards larger pivotal trials.

"Nonetheless, in the near term, sponsors, investigators, and research-service providers expect fully virtual trials to remain limited to a narrow set of use cases, such as a well-characterized drug with few adverse events in a mild indication, with end points suited to remote measurement," McKinsey executives said in a June 2021 article.

Kailash Swarna, managing director and global leader, clinical development, Accenture Life Sciences, who moderated a session on "Disruptions and Digitization Trends in Clinical Research" at the summit, highlighted how COVID-19 catalyzed systemic changes in clinical development and organizations have been forced to lean into virtual methods, leading to an increase in competency and investment in digital health.

On DCTs, he put forth that if industry could engender "confidence" in terms of using technology appropriately, "imagine what we could do in terms of bringing more patients into the clinical trial landscape". Ultimately the goal, he emphasized, is to make clinical development and clinical trials part of the continuum of care.

"So we actually see that from clinical trials to the practice of medicine there is continuity on how we can bring treatments to patients."

The clinical trials segment has been fraught with challenges such as low trial participation and recruitment, poor engagement and retention and high costs. Data from Accenture suggested that 86% of clinical trials do not meet enrollment timelines while 30% of participants identified do not complete the study on average.

Balance Between Digital Innovation And Disruption

Significantly, though, panelist Dr Vijay Prabhakar, head of therapeutic area, clinical development and operations at Boehringer Ingelheim, emphasized that not every patient potentially "likes" DCT and it is important to understand that the choice at the end of the day lies with the patient and the investigators.

"We shouldn't sometimes assume that anything digital is going to reduce complexity, because sometimes digital could also increase complexity. This is where at some point in time, we need to strike a balance between what we need as digital innovation versus being too disruptive that it becomes inconvenient for the patients and investigators," Prabhakar said, among a string of other comments. Regulatory considerations pertaining to digital health technology were also part of the panel discussion.

The BI executive, though, sees a lot of untapped potential despite the pandemic, for instance "lot of future" in artificial intelligence speeding up adjudications, helping people adjudicate endpoints faster using radio mics. (Also see "Considerations For Using Established Versus Novel Endpoints In Decentralized Trials" - Pink Sheet, 18 Mar, 2022.)

"There are so many options that are still not being used," said Prabhakar, a physician trained in intensive care and emergency medicine.

Clinical endpoint adjudication is a standardized process for assessment of safety and efficacy of pharmacologic or device therapies in clinical trials.

The McKinsey article referred to previously also highlighted the need to balance the needs of each stakeholder group in DCTs and

provide them with a "positive, differentiated" experience. Patients, it noted, vary in their comfort with and access to technology and preferences for in-person physician visits versus visits by phone or video. "Patient-centric trial design is critical to mitigating such concerns. It can include, for example, patient training and support, user interfaces tailored to specific patient groups, and the option to choose between a decentralized arm and a conventional arm."

Asundexian Program

Meanwhile Bayer's Koenen also spotlighted the German group's clinical trial approach for the investigational drug asundexian, where it is utilizing various innovative approaches.

Asundexian is an oral inhibitor of Factor XIa being developed as a potential treatment for secondary prevention in patients with a non-cardioembolic ischemic stroke as well as for atrial fibrillation and recent myocardial infarction.

The global head of clinical development and operations outlined how the program has a certain percentage of patients in the US where the DCT approach is used. "We have an agreement with global regulatory authorities that we can use some percentage of patients in this program - we collect the data using the DCT approach."

The program has also used registries to identify patients that can potentially enter the study, therefore making sure that patients with the "right patient characteristic" are approached in order to be included in the trial, and "we do identify those patients in advance." The German multinational is also automating processes of the study "as much as we can" in order to improve the quality as well as the speed that it takes to conduct the trial, he added.

Asundexian is currently being studied in the PACIFIC Phase II clinical trial program that consists of three Phase IIb studies in over 4,000 patients with one of the three medical conditions: atrial fibrillation, a recent non-cardioembolic ischemic stroke or a recent myocardial infarction. It is being studied in all three indications either as a standalone therapy, or in combination with anti-platelet therapy. (Also see "Xarelto Still Climbs As Bayer Touts Successor" - Scrip, 1 Mar, 2022.)

Metadata Driven Automation

Koenen, who has held senior leadership positions in clinical development at GlaxoSmithKline plc, Novo Nordisk, and Bristol Myers Squibb Company along his career journey, underscored the value of using metadata-driven automation to increase efficacy in how trial processes are run; currently these involve significant manual work which is time consuming and also "introduces quality risk."

"If we standardize it, automate this as much as we can and automate the generation of different documents, be it part of the protocol, be it part of the study report, then the quality of documents that we produce will improve and the time it takes to produce these documents will be much less," he emphasized.

As technology evolves - artificial intelligence is expected to play a very important role – the ability to advance such efforts increase, he added.

Real World Data, Predictive Evidence

The Bayer executive also touched upon the growing importance of real world evidence, currently largely used to look at outcomes of different therapeutic approaches in a real world, mostly after drugs have been approved.

"What will happen is that the importance of real world evidence is going to increase and we will increasingly rely on real world evidence to make, for example, regulatory decisions around efficacy and safety as well."

Bayer's Koenen: Decentralized Trials For Pivotal Studies Not 'Black Or White Scenario'

He predicts that world is likely going to shift from a more traditional approach of using mostly trial evidence to make decisions to one that will use different kinds of evidence in order to make decisions. "In the future, real world data and predictive evidence [will] play an even more important role in the insight generation mix."

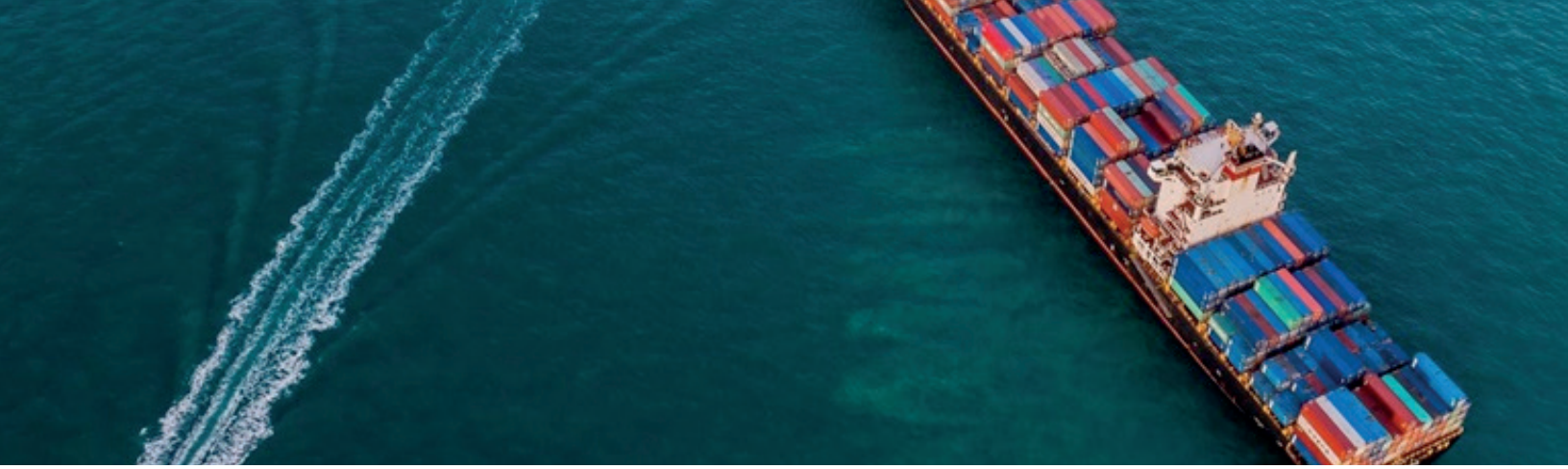
Koenen, however, cautioned that such evidence can only be used if "we are sure that we are collecting, processing, analyzing and interpreting all these different kinds of evidence appropriately, and we have to make sure that we have the systems in place in order to do that."

He also noted that with the use of digital technology in clinical trials alone, the volume of data industry is collecting is going to "explode" and referred to the example of home monitoring and having a patient wear three-lead ECGs (electrocardiograms).

"What if you have a patient wears this for a long, extended period of time? What if you start monitoring sleep, breathing pattern, pulse pressure in your clinical times and over a certain period of time.? Imagine the amount of data that you have to collect and store and process in order to do that."

Hence, it's important for industry to create advanced analytics and data ingestion platforms to handle that.

"So it's our ability to store and collect data and then the ability to process the data, and then make sure that we analyze the data in an appropriate way to draw the right conclusions," he added. With increasing volume of data, data handling capabilities need to be further strengthened, he underscored.



Russia Sanctions, China Lockdown To Pinch Globally With Higher Freight, API Costs

India Better Stocked

Vibha Ravi

06 Apr 2022

Executive Summary

With the Shanghai lockdown extended, Russian vessels blacklisted and oil prices fluctuating, global freight rates are expected to increase further. Apart from a direct hit, pharma manufacturers will also feel the ripple effect as prices of raw materials like APIs increase. Scrip spoke to Indian industry to gauge the impact.

Shanghai, the city with the busiest container port in the world, has announced an extension of a COVID-19 led lockdown. Meanwhile, the Ukraine crisis continues and Russia is expected to face additional sanctions, at least for now.

In today's connected world, the repercussions of such geopolitical developments are not constrained to those directly affected, as pharmaceutical manufacturers painfully discovered during the first lockdown in Wuhan and other cities in China in 2020.

Lloyd's List Intelligence data indicate that over 6,440 vessels are beneficially owned, operated or controlled by Russian interests, also indicating that 347 vessels have not moved since Russia began its incursion into Ukraine and at least 128 foreign-flagged ships are stuck inside Ukraine ports or anchorages.

War risk underwriters are imposing high insurance premiums on owners of vessels trapped in Ukraine while a general cargo ship is sinking after being shelled in Mariupol. EU

Russia Sanctions, China Lockdown To Pinch Globally With Higher Freight, API Costs

Commission president Ursula von der Leyen has now announced a fifth round of sanctions against Russia.

Meanwhile, Danish shipper Maersk has said the Shanghai lockdown will severely hurt trucking services and increase transport costs. "Trucking service in and out [of] Shanghai will be severely impacted by 30% due to a full lockdown on Shanghai's Pudong and Puxi areas in turn until 5th April," the world's second-largest container shipping company said in an advisory before the partial lockdown was indefinitely extended to the entire city.

It had also notified clients that some depots and all warehouses in Shanghai will remain closed from 28 March until further notice.

Though the city has so far managed to keep its deep-water port and airports open, movement on its streets are severely curbed. Shanghai International Port Group, which runs the facility and leases containers, has implemented a closed-loop system within the port, which means employees are to live and work on the premises. (Also see "Uncertain Times: New Lockdowns, Ukraine Challenge Chinese Pharma" - Scrip, 24 Mar, 2022.)

However, COVID-19 test protocols are hindering trucks and barges from handling cargo, with drivers being turned away unless they provide a negative test result within the prior 48 hours. Besides, they are to quarantine on return from Shanghai.

In addition, oil prices have been on an upward trend, which is expected to increase global land transportation costs even further. Statista.com shows the OPEC basket stood at $19.70 per barrel on 14 April 2020 with Brent crude at $29.6 a barrel. In comparison, the OPEC basket was at $106.23 and Brent at $107.53 a barrel on 4 April 2022.

The combined impact is expected to see global freight rates rise further even as pharmaceutical manufacturers have dealt with increased costs since 2020. (Also see "Global Uncertainty Is Impacting Deal-Making, Investment Decisions" - Scrip, 1 Apr, 2022.)

India Better Prepared

Ashok Madan, executive director at Indian Drug Manufacturers' Association (IDMA), with over 1,000 members including small and medium enterprises, told Scrip "all these developments will definitely have an impact, but the extent will depend more on how the situation changes in China. We are keeping a watch."

Like several other countries across the world, India imports raw materials like active pharmaceutical ingredients (API), intermediates and excipients from China. However, it has a disproportionate dependence, even up to 100%, for certain APIs. (Also see "India Steps Up Scrutiny After Chinese API Prices, Military Tensions Rise" - Scrip, 3 Jul, 2020.)

Nevertheless, Madan pointed out that compared to 2020, Indian companies are better prepared this time around. In 2020, apart from the partial lockdowns in China, India itself went into a complete shutdown, though after initial hiccups, classification of pharma as an essential industry allowed it to service customers in and out of the country.

Sudarshan Jain, secretary general of Indian Pharmaceutical Alliance (IPA), which counts India's largest firms among its members, told Scrip "the learning of the last two years has been great. We are keeping inventories of 30-45 days of APIs [active pharmaceutical ingredients] and the large pharma companies have three to four months of finished goods stock."

While the Indian government began an attempt to decrease the industry's heavy dependence on China for APIs and intermediates, the benefits will take time to show, both Jain and Madan felt.

Russia Sanctions, China Lockdown To Pinch Globally With Higher Freight, API Costs

In 2020, the government introduced a INR69.4bn ($917.6m) profit-linked incentive (PLI) scheme for production of certain critical raw materials like penicillin G following which an INR150bn PLI scheme was notified in March 2021 for makers of certain complex formulations, excipients, phytopharmaceuticals, capsules and even invitro diagnostic devices.

"It will take around two to three years from a long-term perspective for the situation to resolve meaningfully. While this government understands the problems we face and has taken active steps to help, we can't change things overnight," IPA's Jain said.

IDMA's Madan concurred, saying the government "is alive to our needs and the industry has never received this level of funding before." However, since higher incentives have been provided to greenfield projects, the benefits will take time to flow down.

Brownfield projects have also received support, but the "level of incentives is 5% compared to 10% for greenfield ones. If existing units had been revived with government help and received technology support from bodies like CSIR [Council of Scientific and Industrial Research], we could have achieved self-sufficiency in APIs and other materials faster," he pointed out.

Sri Lanka, Pakistan Add To Turmoil

While API prices are expected to rise in the short term and could erode companies' profits when inventory runs out, the Russia-Ukraine turbulence could paradoxically also lead to higher sales for some.

"With Russia facing sanctions, it would not like to buy pharma products from multinational companies (MNCs) and given historically good relations between the countries and our manufacturing caliber, it is likely to turn to Indian companies," Madan noted.

MNCs have so far maintained supply lines for medicines to both Russia and Ukraine. Any company conducting business in these two countries can, however, expect payments to be delayed. (Also see "Europe's Generics Industry Takes Action To Maintain Medicines Access In Ukraine" - Pink Sheet, 2 Mar, 2022.)

Front-line Indian firms such as Sun Pharmaceutical Industries Ltd., Dr. Reddy's Laboratories Ltd. and Glenmark Pharmaceuticals Limited are among those with significant activity in the Russia-Commonwealth of Independent States CIS) region. (Also see "Turbulence Ahead For Indian Firms Caught In Russia-Ukraine Conflict" - Scrip, 3 Mar, 2022.)

Meanwhile, the political situation in neighboring Pakistan is deteriorating by the day. The country's Supreme Court is expected to rule on the legality of political exercises leading up to Prime Minister Imran Khan's dissolution of the national assembly and a call for fresh elections.

Sri Lanka has had an economic meltdown with the crisis forcing people to come out on the streets in protest against crippling power cuts and essential commodities' shortage. After imposing a state of emergency, President Gotabaya Rajapaksa revoked it late on 5 April. The ruling coalition appears to have lost majority in the 225-member Parliament, with over 40 MPs declaring themselves independent.

Apart from large Indian companies like Sun Pharma and Cipla Limited, several smaller companies also operate in Sri Lanka. Despite animosity between India and Pakistan, pharmaceutical products are also supplied to the neighbor.

"The RBI (Reserve Bank of India) is evaluating options" to secure payments to Indian companies in Sri Lanka, IPA's Jain told Scrip.

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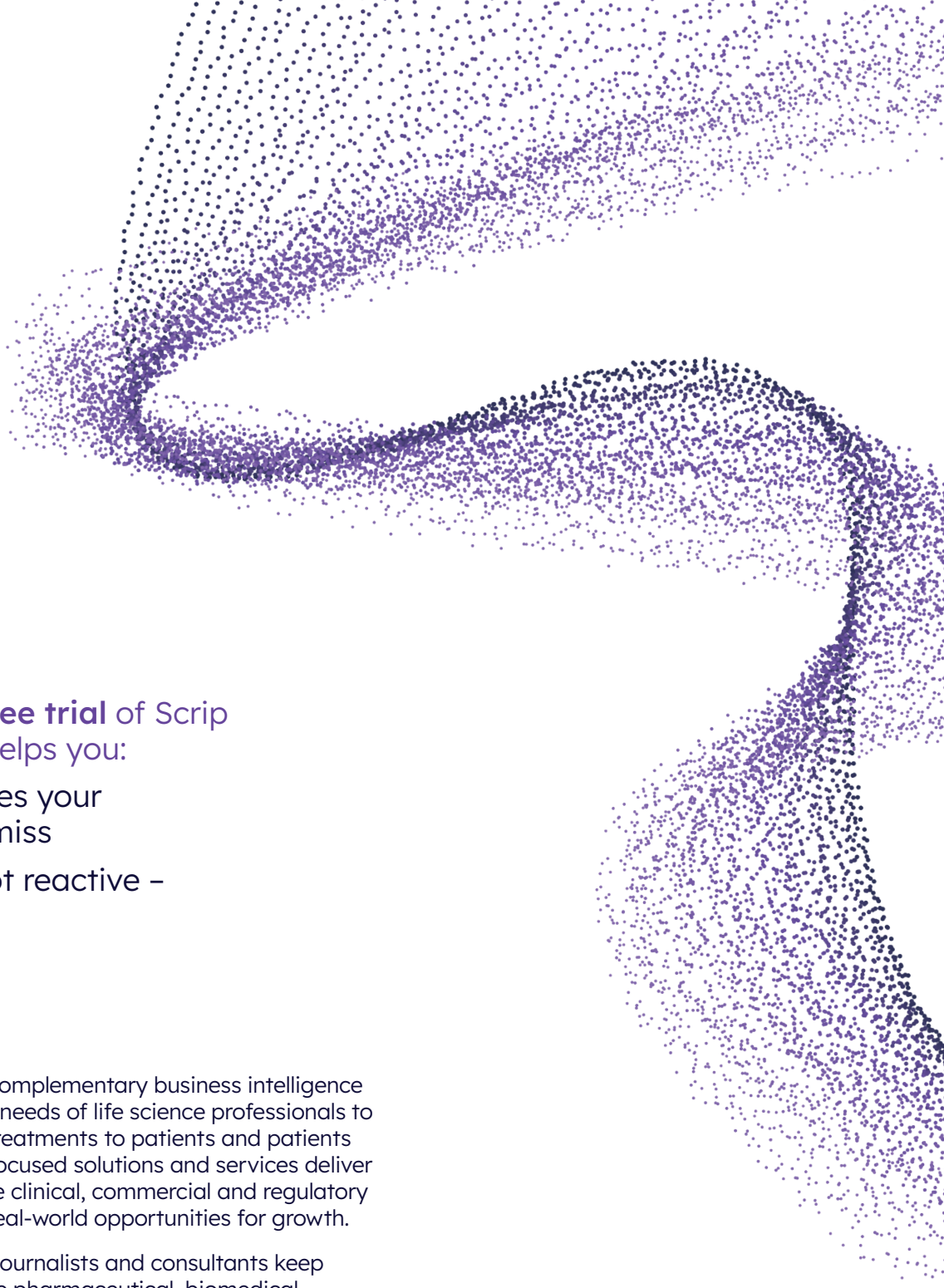

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