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EXPRESS PHARMA

INDIA'S FOREMOST PHARMA & BIOTECH MAGAZINE MARCH 2021, ₹ 40

INTERVIEWS

Nikhil Chopra
CEO and Whole-time Director, JB Chemicals & Pharmaceuticals

Girish Arora
Founder and MD, Alniche Lifesciences

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EXPRESS PHARMA

INDIA'S FOREMOST PHARMA & BIOTECH MAGAZINE
MARCH 2021, ₹40

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Industry *maange* more

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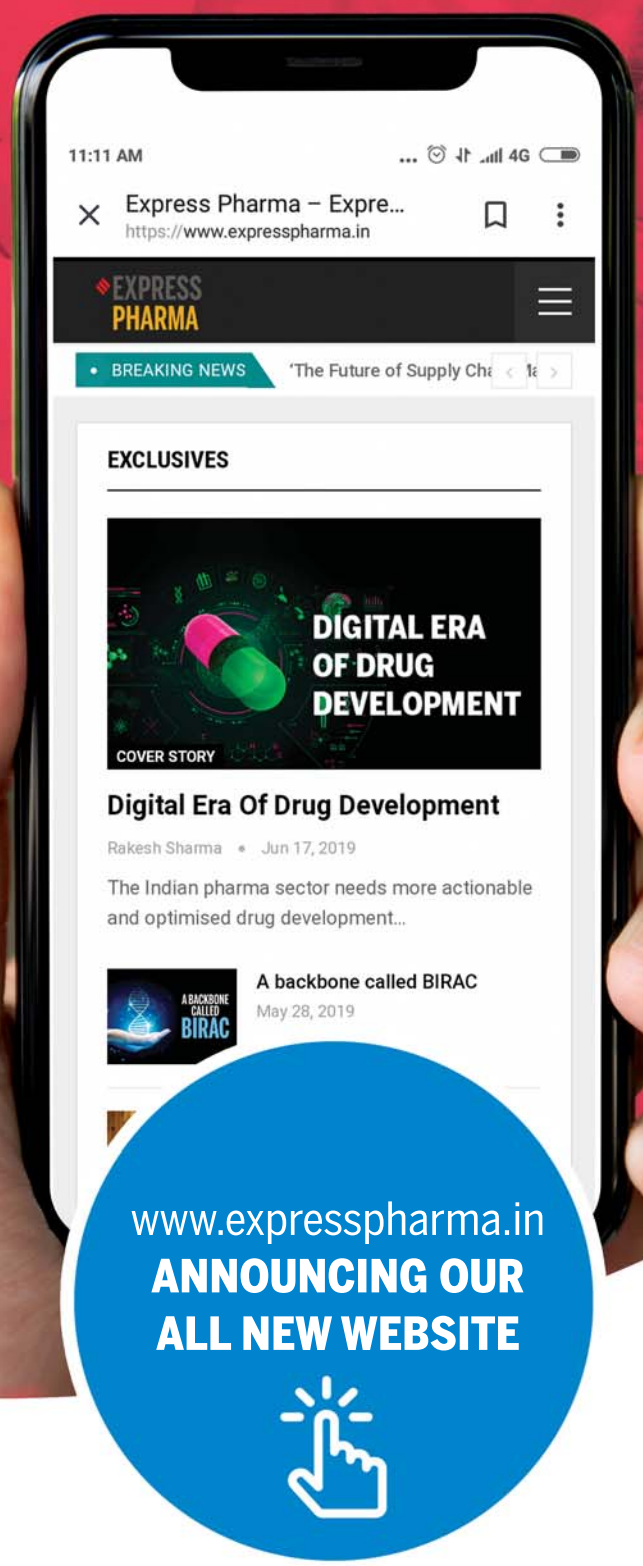

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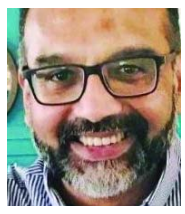

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Who will save the saviours?

A report from Cyfirma, a Singapore/Japan-based Cyber intelligence and threat discovery platform, has details of how cybercriminals from Russia, China, Korea, and the Middle East are reportedly targeting 12 countries including India, to steal COVID vaccine research data, patient information, clinical trials data, supply chain and vaccine production information. As per the report, there are 15 active hacking campaigns underway.

The targets? Pharmaceutical, vaccine and medical device companies, major hospitals, and health departments of governments and approving agencies involved in COVID-19 drug and vaccine R&D, clinical trials and national vaccination trials.

India's Cipla, Dr Reddy's Labs (DRL), Divi's Labs, Torrent Pharma, Abbott India, Sun Pharma, Zydus Cadila have reportedly been the targets of these attacks, in addition to marquee MNCs like GSK, Novo Nordisk, Pfizer, AstraZeneca, etc and hospitals like John Hopkins, Cleveland Clinic, etc. The updated list of targets includes Serum Institute of India (SII), Bharat Biotech, All India Institute of Medical Sciences (AIIMS) and Patanjali.

According to the report, suspected hacking group APT 29 and its affiliates have been active since October 2020 targeting global pharma companies, hospitals working on COVID-19, approving authorities in US, UK, India, Japan, Korea, Spain and Brazil.

The second campaign detailed by the Cyfirma report is run by APT 10 or affiliates and has been active since June 2020, reportedly targeting global vaccine approval authorities, medical devices and appliance companies, pharma companies and hospitals in India, Italy, Australia, Japan, Taiwan, Brazil and Germany.

In the third campaign suspected to be run by a hacking group known as Lazarus or affiliates, medical appliance and device making companies, vaccine approval authorities and pharma companies in US, UK, Japan, South Korea and Mexico were targeted.

According to Cyfirma, the hackers' motives are to create competitive advantage and financial gain through this theft of intellectual property, and cause reputational damage to these companies and by extension, countries.

The common links between the three hacking campaigns described in the Cyfirma report pinpoint vulnerable systems running on weak operating systems, which are being exploited and infiltrated by the hackers.

Even as vaccine manufacturers, hospitals and governments race against a mutating virus, cybercriminals are exploiting weak links in their hurriedly scaled up systems and processes

The cybercriminals, at least in some cases backed clandestinely by their governments, are hitting where it hurts the most. These organisations will have to plug the gaps in their IT firewalls quickly and effectively and save themselves from such cybercriminals while saving the world from viruses and the like.

At stake is not just India's vaccine diplomacy initiatives but also ensuring speedy and equitable distribution of vaccines within our country.

India's COVID-19 vaccination campaign has seen a fair bit of vaccine hesitancy, even among healthcare workers. The irony is that while other countries are hounding companies to ramp up manufacturing and supplies, some companies in India could be left with expired vaccines due to an inefficient distribution and allocation system, or vaccine hesitancy.

The Ministry of Health & Family Welfare did launch a campaign highlighting how prominent doctors have taken the vaccine. And Prime Minister Modi's vaccination on March 1 is being seen as a loaded statement.

Not only did he wait his turn, kicking off the next phase of vaccinations for citizens over 60 years, he chose Bharat Biotech's Covaxin, hopefully setting to rest doubts about the vaccine and its approval process.

But vaccine and pharma companies want the government to go one step further. Unhappy with the price cap of Rs 150/- per shot (which Union Health Minister Dr Harsh Vardhan shelled out on March 2 when he and his wife took their first doses at a private hospital in Delhi), the top brass from companies ranging from SII, Bharat Biotech, DRL, and Cadila Healthcare are said to be meeting PM Modi to ask for more viable prices for their COVID-19 vaccines for distribution in the private sector.

What will be considered fair compensation? Is this about profiteering during the pandemic? Or nurturing an ecosystem vital to save us from the next pandemic? Will the government step up and save the saviors?

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INTERVIEW

My role is to act like a catalyst

Nikhil Chopra recently took over as CEO and Whole-time Director of JB Chemicals & Pharmaceuticals. In a free-wheeling conversation with the ***Express Pharma*** team, he describes how he will take forward the legacy brands as well as build new ones

> JBCPL is growing at a net of 17 to 18 per cent despite the pandemic and is poised with market-beating growth. JBCPL brands continue to grow and gain market share as reported even by external stakeholders

Viveka Roychowdhury: **Could you give us an overview of your brief at JB Chemicals and Pharmaceuticals (JBCPL) as their CEO, post their acquisition by PE firm KKR?**

It's a privilege to be a part of the JBCPL family. I have worked in the pharmaceutical industry for more than two decades and joined JBCPL around four months back. The organisation has done tremendously well over the last four decades and I intend to make the best use of our manufacturing set up along with the strong legacy that the company has established. We have a fantastic asset and we will leverage it to get the best out of the manufacturing capabilities and strong legacy. I am delighted to share that as reported by IMS – JBCPL enjoys five brands in the top 300 as a franchise, a feat achieved by a limited number of companies, which demonstrates the strength of the company.

Our robust manufacturing is primarily based in the southern part of Gujarat where we have a set up in Panoli, Ankleshwar (Bharuch Dist.) and Daman. In the area of lozenges, we have a sizeable and differential opportunity to service our many multinational clients.

I would like to take this opportunity to thank the promoters of JBCPL for their everlasting support in ensuring a seamless transition and helping us further enhance our relationship with external stakeholders. JBCPL has an able leadership team and talent who have been with the company for more than a decade, which put together lays a strong foundation for the company.

My role here is to act as a catalyst by giving strategic directions and empowering the organisation to grow. We are also in the process of identifying capability gaps, if any. We have hired a new R&D lead who will be joining the company in March and have also appointed a new QA/QC head. We will be adding more leaders in the domain of Investor relations and Legal to bolster our leadership team. The leadership team is stitched together and is poised to build momentum and we are charting out the strategic blueprints across geographies.

With respect to India, the COVID-19 pandemic has been a challenging period however, in the last couple of months the market is showing handsome growth. The net December growth reported is 7 to 8 per cent but it is important to note that JBCPL is growing at a net of 17 to 18 per cent despite the pandemic and is poised for market-beating growth. JBCPL brands continue to grow and gain market share as reported even by external stakeholders. We are also determined to leverage our existing brands. We have an extremely capable field force of 2000 people in India who support us by marketing our products.

We want to diversify ourselves into new therapeutic areas and build on our strengths. We have the potential to offer unique differential offerings to HCPs and patients in India. For lozenges, we work closely with several multinational players wherein lifecycle management of the product and becoming more competitive in the market are our priority areas. We are also aspiring on reducing the dependency on the legacy portfolio in the Indian and International market, and offering a more progressive portfolio in the geographies that we are present, for which we are putting together a plan of scaling up our R&D and BD (Business Development) efforts. We are certainly taking steps to enhance productivity and putting up a robust framework of governance to enable the company to grow.

Geographically, around 50 per cent of our business comes from India which is our home market, our next two home markets are South Africa and Russia where we are present for last two to three decades and we have an able leadership and a sturdy sales and distribution infrastructure which will help us offering the right portfolio and deepening our presence in the aforementioned geographies. In ROW (Rest of the World) cluster we are present in Latin America, Sub Saharan Africa, Asia-Pac and Middle-east which is a distributer led model and in the US we have a cost-plus model where we

work with a US pharma company and we do all the developmental and regulatory work for them.

The ongoing pandemic has forced every business to relook and rework its way of operating. To model the pandemic as an opportunity, we need to immerse ourselves in the world of technology. We, at JBCPL, understand the need to get into the world of digital but, that does not mean we don't want to be physically present, we want to complement our physical presence with the help of enabling our team with technology that will facilitate us in bringing customer delight to our internal stakeholders, our people, doctors etc. So, we want to get into the world of 'Phygital' which is a combination of physical and digital. Starting with India, we have put in some processes and systems in place such as sales force automation, sales force excellence, enabling our force technologically such that when they go in the clinic of a doctor they are adequately equipped. We are also getting into the digital promotion of products and also put a patient-centric model which will further help patients.

Viveka Roychowdhury: **What is your strategy for this new phase of JBCPL? Could you give us three opportunities that you are looking at tapping in the short term, mid-term and then in the long term?**
Our biggest bet is India, where we have 2000 people on the ground and 50 per cent of our revenue comes from India. In India, we will continue to leverage the opportunities that we have in-hand organically as we are growing at 17 per cent, compared to the market growth of 7-8 per cent. We want to maintain this momentum and diversify into newer categories that can be in generic formulations, wellness etc. Equally, we will be looking for acquisitions opportunities, buying out brands or buying out mid-sized companies. Post-COVID, the Indian market will continue to grow around 8-10 per cent and we will continue to beat the market by a sizeable margin.

The second opportunity is in the form of lozenges, where we work closely with many big multinationals who have the capability of making big brands. We intend to partner with such companies, help them in life cycle management therefore this business has huge potential to grow because JBCPL is uniquely poised in terms of its offerings and we have a remarkable facility in Daman – one which is only dedicated to lozenges.

Third point, whether it is India, South Africa, Russia (all the geographies where we are present in ROW), we are looking to dive deeper and not go wide. We have enough presence and we are now looking at augmenting the business with the right

progressive portfolio to the doctors, patients which will help us in building an agile company. And this will be backed by scaling up our R&D and BD (Business Development) efforts.

Usha Sharma: **Doktor Mom is one of the main brands that JBCPL is known for. Which are the other existing brands that have similar potential to become blockbusters? What are your plans to ramp up the company's strategies and business, from a branding perspective?**
JBCPL had the capability to build a brand like Doktor Mom and that capability still exists. To give an example, we have got an incredible opportunity in India in the sphere of hypertension. We have a big brand, Cilacar which is close to Rs 300 crore and hypertension is an ailment where there are many sufferings in the country such as uncontrolled hypertension, undiagnosed hypertension. Therefore, it is the need of the hour to serve more number of hypertensive patients. We need to work around beyond the pill strategy here and equally get into newer combinations of calcium channel blockers.

Viveka Roychowdhury: **What are the formulation benefits of the lozenges platform?**
In lozenges, there are medicated and non-medicated lozenges and in both, we have the market-leading capability. We have a varied portfolio of lozenges ranging from nicotine lozenges, sugar and sugar free, curcumin lozenges, vitamin C lozenges etc. With the increased attention on overall well-being, we believe we can play a critical role in catering to this need in India. For lozenges it is crucial that the product remains stable, that it reaches the patient in the same condition from the time of manufacturing and we have demonstrated our expertise in this domain.

Outside India, we are already working with partners in South Africa, Russia, Australia, New Zealand and Canada and now the emphasis is on further collaborating with them to better understand what their research is showing and what newer options are needed in those markets. This enhanced partnership will help us to cater to their asks and also bring us closer to meet their needs and demands.

Usha Sharma: **You just talked about building up your R&D capability and your business plans with partners in other geographies So, how are you planning to strengthen your R&D to support the company's filings in dossier registrations in regulated and semi-regulated markets?**
The good news is that we already have around 14 ANDAs that are approved in the US, where we are closely working with our partner, Rising Pharma, who are our front end and responsible for our sales and distribution. We have an R&D facility in Thane. By March we will be onboarding a new leader and putting the entire team in place which is a combination of R&D developmental and analytical work which already exists but, we want to scale it up.

In the world of regulated markets or non-regulated markets, we are working on how can we work on at least 8-10 ongoing projects and that will eventually help us scale up our efforts in R&D and other developmental work. We are also fortunate that we have a robust API set up in Ankleshwar which helps us with the backward integration work that we want to do for our US formulations. At any given time we want to continue to work on 8 to 10 progressive projects and we will continue to file dossiers with US FDA depending upon the need and the demand from our partner in the US.

Viveka Roychowdhury: **Mr Chopra, you come to JBCPL after a 24-year stint in Cipla, where as the head-India Business, you were known for integrating several businesses. What is the brief from KKR for JBPCL?**
Our discussions with KKR have centred on getting the best out of JBCPL. KKR has the capability of getting us new partners, identified in the world of the contract manufacturing business, they have the capability of scaling up our efforts helping us with acquisitions, mergers etc. The focus is to get the best delivered from the leadership, put robust processes and systems in place, drive healthy EBITDA margins with market-beating growth and continue to do the best for our employees. The promoters of JBCPL have done an excellent job and we are trying to build up the momentum, putting a strategy in place in terms of short to mid-term and also, a blueprint for our geographies with what we want to do in India, South Africa, Russia and how can we infuse the right portfolio which helps us to be a progressive and agile company.

Viveka Roychowdhury: **With your experience in Cipla, and now JBPCL, you have experience in balancing a promoter-family driven approach within a merit/market-driven professional agenda. Any strategies to make this structure work better?**
Every company has a different DNA, Cipla had a different DNA it's an agile company with regards to the way strategies are put in place and the way they are executed. I enjoyed my run in that organisation, I started working as a medical rep in 1996 and it was a dream run. The organisation provided me with the freedom to operate and empowered the teams to undertake initiatives and put things in place.

JBCPL looks more towards brand building and likes to stay more focussed. We are in the process of putting a new go-to-market strategy for India Business how we can optimise our resources and get the best out of our field force and make them more capable. We are focussing more towards aligning our offerings catering to patient needs by putting some patient-centric models, differential offerings to healthcare professionals in the country, what more can we do for the society etc. We are also looking at integrating a digital-first approach by adopting technology that conceptually helps overall operations.

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INTERVIEW

Alniche has planned to enter contract manufacturing through EffiKasia Lifesciences

Girish Arora, Founder and MD, Alniche Lifesciences shares the company's plans and strategies to expand the business and increase profit margins, with **Usha Sharma**

Give us details about Alniche Lifesciences and its ongoing activities

Alniche's path to success commenced in 2007, and within one decade of its operations, it achieved ambitious milestones.

With a strong product portfolio, both domestic as well as those licensed from global pharma, Alniche fulfils the unmet needs of patients in the areas of nephrology, critical care, gastroenterology, dermatology, advanced wound care and neuro-psychiatry.

Recently, the company ventured into the manufacturing with EffiKasia Lifesciences. Why did you take this step?

Alniche has been acing through its ventures since its inception. Adding to the list is a recent initiative - EffiKasia Lifesciences. The newly established state-of-the-art manufacturing unit is aimed at manufacturing pharmaceuticals, nutraceuticals, and cosmeceuticals. With our growing sales across various therapy-verticals, there has always been a need for

back-end integration by setting up our manufacturing plant. EffiKasia is established with the mission of manufacturing for Alniche and as a reliable contract manufacturing organisation. With this initiative, Alniche plans to increase its profit margins and push top-line by expanding sales operations for exports in semi-regulated markets. Additionally, with our own manufacturing setup, the company plans to compete in the institutional tender business thus setting up a new revenue vertical.

EffiKasia Lifesciences is involved in manufacturing pharmaceuticals, nutraceuticals and dermatological products? Which of these are going to get greater focus and why?
Globally, healthcare is shifting towards prophylaxis and the role of nutraceuticals is getting established as an extended vertical of the pharma and wellness industry. Thus, we decided to venture into this segment for manufacturing and marketing various top-of-the-line nutraceutical formulations both in the domestic and exports markets. Moreover, with increasing awareness among the masses especially the younger generation, the use of dermatologicals and cosmeceuticals is increasing exponentially. We shall be formulating differentiated skin and hair care product range.

Presently, which are the therapeutic segments you have tapped? How many products have you already launched? How many more are in the pipeline and by when are they likely to hit the market?
Currently, Alniche is present in six therapeutic segments namely Nephrology, Critical Care, Gastroenterology, Dermatology, advanced wound care and neuropsychiatry. We have more than 350 products in the market which belong to various therapeutic groups.

Alniche is a pioneer in conceptualising and commercialising many novel product concepts in India to enrich product portfolio, like:

- Ketoanalogue range in sachet limiting the intake of fluid for patients with kidney impairment by reducing pill burden
- Auxisoda – enteric-coated tablets preventing GI irritation, Research and patented products (Complipro and Ezepro – Ready-To-Drink Protein Formula) in collaboration with DPSRU. Wetfast MD – Mouth dissolving lozenge reducing the overload of fluid in CKD patients.
- Entasafe – a unique combination of pre-probiotics and minerals to control the adverse effects of long-term use of PPIs.

To promote the 'Make in India' concept and encourage Indian researchers to come up with novel technologies and products, Alniche has formed an R&D alliance with Delhi Pharmaceutical Sciences and Research University (DPSRU), Government of N.C.T. This affiliation of industry and academia promises to augment further development of new products enabling innovations to meet the medical needs of the Indian population.

To facilitate improved healthcare, Alniche is driven by the vision of bringing novel products across various therapies and being the preferred partner of Global Lifesciences Organisations'. These companies include Alliance (UK), FzioMed (US), Adhezion Biomedical (US), Mastix (US), Biovite (Australia), PT Dermozone Pratama (Indonesia), J W Life Science (Korea), Dongkook (Korea), SK Plasma (Korea), Senquin (Netherlands) and Mellow Hope (China).

Next in the pipeline is therapy differentiation and ground-breaking product concepts which are to be engineered in collaboration with various global companies.

How are you enhancing your capabilities in the pharma R&D space?

For any life sciences organisation, R&D is a fundamental aspect, as it is crucial to the long-term success of the pharma industry and the wider life-sciences sector. 10 per cent of Alniche profits are spent on new formulation development and R&D initiatives. The key objective here is to develop effective formulations not only for diseases that are prevalent globally but also for diseases that are specific to India and other tropical countries, thus contributing towards the creation of a healthier world.

Tell us how COVID -19 has changed the paradigm of pharma marketing and what are your strategies to communicate about your brands to healthcare professionals?
2020 became a year targeted with the crisis followed by the global health pandemic. Alniche, being a leading life sciences brand in India, responded by offering its exclusive Critical Care range inclusive of the COVID-19 treatment, supportive and immunity booster therapies, CurCutop tablets (Patented Immunity booster), Vitamin C injection, Ulinastatin injections, Thymosin Alpha 1 injections, Favipiravir tablets and Remdesivir injection.

Implementing the right marketing strategy with the right set of portfolios for the right target audience is the focus for Alniche. A well-designed scientific marketing strategy to repetitively engage with the doctors kept us ahead of competitors. This involves various programmes like organising CMEs, Symposia, Web hosting, Tele-consultations, Disease info and management, advocacy development, Newsrooms, Latest Therapeutic regimen-journal Release, Practice support and decision enhancement tools and few others. Each therapy is promoted by a different team thus bringing the required Positioning focus with minimal overlap.

Adapting to the latest requirements of society in healthcare and technology are the key principles of today. Both being complicated worlds with dynamic natural products has resulted in Alniche's enhanced efforts to promote its brands by employing various digital media techniques like e-mail marketing, web posters and disease-specific promotion on Facebook, Twitter, LinkedIn, Instagram, YouTube and Quora

Will digital marketing be the way forward?
With an expected billion network devices and millions of Indians hooked to the internet, we can expect India to ride the digital age with innovation and be the benchmark for the world. The digital age brings its own set of unique challenges and success that will help the companies take benefit of this technology to market their services and brands to the target audience.

Based on the products, digital marketing campaigns are channelised, to engage with HCP's and gaining customers. It's a cost-effective and versatile marketing vehicle to suit different needs. We have started a Digital marketing initiative "My Healthytude". Through this initiative, we share the latest medical updates with HCPs and consumers on various social media.

What is the manpower strength of the company and do you plan to increase it further?
Currently, we employ field people at various levels from business manager to Director-Marketing, all hierarchies in between. The total strength today is 750. Being a fast-growing company, hiring employees is an ongoing process to match the growth of the market size. In the head office, there is a team of 100 employees who handle various functions supporting the operations of the organisation.

Why does the company plan to expand its manufacturing capacities for contract manufacturing activities, give us a brief update about the business strategy?
The Indian CMO market was valued at $ 9.04 billion in 2019, and it is expected to reach $ 23.72 billion by 2025, registering a CAGR of 17.6 per cent, during the period of 2020-2025.

Over the past few decades, India has taken a major leap from pharmaceutical production, to include contract manufacturing. In basic manufacturing of medical drugs and products, India has a far superior edge over nations, such as Vietnam, China, and Ireland, due to resources including manpower, technically knowledgeable workforce, and WHO-GMP approved production premises.

In addition to its own requirements, Alniche plans to expand into CMO, because of the various advantages it offers. Alniche has strategically planned to enter contract manufacturing through its manufacturing firm EffiKasia Lifesciences. Our business strategy is to enter export markets in less regulated geographies and once we get a firm foot in these markets, we will expand to regulated markets.

Globally, how do see the regulatory landscape evolving?
India is fast becoming the global manufacturing hub for pharma products. Our products match the quality

standards meet some of the most stringent international regulatory bodies like the US FDA, UK MHRA and others. They also match the quality standards of Indian pharmacopoeia, US and British Pharmacopeia. I will give the credit for the quality of our products to the stringent regulatory standards set by Indian FDA (CDSCO). It is good to have an evolved regulatory landscape to manufacture the best quality products and we plan to adhere to the regulatory norms in toto.

How are you strengthening your international business presence?
Currently, Alniche is focused on domestic markets. With the start of manufacturing arm EffiKasia, we have paved the way for international business. We strategies to capture the less regulated markets first and then move on to other markets. To start with, we will enter these markets with Nutraceuticals and Skinceuticals. Post regulatory approval of our manufacturing unit, few countries will remain our focus for international business which are Africa, CIS countries, Middle East, and South-East Asian countries.

For the next two years, what are your business plans? How do you intend to execute them?
In the next two years, Alniche plan to diversify its operations in various field related to pharma business.

- **Exports:** The first and the foremost is "exports" as there is immense business potential in the segment and the market size is huge. Indian pharmaceutical products are having excellent credibility in other countries hence India features among the top five pharma exporters in the world.
- **Institutional business:** The government of India is the largest purchaser of medicines. There are large enterprises that also purchase through tender business like DGAFMS, Indian Railways, ESI, CGHS, NTPC, ITBP, BSF etc. Alniche plans to capture a part of this institutional business pie in the coming years
- **Online B2C in healthcare:** Patients having chronic diseases are regular consumers of medicines. Alniche plans to supply the medicines for chronic therapies directly to the patients by setting up an online facility
- **Expansion in the domestic market:** Alniche will expand its operation in new therapy segments – Cardio-diabetic, Gynec, Ortho as these are fast-growing therapeutic groups with immense business potential

Do you plan to list the entity in the capital market?
Currently, we don't have plans to list Alniche Lifesciences on the Capital market but in future, this might be a reality considering our plan to achieve Rs 1000 crores in the next five years.

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INTERVIEW

COVID-19 has created a level playing field for innovators to get their products to market

Ashutosh Mayank and **Prajakt Raut,** Managing Partners at Supply Chain Labs, Lumis Partners share their insights on new opportunities that will open up for start-ups in the life sciences supply chain sector in the post-pandemic era, in an interview with **Lakshmipriya Nair**

The coronavirus pandemic has made it clear that we need to reboot healthcare to beef up our defence against the current and emerging diseases. What kind of new opportunities will it open up for start-ups in the life sciences supply chain sector? Which will be the major areas to focus on?
Pharma and medical equipment supply chain, warehousing and logistics was always a specialised field with specific requirements, including regulatory compliances. However, the distribution and administration of COVID-19 vaccines have the seriousness and complexities of a different level - think of it as the complexity and scale of holding elections across the country. Given that multiple doses of the vaccine are required adds to the additional trace & track of not just the products but the persons receiving it as well.

Current infrastructure and systems were not designed for these circumstances. As a result, technology will play a major role in quickly filling in the gaps in what is required to respond to Covid. These systems need to be deployed quickly, and they need to be nimble for quick adjustments depending on market circumstances. Add to that,

Ashutosh Mayank
Managing Partner,
Supply Chain Labs,
Lumis Partners

the demand for small-volume, personalised medicines is driving operations to multiproduct facilities that require meticulous tracking. These dynamics open up significant opportunities for start-ups.

At Supply Chain Labs, our start-ups like StaTwig, Koinearth, Aerchain, Invento, etc. have innovative solutions that can help the pharma and biomedical devices companies manage the complexities of the current circumstances with efficiency.

What are the challenges in this sector that prevent large scale investments? How can investments in this arena be de-risked to a certain extent? What will be the role of both, government and the private stakeholders in doing so?
In 2021, drug pricing, health care expenditures, and market accessibility will likely continue to be the main concerns. Medtech companies will continue to face competition from consumer technology companies and new care models. The commercialisation of gene and cell therapies comes at a time of wider drug price scrutiny from policymakers. Patient-centred platforms and consumer health apps are now collecting more data, underlining the express data privacy concerns. Other challenges include risk due to patent expiration, increased clinical development spend and lower investments in R&D as a proportion of sales.

Many more corporations are looking at innovation outsourcing to startups in the field of drug discovery; virtual lab assistance; imaging data for scans and diagnostics to gather that competitive advantage.

At Supply Chain Labs we help corporates discover solutions by startups. Startups and corporates working together is mutually beneficial and helps the entire eco-system. The government is already doing its bit in creating an enabling

Prajakt Raut
Managing Partner,
Supply Chain Labs,
Lumis Partners

environment, and creating possibilities for startups to participate in government programs and procurement.

Post-COVID-19, is it likely that life sciences will lead the start-up success stories coming from India? If yes, what will be the drivers of this trend?
COVID-19 has created a level playing field for innovators to get their products to market. Large pharma companies are already engaging with start-ups to get their products quicker to market. Start-ups like iSera Bio in Pune are already working with large pharma companies to help them deal with the urgency of responding to COVID-19. The changed environment will create a favourable and enabling environment for more innovators to enter the field.

Moreover, not just in pharma and life sciences, adjacent opportunities to build efficiencies in the entire supply chain - from distributed procurement, manufacturing, warehousing, logistics and reverse logistics - corporations and governments are looking at innovations and technologies to build efficiencies, transparency and visibility in the entire supply chain.

As an investor, what is your advice for logistics, supply chain start-ups to tide over these tough times? What are the immediate measures they should take to survive and thrive?
We pick sectors that have large opportunities, and where technology innovations can help address the problems and challenges. Start-ups entering these sectors have to quickly build the competencies and maturity for scale. Our advice to start-ups has always been to build a foundation for scale, and our programs are designed to help them do just that. Our advice to start-ups in the supply chain space - THE TIME IS NOW.

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How will Pharma 2021 unfold?

Dr RB Smarta, CMD, Interlink and VP, HADSA elaborates on ten trends that will greatly influence the pharma industry in 2021-22

2020 was an eye-opening year for every industry and the pharma industry is not an exception. From supply chain disruption due to over-dependence on China to fractured fieldwork and numerous allied unfavourable changes, we faced several challenges and are still facing them.

But, all these changes have taught us many things and now we are evolving. Over-reliance was always dangerous and the COVID situation

played its cards so hard that now we can't afford to oversee any problem and we are getting equipped to fight possible future uncertainties.

It is said that challenges never come without opportunities. The same is applied to our pharma industry which is now evolving through the impact of the COVID-19 pandemic to chase new opportunities.

Also, we have an educated population of patients whose mindset has evolved to a better and greater extent during this period. They have become health conscious because of the pandemic. Even the vaccines will increase the pharma market. So, a new segment is going to emerge i.e., immunisation.

Game-changing year

FY 2021 is likely to be a game-changing year for the healthcare industry. Due to the pandemic experience, the population is focusing on health, fitness and building

immunity. Strengthening health and wellness as well as fitness of the body is going to be a major focus all over the world.

As a result, the pharma industry will no longer be able to focus only on illness while providing medication but will have to keep a balance of how quickly a patient's health is restored. To do that, besides hospitals, building rehabilitation centres, health clinics and gymnasiums along with yoga will be seeing the light of day.

In a nutshell, we are moving towards personalised focus in healthcare. That's one reason we can say that it's a game-changing year after the pandemic.

10 major trends

Below mentioned ten trends will change the game and decide the future of the pharma industry. Let us look at the implications of these ten trends for the year 2021-22, consolidate our thoughts and prioritise them to provide a kind of direction for growth.

Source- Interlink Knowledge cell

1. Vitamin & Minerals supplements (VMS)

With increasing incidence of lifestyle diseases and patients getting inclined towards preventive and curative nutrition, one of the substantially growing segments in FY 2020-21 is 'Vitamins and Minerals supplements'.

With an increasing number of doctors prescribing vitamin and mineral supplements in the patients' treatment regimen, pan-India primary research of Interlink shows that 63 per cent of nutraceuticals products are catered through pharmacists based on generated prescriptions.

This will progress further as medical foods and foods for special diseases open the doors wide open for this sector.

By 2022, the nutraceutical market in India will be worth $8.5 billion and accounting for three per cent of the global market share. Factors contributing to this growth of nutraceuticals are as follows:

a) Busy lifestyle: Easy to carry nutraceutical supplements and products come in handy to fulfil one's nutritional needs in a hectic lifestyle where having a balanced meal may not always be possible

b) Rising patient awareness and body image concerns: Patients are aware of the side-effects of medicines due to the presence of chemical entities. By contrast, nutraceuticals provide natural, plant-based alternatives. Millennials, being weight conscious, are turning to nutraceuticals to lose weight

c) Focus on preventive healthcare: About 62 per cent of the healthcare costs incurred in India are borne by the patients out of their own pockets. Preventive care has received impetus lately due to the rising costs of healthcare

d) Internet penetration: This helped increase the availability and visibility of nutritional supplements in the market

Hence, keeping the above factors in mind, VMS is a lucrative market to tap in 2021-22.

2. Specialty care and patient focus

This is a promising area emerging with multiple patient-centric formulations which will add value to build robust patient engagements. Following are the factors influencing the growth of this sector:

a) Rise in cell and gene therapies: The global gene therapy market was valued at $3.61 billion in 2019 and is projected to reach $35.67 billion by 2027.

In 2019, the oncology segment accounted for a share of over 40 per cent in the global cell and gene therapy market and more than 60 per cent of the current gene therapy clinical trials are targeting cancer. With the approval of several such therapies, there is a shift towards effective patient-specific treatments. This will further positively propel the cell and gene therapy market in 2021-22.

b) Consumer healthcare market is on the rise: Prescription drugs are turning into self-medicated ones. Companies are relying on consumer insights to enhance their channel management and merchandising capabilities as well as to lower their margins.

Looking at this scenario, we can say that the growing market of patient-specific medicines will make some impressive moves in 2021-22.

3. Heritage brands

Heritage brands are the cash counts of many companies and a majority of the volume is generated by these cash counts who directly fund R&D work and new product development.

Besides, it has been observed for many years that they grow at a lesser pace but contribute to market share and ranking of the brands. They are also responsible for the growth of the company.

Many heritage brands have seen the process of evolution by either re-composing their ingredients or by adding certain relevant ingredients or by creating additional brands for better treatment of existing as well as new customers.

The issue of losing earlier target customers get properly addressed when companies create new usages, new indications for the existing or new customers.

Repurposing the heritage molecule is another aspect of extending the lifecycle of the heritage molecule so that new indications and new customer groups are formed.

4. Biosimilars

As seen in 2020, biosimilars will continue to take a share of the market and substitute generic products demand in 2021.

Indian pharma companies such as Biocon, Glenmark Pharmaceuticals, and Zydus Wellness are leading the race. Biocon earned Rs 1,517 crore or nearly 28 per cent revenue from biosimilars in FY19. However, factors such as access to critical technology, regulatory guidelines and the price difference between biosimilars and the underlying biologics are key to their adoption.

The price gap between the two has significantly widened to over 60 per cent for some drugs in Europe from just over 20 per cent a few years ago. A larger price difference will help in greater and faster adoption of biosimilars.

Increased investment by key market players, rising burden of chronic diseases, the patent cliff of leading biologic drugs, surging demand and acceptability for innovative therapies and rise in niche therapies are some of the factors that will continue to boost the growth of biosimilars in 2021-22.

5. E-commerce

E-commerce will create new footprints in servicing the patients and create a new stream of revenue in 2021.

E-pharmacy in particular received a great impetus in the current pandemic which ensured that patients received their medication even in the lockdown. North America and Europe are currently leading the e-pharmacy market. The major e-pharmacy players in India are Medlife, Netmeds, 1mg,

Pharmeasy, Myra, Careongo and Pharmasafe.

The following factors will ensure sustained growth for this industry in India:

a) Rapid internet penetration: There are 509.8 million internet users and 600 million smartphone users in India. The top 9 Indian cities will account for 35 per cent of all urban Internet users. Internet users will further increase due to GOI's 'Digital India' initiative.

b) Initiatives by the Government: A national health portal providing information in different languages to create awareness about health programs and services.

Online registration system covering major functional areas like patient care, laboratory services, workflow-based documentation information exchange, medical records management.

e-hospital@nic providing services for citizens for taking online registrations and appointments, payments of fees, diagnostic reports viewing online, online blood availability etc.

Sugam portal for online submission of applications, tracking, approval processing for drugs, clinical trials, medical devices, vaccines.

c) Increase in health insurance facilities

d) Increased spending on medicines – 9-12 per cent CAGR from 2018 to 2022 is expected.

However, low industry margins, increased competition, rising pressure on the price, possible drug abuse resulting from sales without prescription, lack of documentation and tracking and poor inventory management are some of the major challenges faced by retail pharmacies which will further increase the adaptivity toward E-commerce and will further propel the growth of this sector in 2021.

SR. NO.	10 TRENDS	IMPLICATIONS FOR GROWTH
1	Vitamin & Minerals supplements (VMS)	Growth driver
2	Speciality care and patient focus	Growth driver
3	Heritage Brands	Growth driver
4	Biosimilars	Growth initiator
5	E- commerce	Growth driver for prescription as well OTC brands
6	Initiative in inventing, manufacturing and distributing vaccines	Immediate growth booster from prevention point of view
7	AYUSH awareness	Driving toward health
8	API manufacturing sector	Additional boost towards profitability and availability
9	CROs and AI	Boon for new product introduction
10	Pharmaceutical exports	Growth escalator

Source- Interlink Knowledge cell

6. Initiatives in inventing, manufacturing and distributing vaccines

AstraZeneca-Oxford University collaboration in vaccine production, Serum Institute of India, Bharat Biotech India are expected to strike gold in 2021-22 owing to the increasing demand for vaccines.

The constant rise in AI adoption is fuelling also inventions and surging high-end manufacturing which will further boost distribution channels all around the world due to higher availability and persistent production.

The vaccine business is expected to flourish like never seen before and the industry is getting well equipped to make some excellent moves in this field in the upcoming years.

7. AYUSH awareness

Awareness of Ayush and integrated medicines will increase among the Indian population due to the Indian Government's support for Ayurvedic and Homeopathic therapies.

India's Ayurveda product exports, which are currently at $3 billion, are expected to grow in 2021-22 high due to evolving mindsets of the population toward herbal nutritional remedies. In the 2019 Union Budget, the Government increased the allocation to the Ministry of AYUSH by 15 per cent to Rs 1,939.76 crore up from Rs 1,692.77 crore from the previous fiscal. The Government has a target of setting up 12,500 AYUSH centres in India which can boost the growth of this sector.

Ayurvedic ingredients-based formulations ranging from shampoos, toothpastes, packaged juices, nutritional supplements, cough syrups etc are being used by a huge amount population for the past few years and it will continue to be an emerging field in 2021-22.

8. API manufacturing

Due to the severe shortage caused by supply chain disruption due to the COVID situation, API manufacturers in 2021 will reshape their supply chain strategies by adopting multiple suppliers and increasing reliance on regional manufacturers.

New regulations can be seen in the domestic supply of essential APIs to ensure the ''country of origin''. Also, there will be a good inclination among manufacturers toward achieving global quality standards for medicines.

Such initiatives by API manufacturers will strengthen the availability of raw materials and APIs in the upcoming years.

9. CROs and AI

Investments in CROs are increasing and paving way for new products. The penetration of CROs in the pharma industry would increase in 2021. With increasing mergers and acquisitions, CROs will grow significantly this year. As pharma companies are increasingly adopting globalisation, CROs are also expected to go global to expand their reach.

With increasing adaptiveness toward remote working and digitalisation, leaderships and managements of industries are expected to invest huge capital in artificial intelligence (AI) and technology in 2021.

The usefulness of AI in identifying candidates for vaccines and trials, conducting virtual trials, R&D, supply chain and manufacturing are the major factors that will boost the willingness of industries to invest in AI.

AI and digitisation will fill up the pipelines in 2021 by enhancing the quality of existing drugs, creating new drugs and promoting the best services in the pharma industry.

10. Pharma exports

Pharma exports will increase due to increasing demand abroad. With supply chain disruption from China, many nations are moving toward possible available options to achieve APIs which will lead to a rise in exports.

Indian pharma industry exports will touch $25 billion in the current financial year, up from $20.5 billion in 2019-20. Major exports are affordable generic medicines, and this year in particular, as mentioned in the sixth trend, the world is looking at India for COVID-19 vaccines.

These ten growth drivers will change the fulcrum of the pharma industry and move it towards wellness from illness, and boost it from the availability as well as profitability point of view.

Looking at the potential and influence of these growth drivers, it will be possible to achieve 12-14 per cent growth in FY 2021-22. Also, a few Indian pharma companies will work backwards towards prevention but take the industry forward in terms of growth.

IS WOMEN'S HEALTH GAINING MOMENTUM?

In *Express Pharma's* Women's Day Special issue, some industry observers and pharma stakeholders share insights on opportunities, challenges and focus on women's health segment as it continues to evolve and advance

By **LAKSHMIPRIYA NAIR**

Despite high unmet need across many conditions, the pipeline for women's health is sparse

According to GlobalData's Pharma Intelligence Center, as of February 18, 2021, 287 drugs are in development for various women's health-related conditions*. Among these pipeline candidates, 42 per cent are in Phase II development stage or beyond. Approximately 31 per cent of the overall women's health pipeline is assessing candidates for female infertility followed by 22 per cent for cervical intraepithelial neoplasia (CIN) and 14 per cent for endometriosis.

Considering the overall research and development activities within this space, there were a minimal number of women's health company acquisitions by Big Pharma in the last few years. In August 2020, Bayer acquired KaNDy Therapeutics for a sum of $875 million to expand its drug development pipeline in women's healthcare.

Prashant Khadayate, Practice Head of Pharma at GlobalData

Genericisation: A barrier to entry of novel therapies

One of the major drivers is the growing incidence of female health conditions. Infertility is becoming more prevalent as women are postponing pregnancy until a reproductively older age when fertility has decreased. Endometriosis and uterine fibroids are receiving increased disease awareness and earlier diagnoses. There is also an increasing need for contraceptives as certain government initiatives aim to curb population growth.

The current treatment of many female health conditions is highly genericised which represents a barrier to the entry of novel therapies. Hesitancy also remains for use of hormonal contraceptives due to potential unwanted side-effects and cultural or religious reasons. Despite the high unmet need across many conditions, the pipeline is sparse and the female population ages 12–54 is projected to decrease across certain markets.

Significant unmet needs remain

Several novel products, many with improved routes of administration, have recently launched across the female health space. Multiple competing companies have entered the space with their own oral GnRH antagonist attempting to capture market share for endometriosis and uterine fibroid indications.

New forms of contraceptives will offer more options for women.

The infertility drug paradigm has largely remained unchanged, although improved versions of the original fertility drugs have made their way into the market.

Digital technologies are advancing female health

Femtech includes digital technologies that aim to improve women's health, with menstrual health and reproductive health trackers being two of its fastest-growing sectors.

Despite major progress in treating patients, significant unmet needs remain such as improving the poor side-effect profiles and low patient compliance of contraceptives, sufficiently addressing the underlying pathology of conditions such as endometriosis and uterine fibroids and novel treatment options for menopausal symptoms, preterm birth, post-partum hemorrhage and vulvar and vaginal atrophy.

** Female-specific cancer indications like breast, cervical, and ovarian cancer are classified under the oncology space by pharma companies and are thus not considered within the scope of the women's health indications.*

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Continued investment in women's health will enhance health outcomes, quality of life and gender equality

Women's health has oft been a neglected area, and COVID-19 disruptions further exacerbated limitations in women's access to healthcare services and infrastructure. Thus, there is an urgent need to invest in providing access to health information, services and preventative tools.

Globally, Bayer continues to invest in breakthrough innovation in healthcare by continuing to build a strong development pipeline advancing more than 50 projects through the clinical development phases with women's health as a key focus area. A recent attractive asset addition through the acquisition of KaNDy Therapeutics supports the investment in women's health advancements, with interventions for menopause symptoms currently in development.

Providing women evidence-based solutions to empower them to take charge of their health is the need of the hour. Continued investment in women's health will promote enhanced health outcomes, quality of life and gender equality, with these effects cascading across other areas of women's lives.

Manoj Saxena, MD, Bayer Zydus Pharma and Country Division Head, South Asia – Pharmaceuticals

Plugging gaps with digitalisation

'Bayer For Women', a dedicated social media platform and 'Bare your Pain' application are some of the key digital interventions that have empowered women by equipping them with more information about managing their health. In 2020, Bayer also partnered with The Federation of Obstetric and Gynaecological Societies of India (FOGSI) to drive awareness of its digital chatbot service 'Ask Tanu,' which provides round-the-clock, credible information and advice on contraception and family planning. Such solutions can bridge knowledge gaps in sexual and reproductive health, thus overcoming traditional barriers such as stigma.

Several barriers to women's health persist, including social and cultural taboos that lead to reduced conversations on sexual and reproductive health. Moreover, decreased in-person access to healthcare practitioners due to the prevailing circumstances in 2020 has posed an additional challenge, contributing to worrying trends of increased maternal and child mortality and miscarriage.1There is a crucial need to drive new and innovative ways for women to access health solutions at scale, so they can make informed decisions and get the care they need. Advancing digitisation has thus emerged as a key growth driver in the sector, enabling accessible support, as well as remote consultation and care services.

Now, more than ever, a holistic health and wellness approach is central to delivering care. That is why Bayer has invested in digital solutions to empower women to manage their health.

Need to approach women's health holistically

2020 marked the 60th anniversary of the contraceptive pill, which has opened a world of opportunity by giving women and couples the right to have a child by choice, not chance. But it was also the year when access to sexual and reproductive health services was interrupted, thus threatening gains to women's health outcomes made over decades. Restoring access to these vital services, while also ensuring the deployment of technology-enabled solutions will help ensure continued progress on the fronts of sexual and reproductive health. Such solutions also promote increased transparency and dialogue on contraceptive and family planning options.

There is also an emerging focus on managing disease conditions holistically, with greater personalisation to address women's unique needs. Here too, digital resources such as chatbots or apps can play a vital role. By approaching women's health holistically and complementing the journey of care with trusted, sustainable solutions, we can help women put their health needs first and get the care they deserve.

There are stringent regulations in place for approval of drugs against women's diseases

One of Lupin's differentiators has been the branded portfolio as an engine for growth. This includes building a world-class Women's Health portfolio in US, India and EU.

A growing portfolio

Lupin's Specialty portfolio in the US is 100 per cent focused on Women's Health. Introduced back in 2000, Lupin's Suprax (cefixime) oral suspension today is an established antibiotic to effectively treat UTIs and other bacterial infections.

With the acquisition of Gavis Pharmaceuticals LLC in the US, Lupin added Methergine to its Women's Health portfolio. In 2016, Lupin announced the re-introduction of Methergine for the prevention and management of Postpartum haemorrhage (PPH). The next year, the company acquired Symbiomix Therapeutics LLC to obtain its brand Solosec and launched it in 2018 for the treatment of Bacterial Vaginosis (BV).

The company also enjoys a considerable market share in the women's oral contraceptive segment in the US ($40 million) and EU.

Lupin was the first company to introduce a medication for cervical erosion before which surgical intervention was the only mode of treatment. In 2020, the company also launched a non-hormonal product to support women transitioning to menopause.

Lupin's iron supplement is the fourth largest prescription brand in its category in India. It also introduced India's first small-sized calcium tablet which, market survey reveals, is especially preferred by women during pregnancy.

Lucrative opportunities galore

The global women's healthcare market is projected to grow primarily driven by factors such as the growing incidence of chronic health conditions among women, a growing demand for novel products and increased government spending on healthcare.

While the market has significant potential, the competition is also intense as there are numerous players competing for market share. There are also stringent regulations in place for approval of drugs against women's diseases, especially for treatments aimed at hormonal disorders. However, a growing women's population and geriatric population globally, coupled with the potential demand of advanced products offer lucrative opportunities for the industry to invest in.

-Spokesperson from Lupin

There is a lot of potential in women's healthcare segment in India

Pharma majors are massively investing in the women's health segment. For instance, Cipla last year had announced acquisition of four brands - CPink, CDense, Productiv and Folinine, from Wanbury, to increase its presence in women's health. The products sold under these brands would address health issues arising due to nutritional deficiencies or insufficiencies. Another key deal is Ahmedabad-based Torrent Pharma's acquisition of women healthcare brands Regestrone and Pregachieve from Swiss pharma major Novartis AG, with an estimated deal size of Rs 500 crores. These brands are prescribed by gynaecologists for addressing multiple health issues. It is notable that Torrent Pharma had also acquired key brands like Shelcal and Deviry from Elder Pharma, in the women's healthcare segment. All this demonstrates pharma investments made to benefit from the potential for growth in the women's healthcare segment.

Arvind Sharma, Partner, Shardul Amarchand Mangaldas & Co

Drivers and restraints

It is expected that the women's health market will grow at 4.96 per cent till 2026. Key drivers in this segment would include:

(a) Government's increased focus for healthcare

(b) Rise in R&D activities of pharma manufacturers for providing better healthcare to women

(c) Lifestyle challenges

(d) Potential to provide qualitative healthcare services for women.

On the flip side, key restraints would be

(a) expiry of certain patents of pharma products; huge financial costs associated with clinical services; inadequate healthcare infrastructure and comparatively low levels of awareness.

Femtech is a key focus area

With 50 per cent of the population as target customers, and with the women's healthcare market expected to reach $50 billion by 2025, Femtech (female technology) is the key focus area in the women's health market, and this is the right time for pharma companies to increase presence in this sector. Femtech refers to software and products that use technology to improve women's health and manage women's health issues. In this tech dominated scenario, connected devices and mobile applications will provide key and timely solutions to women. New business models such as telemedicine and remote monitoring platforms will emerge and are expected to play a key role in the women's health segment. There is a lot of potential in the women's healthcare segment in India, and this will attract top global investors.

Women's health therapeutics have established strong presence in global pharma market

Women's health therapeutics have a strong presence in the global pharma market, and that presence is expected to increase significantly. In today's times, pharma companies in the women's healthcare space are expanding their R&D base and increasing the efforts to expand beyond reproductive health into key women's health areas, such as endometriosis, polycystic ovary syndrome and the symptoms of menopause.

Challenges and growth drivers

One of the challenges has been women's healthcare subjects especially those related to fertility, menstruation, intimate hygiene, birth control and sexual wellness are considered taboo to even discuss. While rising endeavours by government to encourage people about the

Shuchi Ray, Partner, Deloitte India

adoption of safety in women healthcare is indirectly contributing to the growth of women healthcare market, the investment in women health is continues to be limited considering the risks and expenses associated with it. There are several side-effects believed to have associated with women intensive surgeries and drugs. Producers are trying to come up with solutions that mitigate side-effects and are less cumbersome, which could offer lucrative opportunities for the growth of women's health market.

Prevention is the key for women's health

Women are demanding equal access to safety, health, and opportunities for empowerment. It is no secret that women today are overcoming barriers and are leading busier lives than ever before. Times are changing, and various women centric movements around the globe have undulated the pharma industry. In addition to fertility and reproductive conditions, which are typically associated with women's health, there are many other diseases, such as postmenopausal osteoporosis, osteoarthritis, Alzheimer's disease, depression, urinary incontinence, multiple sclerosis, etc., that disproportionately affect women compared with men. Many of the large pharma companies have units or divisions that focus on these diseases that disproportionately affect women's health.

Overall, women's health therapeutics have established a strong presence in the global pharma market over the last few decades and the market is expected to grow moderately. Innovations coupled with technology focusing on correct nutrition and safety i.e. prevention is the key for Women's health.

Increased demand for high quality, safer alternative therapy options that offer reliable outcomes

Indian fertility market is more than 120 million EUR, growing rapidly at 9-12 per cent annual growth. Market once limited to metro and tier-I cities sees a lot of expansion in tier-II, III markets with more than 1500 centers coming from clinic chains as well as stand-alone segment. There is increased demand for high quality, safer alternative therapy options that offer reliable outcomes.

As per E&Y report (2015), there are an estimated 27.5 million infertile couples in India (approx. 10-15 per cent married couples). With more and more women prioritising education and career, marriage and motherhood age is getting pushed back. Coupled with lifestyle changes, it has led to increase in cases of infertility. Being the leaders in the field of infertility, Merck strives to not only provide top quality drugs for the treatment but works in all the allied fields like lab technology, digital tools to enable compliance and awareness etc and bring better clinical outcomes. Our partnerships with Philips and Genea Biomedx are an indication of our commitment in the field of women's infertility.

Awareness and access are propelling progress

The growth drivers of this segment are increasing awareness around women's health in India, working women professionals in certain key pockets of India, eradicating the stigma faced by women in society due to infertility, busting myths and superstitions surrounding the treatment of infertility and strong catchy marketing initiatives, better understanding/diagnosis, openness of talking about problems related to fertility etc., support groups for women suffering from infertility and those embarking on the journey of treatment.

Likewise, improved access due to fertility centers opening up in tier-2 and 3 cities of the country, more gynaecologists getting trained in ART for treatment of infertility is also accelerating the segment's progress.

Challenges for this segment are low penetration in rural markets due to less awareness of infertility, couples hesitant to restart IVF treatment post pandemic – economic impact and fear of infection, overall treatment cycle and lifestyle changes that needs to be incorporated, non-medical treatments for infertility delaying the women reaching IVF centers and thus losing out on valuable time and decreasing the success rates, as well as patient drop-outs from the treatment due to various socio-economic reasons.

Working towards novel solutions

Merck continues to be continued to bringing joy in the life of childless couples seeking parenthood through drugs and technology. Towards this, Merck Healthcare India plans to introduce a new combination drug (first time and only such combination) which will help a certain section of patients. Also, Merck will work towards the innovative and novel digital health solutions for improving patient compliance and adherence to treatment to improve success rates.

- Spokesperson from Merck Healthcare India

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INTERVIEW

Agilent continues to focus on strategic M&A, R&D investment to expand product portfolio

Samir Vyas, Country Manager, Agilent India says India companies are now moving into the global biopharma market and gives his views on the role of policies like Make in India/ *Atmanirbhar Bharat*, a more vigilant US FDA after the sartan episode and Agilent solutions for these challenges, in an interaction with **Viveka Roychowdhury**

India is termed the 'Pharmacy of the global South and is preparing to meet a sizeable portion of the global demand for COVID-19 vaccines. Where is the country ranked globally in the pharma and biopharma world?
There is no doubt that India has the potential, capability, and capacity to supply good quality and effective therapeutic, nutritional, and wellbeing products with higher affordability. India ranks third worldwide in the production of pharmaceuticals, where eight out of ten global generic companies are from this country. Although Indian companies are known for producing generic pharma drugs, many companies are now moving into the global biopharma market to enable revolutionised treatment and prevention of many disabling and life-threatening diseases. India is among the top 12 destinations for biotechnology in the world, with approximately three per cent share in the global biotechnology industry[1].

In recent times, India has strongly emerged as a global pharmacy, with the effective supply of critical medicines to over 150 countries. India is fast emerging as the vaccine hub for the world with the capacity of contributing around 60-70 per cent of the global vaccine supply for COVID-19.

> India is one of the geographies for Agilent where we see great potential and we will continue to focus on expanding our local footprint

But even with the many achievements, India finds itself critically dependent on external sources for crucial parts of the value chain like certain key starting materials and APIs, which need to be imported. How has this hampered the growth of the country's biopharma sector?
While it is true that India used to import almost 70 per cent of raw materials for pharma manufacturing, we focused more on building the capacity for finished products and continued our dependency on offshoring the starting materials[2]. This pandemic has exposed and highlighted the need for India to come up with strategic initiatives and a robust plan to reduce the dependency of sourcing the starting materials and equipment for requirements as critical as public health care. Long manufacturing cycles and stringent quality standards resulted in low margins for pharma companies and encouraged them to import APIs, rather than produce them domestically. Although, it has become evident that the impact of supply chain disruption was relatively less on the biopharma segment rather than the generic pharma industries.

Can policies like Make in India/Atmanirbhar Bharat set this balance, right? What is your take on this?
I am confident that these measures will facilitate growth for the Indian pharma/biopharma industries, thus creating a more self-reliant and sustainable ecosystem. We expect a more focused approach from the government with respect to capacity building, ease of doing business and growing investment towards infrastructure development. Having said that, it would be equally important to maintain excellent partnerships and continue collaborating with global companies to enable exchange of technology, competency, and experience in creating safe and affordable medicines.

Global regulators are becoming more stringent and holding pharma companies accountable for the quality of their

suppliers as well. The recalls of medicines with trace amounts of carcinogenic NDMA in medicines is a recent ongoing example. How can Agilent help companies for analysis and QC of input materials, as regulators up the ante by mandating more stringent testing at every point of the value chain?
The healthcare sector operates in a very dynamic environment and small changes in regulatory or safety guidelines have a significant impact. Historically, the pharmaceutical industry has been functioning with good manufacturing and laboratory practices and with time we have seen the journey of regularity and compliance evolution to provide the safest medicine. During FY 2015-19, we saw a rising trend with an increase of 'warning letters' issued by the US Food & Drug Administrator (FDA), whereas FY 2020 has shown a significant drop which is likely due to restriction in travel/inspection because of COVID-19.

Another major focus area for regulators is to evaluate and reshape the carcinogens risk assessment in human drugs. After the Sartan episode, the FDA is becoming more and more vigilant and asking manufacturers to identify the root cause of these nitrosamine impurities and to prevent the recurrence of this episode in the future. At Agilent, we have established the cutting-edge Geno Toxic Impurity (GTI) analytical workflow, which includes a combination of advanced technology, high-throughput sample preparation, and an integrated and compliant software platform. To provide trusted answers to our customers, we need to work with them at each step of their value chain. It is essential that we address challenges at the R&D stage, all the way until the finished product is released. Our solution readiness with a strong service network has really helped in setting up a robust and reliable analytical methodology at our customers' laboratories.

Regulators are also demanding more documentation to record test results from QC and R&D labs as well as the manufacturing plants. What are some of the technology solutions that pharma companies will need to deploy to stay on top of evolving regulations?
The common myth is that the applicable regulations are new. But 21 CFR Part 11, Electronic Records; Electronic Signature was first released in 1997[3]. As the regulatory norms have become more and more stringent, the evolution from lab informatics is becoming a silver lining. Credible lab results depend on the quality and reliability of testing data, regardless of which industry or function the lab serves. An end-to-end integrated, and harmonised software platform plays a key role in enabling effective lab compliance Agilent is constantly investing to expand its lab informatic portfolio and with the successful acquisition of Genohm, we have got the new capability of LIMS, workflow management, and expansion of ELN capability to help lab users in generating more reliable and efficient results. Now the Agilent's OpenLab Software portfolio is an integrated suite of products that includes sample management, data acquisition, data analysis, data management, and lab workflow management.

With increased documentation, data integrity issues and possibilities of manual errors increase. What are the automation solutions available?
Agilent recognises the pain point of our customers around the manual approach in managing both high and low throughput areas of their laboratory. Most laboratory challenges are associated with data handling and sample preparation. To enable automated data handling, Agilent provides an end-to-end integrated software solution, which covers the analytical workflow from the moment the analytical request is generated until the data are archived. We have also built automation capability into the sample preparation side, as manual sample preparation can be variable and error-prone leading to time-consuming rework and poor results. Agilent's patented AssayMAP Bravo sample prep platform provides complete automation and ensures consistent, reproducible, and faster results. While automation is becoming an integral part of each advanced laboratory, we also ensure that it comes with ease of operation as well as affordability.

It is essential that we address challenges at the R&D stage, all the way until the finished product is released. Our solution readiness with a strong service network has really helped in setting up a robust and reliable analytical methodology at our customers' laboratories

What are the new technologies and solutions in the pipeline?
While Agilent continues to focus on strategic M&A, we are also committed to R&D investment for expanding our compelling product portfolio for addressing emerging complex analytical testing challenges. We see changes to the landscape of an analytical laboratory, where there is a higher demand for reducing the cost and increasing turnaround times without compromising on the reliability of the results. It becomes very important for a technology partner like Agilent to work very closely with its customers and understand their unmet needs so our innovations can make the right contribution to the laboratory's success.

One of the focus areas for Agilent is to expand its capabilities and offer a complete biopharma workflow solutions portfolio. Our biopharma customers are moving away from classical offline QA/QC to more online/at-line testing, so they can decrease associated manufacturing costs and have a faster and more efficient release of the final product. Our biopharma strategies are very much focused on developing several analytical techniques so that we can provide trusted answers to the emerging and challenging needs of the current laboratory. The successful acquisition of Cobalt, ProZyme, and BioTek add core value to our existing biopharma portfolio, which already comprises cutting-edge technologies like 1290 Infinity II Bio LC, 6545XT Bio Q-TOF, and AdvanceBio analytical columns.

Along with a focus on product innovation, we continue building our strong service network and expanding new compliance services to ensure our customers get a one-stop solution with peace of mind when they choose Agilent. In addition to our industry-leading qualification services portfolio, we have now added a computer system validation and lab management solution, called iLab.

What has been the investment of Agilent in India, in terms of headcount, facilities etc.? Any expansion plans for the India market?
India is one of the geographies for Agilent where we see great potential and we will continue to focus on expanding our local footprint. We have an industry-leading talented team of more than 500 employees in India that work with our customers which represent almost every leading sector. We have about 10 sales offices across India and three Center of Excellence laboratories to ensure we stay in good proximity with our customers from the North, South, and West parts of the country. Agilent has made a significant investment in the Manesar campus, where there are about 1100 plus employees focusing on global support services.

Agilent is also committed to academia-industry collaboration; bringing new initiatives to support research and skill development. This year Agilent's global Thought Leader Award was conferred to IIT-Delhi Professor Anurag Rathore for his contributions in the field of biopharma research. We are looking forward to driving more academia-based collaborations, which can help improve quality of life.

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INSIGHT

Futuristic approach to Regulatory Intelligence

Umesh Kurra, Manager – Global Regulatory Services, Freyr Solutions elaborates about the right approach to regulatory intelligence and explains how it will benefit in faster time to market while taking proactive regulatory decisions for global implementation, and improved operational excellence

Launching innovative products across global markets is an effective revenue generation method for life sciences companies. Regulatory compliance and approvals being the driving factors behind any successful launch, inadequate regulatory information can trigger an increase in costs and time-to-market. The role of a comprehensive regulatory intelligence (RI) approach is paramount in the launch process.

The life sciences industry is governed by continuously evolving regulations requiring industry players to stay informed and stay compliant. Keeping up with the ever-changing regulatory landscape can be challenging for life sciences manufacturers.

Furthermore, collation of the enormous amount of information, understanding and interpreting all the regulatory updates available on the Health Authority (HA) websites, third-party databases, and adapting to the new regulations puts an additional burden on the company resources. To counter these challenges and hurdles, an increasing number of organisations prefer to rely on RI tools and services. These tools and services assist in creating a compliant strategy and execution plan thereby avoiding any mishaps throughout the product lifecycle. For over a decade now, large and enterprise companies have been investing in a dedicated RI function. Despite the integration of RI tools, solutions, or support, organisations still face difficulties in decoding the regulations and

complying with them. This could partly be due to the inefficiency of existing tools to tackle end-to-end RI on a global scale.

In this digital era, information is infinite. In fact, with so much information on hand, companies struggle to segregate useful information. Not all data is relevant to the companies and there can be a significant amount of noise that regulatory professionals need to filter. The information needs to be processed effectively for regulatory compliance and even the filtered-out information can also prove to be useful, with an effective approach for RI.

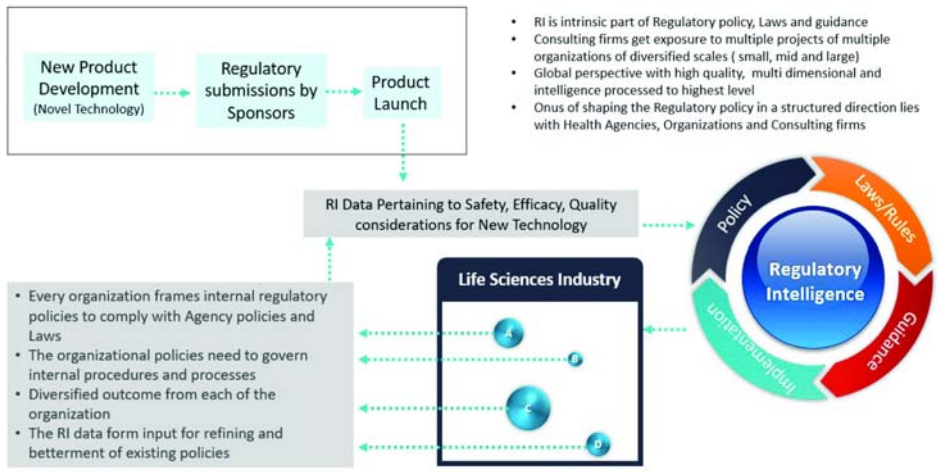
Moreover, as described in *Table 1*, different stakeholders responsible for regulatory compliance have different requirements. RI helps in meeting all these diverse needs.

So, what then constitutes the requirements for an ideal RI approach? An ideal 360° RI support must encompass and support regulatory functions of Global Regulatory Affairs, Quality Assurance, CMC, Submissions, Labeling, Artwork and Packaging, Pharmacovigilance, Supply Chain, Technology and IT, Regulatory Policy, and Marketing.

TABLE 1: STAKEHOLDERS' REQUIREMENTS FOR REGULATORY COMPLIANCE

Manufacturer Requirements	Health Agency Requirements	Regulatory Intelligence
◗ Focused view on the therapeutic segment of interest ◗ Regulatory Intelligence data pertaining to competitor/precedence products ◗ To get it right-the-first time of Regulatory approach and avoid any regulatory blockades in the product life cycle	◗ A holistic view on the developmental landscape ◗ New technological advancements in each therapeutic segment ◗ Monitor the advancements to understand the need for more stringent regulations and data requirements ◗ Identify the need for new policies, laws, and directives	◗ Understand new technologies and build internal capabilities ◗ Identify applicable regulations ◗ Track and be updated on new advancements in regulations ◗ Understand and identify test requirements and optimum data requirement for Regulatory submissions ◗ Regulatory pathways for registration ◗ Optimise data and documentation forglobal registrations

FIGURE 1: BRIDGING THE GAP BETWEEN RI AND REGULATORY POLICY



From a bird's eye view, the RI process seems effortless – gathering data, analysing information, and creating a regulatory strategy. RI is the key to unlock superior regulatory submission strategies and new market decisions. However, each step in this process includes a multitude of steps and brings with it its own set of challenges.

Comprehensive approach to RI

A wholesome approach for RI includes:

◗ **Primary research** that covers data sources across country updates, regulatory updates, congress coverage, trade associations coverage, authority and ministry coverage, key opinion leaders, and key influencers.

◗ **Secondary research** that encompasses data about country/product regulatory landscape, ongoing literature review, regulatory updates, clinical intelligence, HA updates, news and research, regulatory precedent of the policy, impact on the policy, lead countries and follow up countries.

◗ **A technology** solution that is a web-based, metadata-driven RI platform, real-time tracking and update, multiple information sources, actionable, auditable, collaborative, social, and compare documents, regulations, and requirements globally.

◗ **GRX Framework** – IMPACT integrated with other technologies, in-house integration with DMS, PLM, submissions and other software, reusable content.

◗ **Real-time** distribution and action, real-time impact assessment of regulations and changes assign activities across departments for timely action.

◗ **Reporting and audit** – Country/product specific comprehensive analysis, Newsletters and periodic reports, real-time news updates, on-demand reports, audit actions for compliance with changing regulations.

Another key aspect of regulatory compliance for organisations is being synchronous with regulatory policy and unmasking the gaps between regulatory policy and RI. Paving the way for the synchronous functioning of an organisation demands relentless efforts and support – both technological and functional.

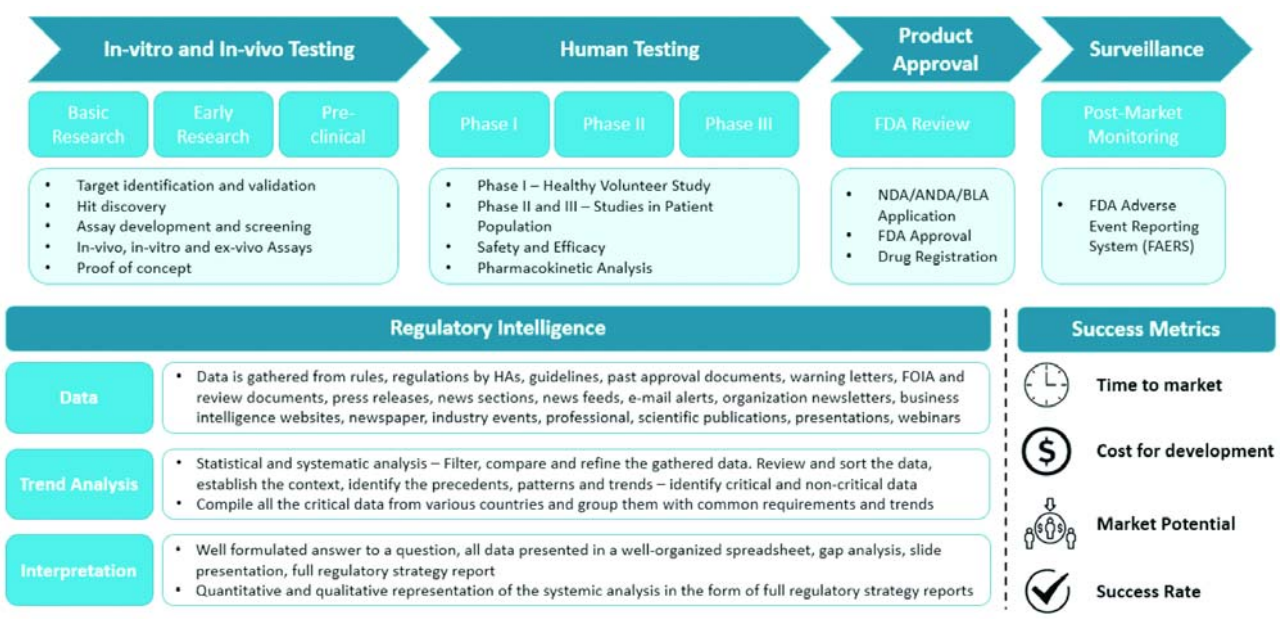
As shown in Figure 1, every organisation should create an internal regulatory policy to comply with the HA policies and laws. Organisational policies need to govern internal procedures and processes. The RI data form the input for refining and enhancing existing policies.

> Despite the integration of RI tools, solutions, or support, organisations still face difficulties in decoding the regulations and complying with them. This could partly be due to the inefficiency of existing tools to tackle end-to-end RI on a global scale

TABLE 2: BRIDGING THE GAP BETWEEN RI AND REGULATORY POLICY

RI Trends	Description	Value Proposition
Competitor Intelligence	Regulatory status or Regulatory evaluation of a competitor product.	Determines the likelihood of success of own strategy and gauges launch time if need to be 'first in line'.
Environmental Intelligence	Existence, implementation and use of legislation, regulatory frameworks, tools, or initiatives on a specific pharmaceutical topic.	Enables identification of requirements, rewards, and incentives, as well as regulator acceptability and competence.
Due Diligence Support	Scenario and risk management planning in relation to an in-licensing opportunity.	Enables identification of potential risks that may impact regulatory success. Aids go/no-go decision-making.
Procedural Intelligence	Practical experience in the interpretation or application of regulatory provisions that relate to a regulatory procedure.	Clarifies whether the situation falls within known instances. Shapes dialogue with regulators if required; to justify the position.
Regulatory Precedents	Known instances of a novel regulatory approach or deviation from normal practice (success or failure).	Helps determine the likelihood of success and any key differentiators that might persuade regulators to accept the client's position.
Metrics	The mathematical occurrence of a regulatory event or time span for a regulatory procedure.	Aids submission and launch planning and internal benchmarking against industry standards.

FIGURE 2: RI ACROSS PRODUCT LIFE CYCLE (US FDA EXAMPLE)



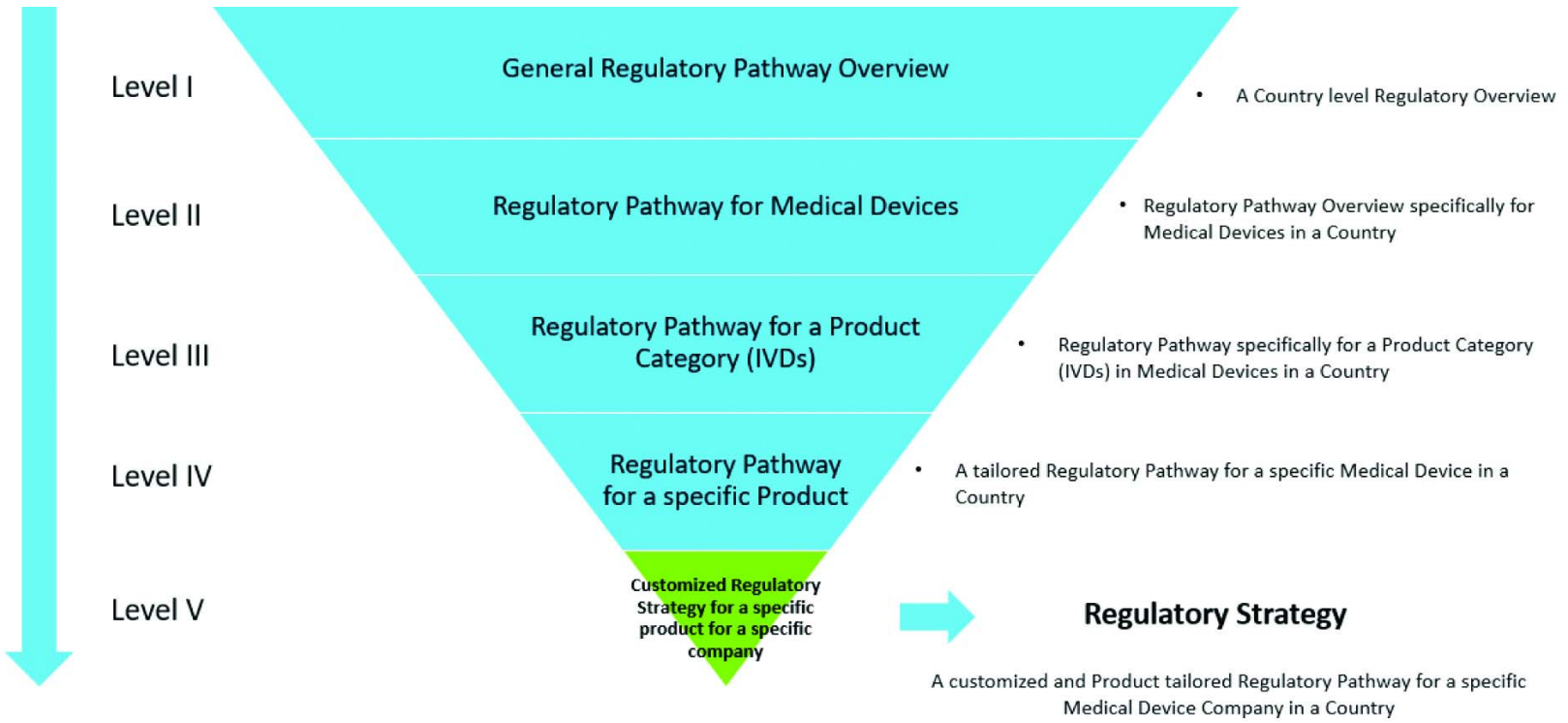
Value proposition of RI

RI can be gathered, assessed, and used across various stages of the product life cycle. Its value proposition is immense in understanding the current trends and taking necessary actions for addressing both; functional and business needs of an organisation. As described in *Table 2* and *Figure 2*, the value proposition of RI is multi-faceted and is significant throughout the product life cycle.

Regulatory strategy

A regulatory strategy is an authorised approach that

FIGURE 3: MULTI-LEVEL APPROACH FOR PRODUCT AND COUNTRY SPECIFIC REGULATORY STRATEGY



coordinates with regulatory affairs to launch an overhauled pharma product/device into a market, backed with a brilliant marketing plan. A regulatory strategy defines the plan for developing a product with the goal of obtaining regulatory approvals without any hassles in the desired markets. It also includes a plan for life cycle management/maintenance.

The regulatory strategy process aims at offering a comprehensive elucidation of the project, apart from distinguishing the relevant regulatory elements that need to be addressed to promote the product.

A global regulatory strategy program must fulfil the following criteria:

◗ **Fundamental target product profile** – The marked analytical implications alongwith predictable labeling petitions of the product should be configurated with the fundamental target product profile

◗ **Changing regulatory environment** – The program shall determine the continuously evolvingRegulatory environment that further involves pursuit of a revived legislation and standards for requirements

◗ **Facilitate new development tools** – The program should leverage newly acknowledged development tools that save time and expense. Those tools should also ardently enhance compliance of foreign data to access global markets.

◗ **Predictable future approval requisites** – The program shall determine predictable future approval requisites aligning with present approval prototypes and progressing clinical programs. The requisites may include comparisons, deadlines, statistical paradigms etc.

◗ **Proactively recognise challenges** – The program should ardently recognise challenges that are responsible for delaying analytical development. It should also explain the creative approaches initiated to circumvent these challenges.

◗ **Distinguish key opportunities** – The program should be able to distinguish key opportunities to engage global Regulatory authorities to assist these discussions.

◗ **Eliminate developmental risk** –The program should be able to eliminate the developmental risk if any, whilst boosting the potential for commercial success.

Multi-level approach for a product and country-specific regulatory strategy

In parallel to having a global regulatory strategy, it is equally important to have a country-specific regulatory strategy as companies tend to simultaneously start the registration process in multiple desired markets; particularly in emerging markets, to expedite the overall registration process and reduce their time to market. As shown in *Figure 3*, there are multiple levels in devising an effective regulatory strategy. A country-specific regulatory strategy is the most advanced level of RI and it must be specific to a particular product and company.

The key outcomes of RI and regulatory strategy

■ **Timely and consistent submissions across global markets**

◗ Effective approval process

◗ Uniform versions of documents

◗ Better planning for turnaround time and quality metrics

■ **Compliance**

◗ Market-specific process adherence

◗ Harmonised documentation and quality standards across markets

■ **Policy and strategy**

◗ Proactive product/market-strategy

◗ Policy adaptation andinternal/external influence

■ **Supporting business as usual**

◗ Support day-to-day intelligence needs for micro and macrodecisions

◗ Real-time knowledge support

◗ Accelerated training

■ **Impact on patient safety and brand image**

◗ Consistency across markets impacting brand image

◗ Accelerated response to changes in regulations

■ **New regulatory opportunities and portfolio maximisation**

◗ Market-specific process adherence

◗ Harmonised documentation and quality standards across markets

■ **Centralised intelligence delivery platform**

◗ Global submissions, dossier preparation, CMC management, artwork and label management

◗ Global intelligence-driven approach

◗ Compliance monitoring and business risk management

■ **Productivity, efficiency, and cost**

◗ Informed decisions

◗ Improved compliance

◗ Intelligence - driven approach

◗ Internal links

To conclude, the right approach to RI will benefit in faster time to market, lesser cost for development, greater market potential, higher success rate, proactive regulatory decisions, global implementation, and improved operational excellence. What is your approach towards RI? Define it carefully and in a compliant manner. Stay informed. Stay compliant.

Industry *maange* more

Recently, the Ministry of Environment, Forest and Climate Change (MoEF) made an amendment by bringing APIs and intermediates under a single category for environmental clearance. This move is expected to benefit the industry by speeding up the manufacturing process of pharma formulations. Now, industry experts opine that relaxation of certain other norms and approval processes can accelerate the industry's further growth and enable it to become self-sufficient

By **Usha Sharma**

There is increased flexibility for API manufacturers to change product mix as per market requirements

SV VEERAMANI
Past National President, IDMA, Chairman and MD, Fourrts (India) Laboratories

This is indeed a welcome move from the Government. Earlier the new environmental clearances were given product-wise and it was causing inordinate delays. As a result, manufacturing progressive new molecules in place of obsolete ones was not easy and opportunities were lost on this count. Now, by agreeing to provide environmental clearances under a single category for APIs and intermediates, there is increased flexibility on the part of API manufacturers to change their product mix as per market requirements. We hope that the Government will implement this without any delay. The new rule has been formed by MoEF due to DoP's initiative and we hope that they will ensure its implementation. Besides, the PLI schemes mooted by DoP encourages the production of API and intermediates import substitutes, which can be carried out by industry with quicker environmental clearances. On the part of MoEF, we hope that they will provide clearance without any delay.

The notification is still silent on capacity enhancement within the approved pollution loads

BR SIKRI
VP, BDMA, and Chairman, FOPE

The Environmental Clearance (EC) is taken under a specific project category like 5(f) for bulk drugs and intermediates. Change of product mix within the same category is now allowed without seeking fresh EC. This is very much needed for the bulk drug industry as the products keep changing very frequently as they become obsolete or new drugs with better efficacy are introduced regularly and globally.

EC is given for specific pollution discharge loads. Hence seeking fresh EC for modernisation, change in process technology and capacity enhancement is not logical when there is no increase in pollution load. Though the notification allows for a change of product mix, it is still silent on capacity enhancement within the approved pollution loads. As far as environmental compliance is concerned it is the quantum of pollution load that needs to be addressed and not the quantity of products produced as long as they are from the same category for which EC has been given. With the improvement in technologies and process changes, there is a possibility to increase production and reduce the pollution generated. If capacity enhancement is also allowed it would lead to process innovations and make our industry globally competitive.

The following initiatives should be taken up by the government to encourage the drug industry:

- The government should facilitate providing world-class environment control systems by involving expert agencies like CPCB, NEERI and charge the industry for the services provided rather than always punishing the industry for any default.
- Develop large scale pharma clusters with world-class infrastructure, plug and play facilities and environment control facilities which can reduce the quantum of investment and operation costs due to the economy of scale.
- Encourage R&D and skill development

This initiative, along with PLI scheme, will increase investments in this sector and make India *Atmanirbhar*

We welcome this move from MoEF. This move will have a far-reaching positive impact on how the bulk drug and intermediate industry works in India and will go a long way in improving the ease of doing business. The KDPMA had been pursuing this demand at every forum for about a decade. Hopefully, this initiative, along with the PLI scheme, will increase investment in this important sector and make India *Atmanirbhar*. We have repeatedly stressed the fact that we cannot have such a strategically important, world-class formulation industry depending on imports of bulk drugs. Having said that, we need to gear up our research capabilities with a multidisciplinary approach like Artificial Intelligence and Machine learning.

Hopefully, with the impending launch of 5G, our expertise in IT will be an added advantage. We expect the government to firmly handhold this sector. In the long run, if we have to globally competitive, we need to build up large global scale capacities, process improvements to cut cost, obtain regulatory approvals.

HARISH JAIN
Secretary, Karnataka Drugs and Pharmaceutical Manufacturers Association

There is a need to establish an 'API monitoring cell'

It is a welcome move as now API manufacturers are free to manufacture desired molecules as per market requirements and do not need to knock PCB clearances for every alteration as per permissible pollutions limits as both, excipients and APIs, are treated now as a single category.

It was a long pending demand of bulk drug manufacturers and it will be a booster dose for upcoming PLI schemes and bulk drug parks.

Besides this, we expect from the DoP that Section 33 P guidelines should become Rules, to protect genuine manufacturers and punish spurious drugs manufacturers. Several prosecution cases/ litigations are pending all over India's lower and session courts, on hand holding procedures and decriminalisation for genuine manufacturers is the need of the hour.

There is a need to establish an 'API monitoring cell' as price fluctuations during this pandemic has affected the entire formulations market, for e.g. Paracetamol price has shot up from Rs 300 to Rs 585, but prices of the final product which is controlled by the NPPA remained the same.

Therefore, a mechanism required to support the bulk drug industry and importers to get the final product from formulators at a reasonable price.

There is also a need to protect the MSME industry for better participation of *Jan Aushadhi* to various State Government's tender which needs to remove clause of Rs 25 crore turnover for last four consecutive years, and should not make it mandatory the requirements of WHO-GMP as it is needed for the Export purpose and not required for the domestic market. Wherein, our own Schedule-M and GMP compliance requirements are enough and across the country primarily licences are granted by State FDA on such basis.

The Government should also allow new plants, manufacturing units for Government tender participation to promote 'Make in India', which is lacking in the present scenario.

DR RAJESH GUPTA
President, Himachal Drug Manufacturers Association

Inspector Raj to be disbanded

- Speedy clearance of PLI awardees in one our two months facilitated by DOP if data is completed in all respects.
- In case of the commitment of Zero Discharge, all PLI awardees to be allowed to fast-track their projects with periodic review with state and central agencies by self-declarations.
- Inspector Raj to be disbanded. Online monitoring to be a faceless assessment.
- NGT to have SMEs on board with extensive knowledge.

If these above-raised points by industry stakeholders are analysed and implemented then it is likely that the API, intermediates manufacturing activities will get a further boost in the country.

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DR DINESH DUA
Immediate past Chairman, Pharmexcil and Director, Nectar Lifesciences

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CARBOPOL® 980 NF POLYMER:
- Polymer of choice for clear hydroalcoholic or aqueous formulations
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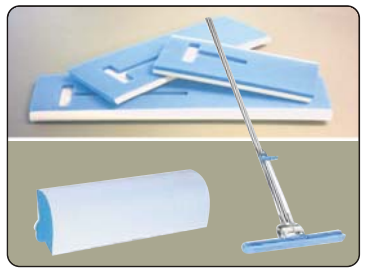
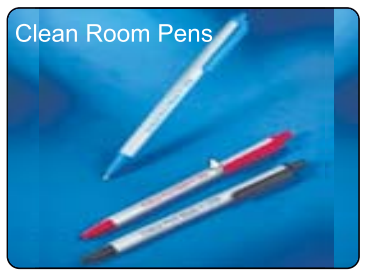
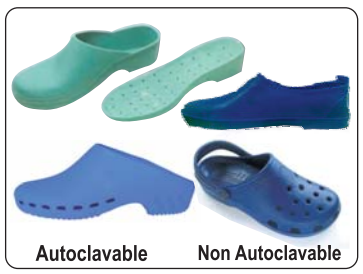


Clean Room Mopping Systems

Rust Removal System

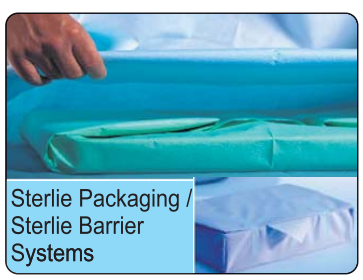


Clean Room Stationery



Clean Room Shoes

Autoclavable Goggles

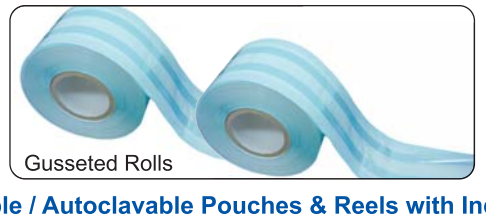


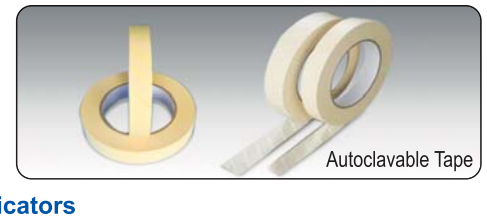
Sterlie Packaging

Clean Room Wipes

Fogger for Fumigation

Autoclavable Clean Room Trolley Systems: Plastic & Stainless Steel





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AVISH SUBNIL

CILICANT launches third manufacturing facility in Pune

The new cGMP compliant facility has upped its production capability by three times and backs end-to-end production and distribution operations

Active packaging firm, CILICANT, recently announced the launch of its third manufacturing facility in Pune.

The company informs that its new cGMP compliant facility has upped its production capability by three times and backs end-to-end production and distribution operations to support increasing demand from pharma and medical devices segments, during and post the pandemic.

In a statement, the company said that its state-of-the-art manufacturing facility deploys the latest technology for production; machines that not only deliver the best quality but also have greater production capability.

The statement adds, "Cilicant is reputed for its unwavering focus on safety and quality. All products are manufactured in a classified cleanroom. And every employee adheres to meticulous safety standards established in accordance with industry and regulatory best practices. By holding DMF with USFDA and Health Canada and ISO 15378:2017, quality assurance is a big part of Cilicant's operations."

At its in-house Quality control lab, both raw materials and finished products are tested as per the current US pharmacopoeia testing standards and engages high-tech instruments for all its testing.

The state-of-the-art manufacturing facility deploys the latest technology for production; machines that not only deliver the best quality but also have greater production capability

Manish Jain, Founder, CILICANT, commented, "Continuous improvement has been the crux of CILICANT's growth, with our new state-of-the-art manufacturing facility, we intend to serve our customers better than before'. We thank our customers who have not only supported but encouraged us to outdo ourselves every time, it is due to them we have achieved this endeavour."

Sumeet Sharma, Sales Director, CILICANT added, "The opening of the new manufacturing facility is an important step towards realising our goals to achieve current market demand of desiccants. The third manufacturing facility will be the first of many important changes in line with high-quality standards and will suffice the high demand of the end-user. This facility is expected to generate sales of desiccants and capture the major share of the desiccant market for the year 21-22, primarily handle all pharma clients based in India to suffice the requirement of the regulated market. Our sales team is absolutely on their toes and very energetic to serve the industry and work closely with clients with the addition of the new facility'.

Fahmim Hussain, Marketing Director, CILICANT said, "Since its inception, Cilicant has envisioned itself not only as an active packaging manufacturing company but as a brand, an Indian brand that is capable of being global. The establishment of the third manufacturing facility is just another feather in the cap and we hope to have many in the coming years to fulfil the dream to be a global brand".

For more information,
visit cilicant.com

Mack Pharmatech: Quick, prompt and reliable service

Launching an array of products for the pharma sector, Mack Pharmatech has come a long way to excel in business strategy

Nashik-based Mack Pharmatech, a leading pharma and laboratory equipment manufacturer, having its presence since 1999, is eyeing to spread its business in the US and the European market. Providing an array of products for the pharma and the healthcare industry, the company has charted its growth plans after meticulously studying the market sentiment.

In 1999, Manoj Chaudhari, partner, Mack Pharmatech and Dr Kiran Badgujar, Director, Mack Pharmatech started a service-based business. Both of them shared an engineering background.

Says Dr Kiran Badgujar, Director, Mack Pharmatech, "We have worked our way up from the absolute ground level. We do not believe in copy-paste when it comes to technology. We develop our products. Starting as two individuals, today we have an employee-strength of 200. We have a pan-India presence of service stations."

Mack Pharmatech has its business presence across the country and covers almost 95 per cent of the business in South India. The company supplies its products to major pharma companies such as Aurobindo Pharmaceuticals, Dr Reddy's Laboratories and Cipla to list a few. It has received European CE Certification and all the products are CE marked.

Dr Badgujar mentions, "As a company policy, we offer jobs to those who are in need and treat them as part of our extended family. We can say it with pride that our attrition rate continues to remain low."

The company adopts a centralised control model and all the sales and services are operated from the Nashik office.

Dr Badgujar is optimistic about the Indian market and says that the company procures its supplies from Indian companies. He elaborates, "We manufacture from the ground up. The whole manufacturing ecosystem has developed in India. India remains a leading nation when it comes to manufacturing and this can be stated about the pharma sector. When it comes to capsule or tablet making machines, Indian companies are amongst the top manufacturers in the world.

When it comes to targeting export destinations, the key challenge which the company faces is identifying the right distributor having a deep knowledge of the market. Matching the quality standards and quality control up to the maximum level with European companies such as those from Germany is the biggest challenge.

According to Dr Badgujar, the government needs to introduce newer schemes to promote exports to create a strong branding push for the products manufactured in India. He mentions that the message must go out strongly through international trade expositions that products made in India stand for quality. Innovative products manufactured in India too need to be promoted at such global pharma exhibitions.

The company has high hopes from the Central government the way it is allowing companies to conduct business.

Dr Badgujar opines that with GST, things have become simpler from a procedural standpoint. Many laborious processes have become simpler and seamless after the implementation. About four to five per cent drop in product prices can also be witnessed. According to him, there is a dual benefit for both the suppliers as well as buyers. As a result of these changes, sales too have improved dramatically since the GST implementation.

The company has also been able to successfully launch a new range of innovative products. Dr Badgujar says, "We introduce regular product upgrades. We plan to launch star-ratings, something along the lines of electronic white goods in terms of power efficiency. Also, recently we have introduced biometric. The machines designed are controlled by the software and can be easily operated from any area with good internet connectivity."

Mack Pharmatech has its presence in Bangladesh and Malaysia. Besides, it has its operations in Ghana, Turkey, South Africa and Uzbekistan. The company is working with channel partners in all these countries. The company is likely foray into the South Asian and Middle Eastern markets.

Dr Badgujar says, "Our major focus is on Malaysia. Incidentally, in countries like Malaysia, Indian companies face stiff competition from other Indian companies operating in that market. When it comes to product quality as well as pricing, India remains the best option. In the future, newer markets are bound to open up. We haven't conducted any exhibition for the European market so far. However, our next target is to securely entry into the European as well as the US markets."

Currently, the company participates in about five international exhibitions and there are plans to participate in 10 exhibitions by the next year.

The company has taken part in trade exhibitions in Thailand, Indonesia, Nepal and Bangladesh. By next year, the focus is to enter the markets such as Turkey, Central America and Germany (Frankfurt). According to Dr Badgujar, foraying the US and European markets is the goal now.

Yokogawa, HIROTSU BIO SCIENCE sign investment and partnership agreement

Collaboration to widen use of N-NOSE cancer screening test

Yokogawa Electric Corporation and HIROTSU BIO SCIENCE (HBS) announce that they have signed an investment and partnership agreement with the goal of expanding the use of HBS's N-NOSE cancer screening test service, which utilises the highly sensitive olfactory sensory functions of nematodes to detect cancer. Under this agreement, Yokogawa will invest in HBS, and be responsible for the manufacturing and maintenance of N-NOSE's automatic analysis equipment. The two companies are also aiming to develop new automatic analysis equipment and promote the global growth of the N-NOSE business.

Issues with cancer screening include the difficulty of detecting cancer at an early stage and the fact that not enough people are having these tests, and this can be attributed to the lack of a primary screening test method that can easily detect many kinds of cancer with high accuracy and at low cost. These issues have become particularly acute during the COVID-19 pandemic as many people with underlying diseases are reluctant to risk exposure to the virus by visiting medical institutions to undergo testing.

The N-NOSE service presents a solution to these issues, but to provide this service to a broader segment of the market, HBS must now scale up the production of its automatic analysis equipment. With Yokogawa's manufacturing capacity and life science know-how, the two companies will be able to build a system for the mass production and maintenance of this automatic analysis equipment and meet the expected growth in demand for testing. They will also explore collaboration in the development of next-generation automatic analysis equipment and the global expansion of the N-NOSE business. For this business, HBS will provide nematode cancer screening technology and know-how, and Yokogawa will leverage its core measurement, control, and information technologies, and a global network that spans 62 countries.

> The N-NOSE primary screening service uses nematodes, organisms that are about one millimeter long, have an excellent sense of smell, and are inexpensive to nurture, to detect cancer from trace amounts of odorants in urine samples

To share the risks and returns of these collaboration activities, the two companies have agreed to adopt the same revenue sharing method used by many companies in the IT software and systems sectors.

"The N-NOSE primary screening service uses nematodes, organisms that are about one millimeter long, have an excellent sense of smell, and are inexpensive to nurture, to detect cancer from trace amounts of odorants in urine samples. HBS research has found that nematodes are able to detect at a very early stage (0 or 1) 15 different cancers, including gastric, colorectal, and lung cancer, with a probability of about 86 per cent. This comprehensive cancer test only requires the one-time submission of a urine sample and costs much less to administer than other currently available tests," informed the companies through a statement.

HBS launched the N-NOSE service in January 2020. The company is now planning for the spring 2021 launch in Japan of an "N-NOSE at home" service that can be conducted at home.

Regarding the partnership, Takaaki Hirotsu, HBS president and CEO, commented, "N-NOSE, a nematode cancer test, aims to become an annual test for all people in the world as a primary screening cancer test. In order to achieve this goal, high throughput, mass production, and global support of the automated analysis system are essential, and we consider the alliance with Yokogawa Electric Corporation to be of utmost importance in promoting the N-NOSE business. Another feature of this project is that we will be adopting a revenue sharing method for hardware technology, which is very rare. This is a new form of collaboration between a venture company and a large corporation, and we hope that new value that will change the world will be created from it."

Hitoshi Nara, Yokogawa President and CEO, said, "For Yokogawa, this collaboration is an important co-innovation initiative for achieving well-being for all, which is one of our "Three goals" for sustainability, and we believe that this will make a significant contribution to society. We will use this agreement as a starting point to build a strong relationship with HIROTSU BIO SCIENCE, and work toward further value co-creation."

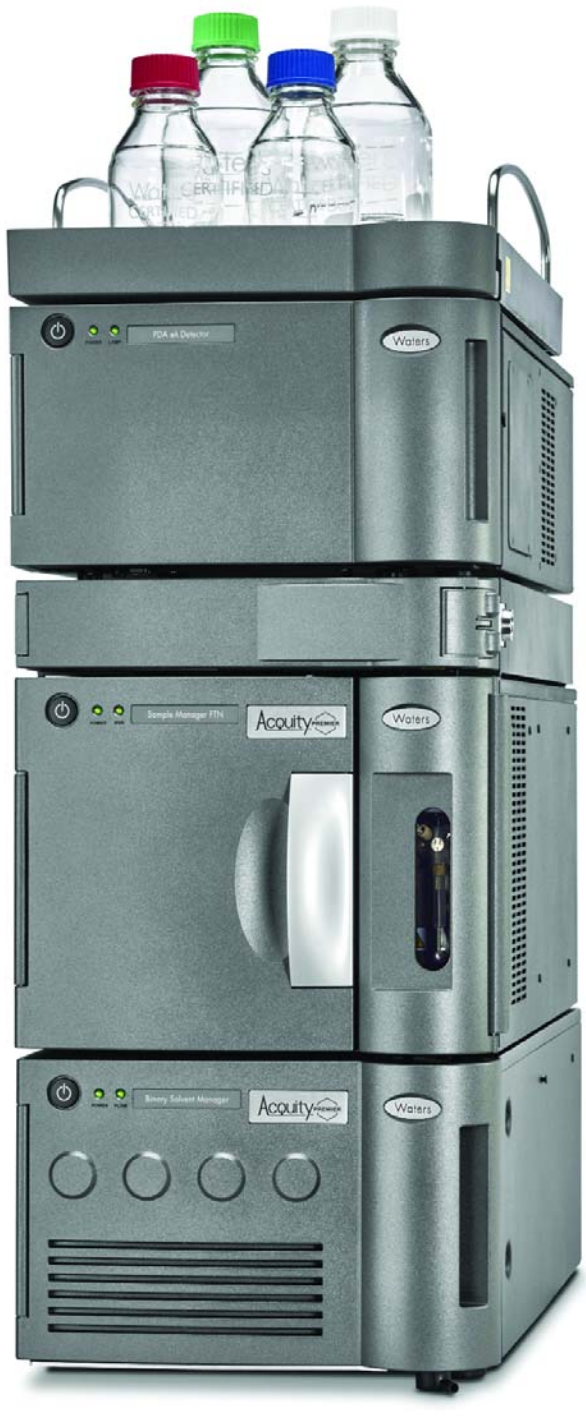
Waters launches new ACQUITY PREMIER liquid chromatography solution

ACQUITY PREMIER system and column chemistries work together to provide enhanced analytical data quality and greater confidence in separation results

Waters Corporation introduced the Waters ACQUITY PREMIER Solution, the next generation in liquid chromatographs featuring Waters' breakthrough MaxPeak High Performance Surface (HPS) technology. The solution leverages HPS to vastly improve analytical data quality and eliminate the need for time-consuming and costly passivation.

ACQUITY PREMIER is a universal liquid chromatograph (LC) solution that combines the ACQUITY PREMIER System with ACQUITY PREMIER Columns with MaxPeak HPS technology. It is designed to alleviate the problem of analyte/metal surface interactions when analysing organic acids, organophosphates, oligonucleotides, phosphopeptides, acidic glycans and phospholipids by reversed phase and hydrophilic interaction chromatography. For these analyses, the new ACQUITY PREMIER solution cuts the time from sample to results, improves analyte recovery and assay-to-assay reproducibility, to give separation scientists greater assurance in the integrity of their qualitative and quantitative analytical results.

"The ACQUITY PREMIER Solution represents our biggest innovation in separation science since UPLC. Chromatography has an immeasurable impact on the development of novel therapeutics and treatments for innumerable diseases. The result of decades of separations science know-how along with the combined efforts of our materials scientists, chemists and engineers,



ACQUITY PREMIER addresses a long-standing problem that has held back scientific progress long enough. We firmly believe it will redefine the value that separations science brings to scientific achievement," said Ian King, Senior VP, Global Products, Waters Corporation.

MaxPeak High Performance Surface Technology

MaxPeak HPS technology is a hybrid organic/inorganic surface technology that forms a barrier between the sample and the metal surfaces of both the system and column. By mitigating, or eliminating altogether, non-specific adsorption, the ACQUITY PREMIER Solution offers many benefits, among them:

- increased analyte recovery with 10-100X improvement in detectioni sensitivity for low-level phosphorylated and carboxylated analytes reducing the risk of unseen analytes going undetected
- sharper peak shapes and greater peak capacity for more accurate analyte identification and data interpretation
- greater reproducibility for separations prone to adsorptive losses meaning less rework or troubleshooting, and more confidence in results
- no more system passivation to waste valuable sample material or tie up instrument cycles
- eases the transfer of methods from site-to-site and from company-to-company
- offers UPLC performance for the analysis of both metal-sensitive and non-metal-sensitive analytes making it a truly universal liquid chromatography solution

"This approach solves a real problem with the analysis of some particularly troublesome analytes. The improvements in peak shape and signal-to-noise ratio at low concentrations of analytes like phosphorylated drugs and lipids are obvious at a glance and very impressive, and it will make the lives of many analysts much easier," said noted expert and consultant Prof. Ian Wilson, Faculty of Medicine, Dept. of Metabolism, Digestion and Reproduction, Imperial College London.

The ACQUITY PREMIER System and ACQUITY PREMIER columns are now available worldwide from Waters.

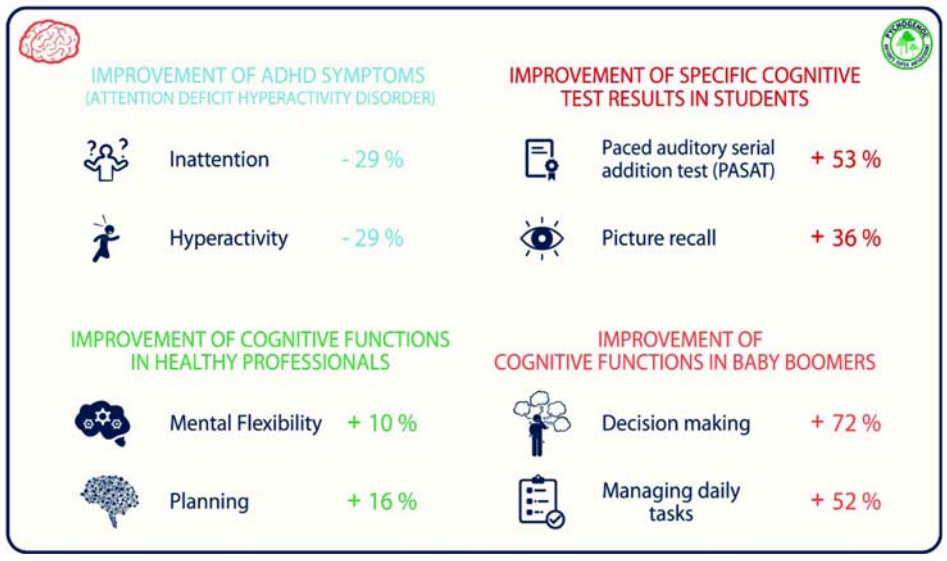
It is designed to alleviate the problem of analyte/metal surface interactions when analysing organic acids, organophosphates, oligonucleotides, phosphopeptides, acidic glycans and phospholipids by reversed phase and hydrophilic interaction chromatography

Pycnogenol for cognitive function at every stage of life

Franziska Weichmann, Manager of Scientific Communications and Product Development, HORPHAG informs that Pycnogenol has shown a broad spectrum of cognitive related benefits in all age groups and the underlying mechanism of action is based on its ability to regulate the endothelial function via adjusting nitric oxide (NO) production

A normal cognitive function is a prerequisite for a healthy life. The brain function may be altered in caseof either hyperactivity or hypo-activity of the brain. Hyperactivity is frequently observed in children, commonly referred to as Attention Deficit Hyperactivity Disorder (ADHD), whereas the decline of brain activity is related to the aging process.

Remarkably, Pycnogenol French maritime pine bark extract has shown a broad spectrum of cognitive related benefits in all age groups. These benefits range from reducing hyperactivity in children [1-3], to improving cognitive function in students, healthy adults and elderly people [4-9].



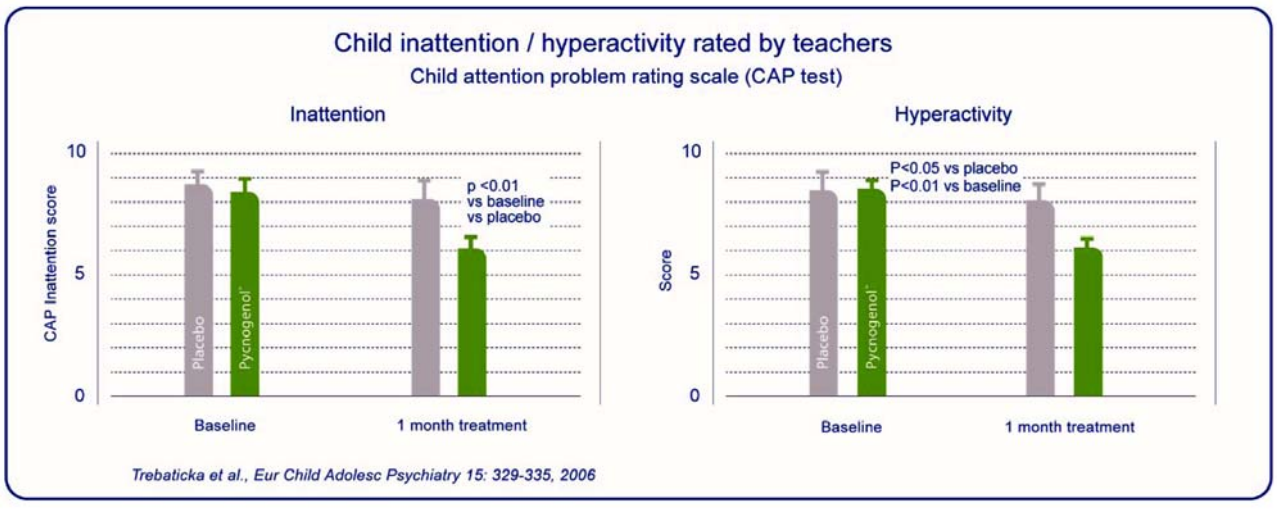
Pycnogenol regulates cellular NO concentration, which affects brain function

The underlying mechanism of action of Pycnogenol is based on its ability to regulate the endothelial function via adjusting nitric oxide (NO) production [10, 11]. It has been shown that NO has beneficial effects on brain function [12]. NO is capable of relaxing constricted blood vessels, normalising blood pressure and helping to protect tissues from damage, caused by low blood supply [13]. By regulating vascular smooth muscle relaxation, NO leads to increased blood flow, which ensures sufficient supply of oxygen to neuronal cells [14]. In addition, NO has been found to regulate neuronal functions and helps to modulate key neurotransmitters, thus contributing to processing signals in the brain [15, 16]. Interestingly, the active metabolites of Pycnogenol build up inside the endothelial blood cells and have been proven to pass the blood-brain barrier [11].

Pycnogenol regulates the NO production in two ways. The endothelial NO synthase (eNOS), generating normal concentrations of NO from L-arginine in the cell, is stimulated by Pycnogenol. At the same time, Pycnogenol prevents a toxic overproduction of NO by downregulating the inducible NO synthase (iNOS) - a well-established source of nitric oxide (NO*) during inflammation [11, 17]. In this way, Pycnogenol naturally modulates the multiple effects of NO in the brain.

Improvement of ADHD symptoms in children

ADHD (attention deficit hyperactivity disorder) is a frequent brain hyperactivity disorder, mainly affecting children. A common medication for this condition is Methylphenidate (Ritalin), but it is associated with various adverse effects (18). A double-blind, randomized, placebo-controlled clinical study could show that intake of Pycnogenol (1 mg per kg and day) for four weeks relieved hyperactivity and improved attention of children with ADHD by 29 per cent respectively, as rated by teachers and parents [1]. No side effects were reported. Another study investigated the levels of stress hormones (catecholamines) after Pycnogenol supplementation in ADHD affected children [2]. The concentrations of this group of hormones (including adrenaline, noradrenaline, and dopamine) were normalised in ADHD patients with Pycnogenol supplementation, which consequently leads to less hyperactivity. Oxidative stress (measured conversely as plasma total antioxidant status) and DNA damage incidents (as measured by the levels of



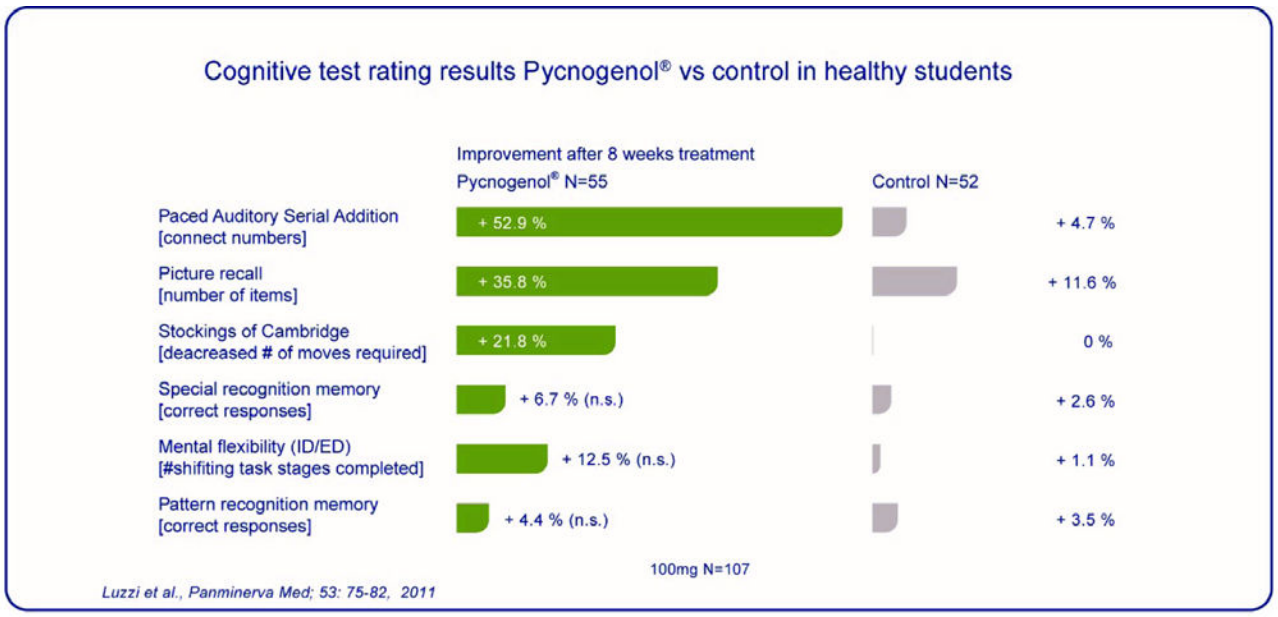
8-oxoG as representative of oxidatively damaged purines) were significantly reduced by 6.3 per cent and 35.4 per cent respectively [3].

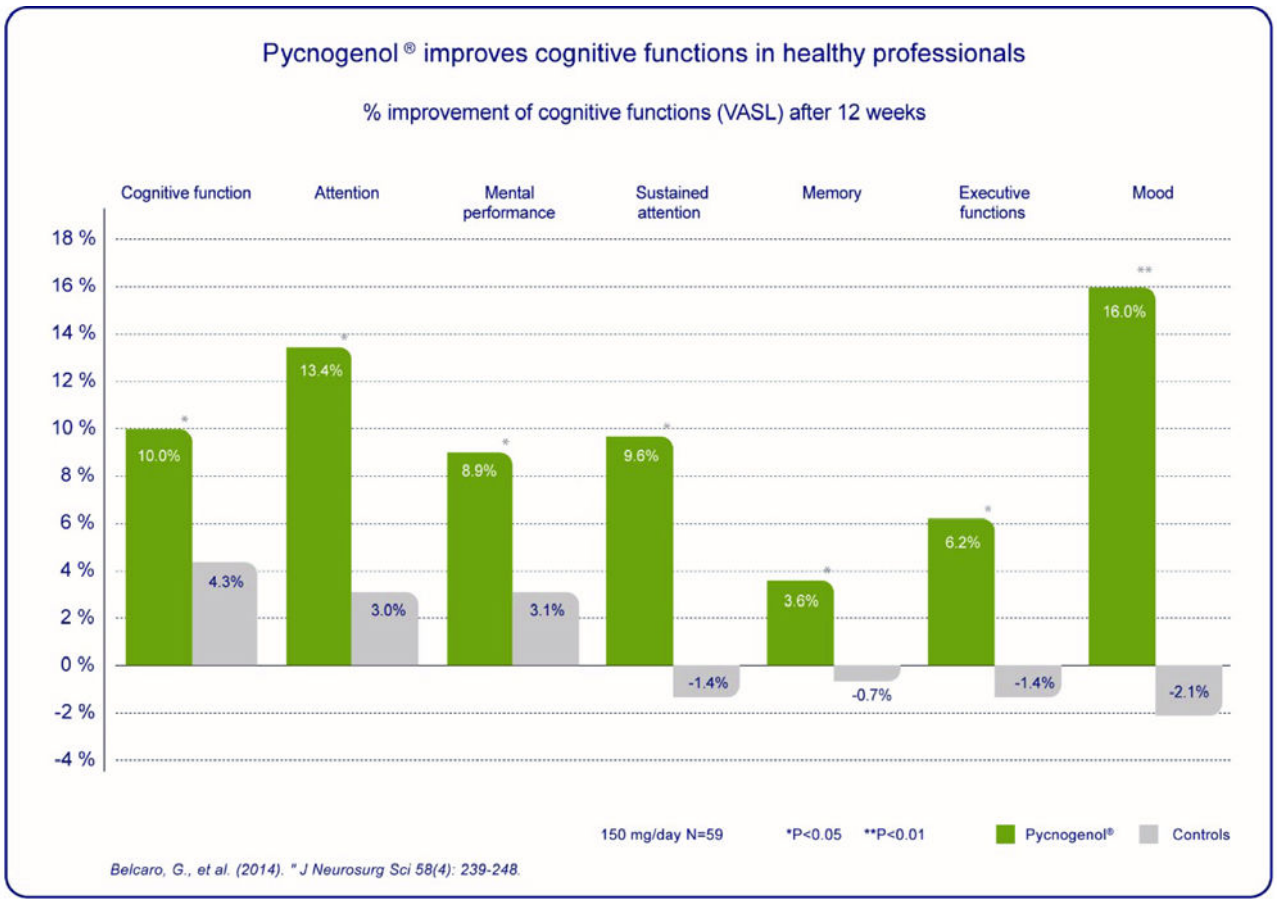
Enhanced mental performance in students

In an observational study, 53 healthy students, aged 18 to 27 years were supplemented with 100 mg Pycnogenol a day for 8 weeks; another group of 55 students was used as control subjects [4]. The effects of Pycnogenol on cognitive function and mental performance were investigated, using different tests. For example, the paced auditory serial addition task (PASAT) wasused for assessing the sustained attention. For evaluating the spatial recognition and working memory abilities, CANTAB (Cambridge neuropsychological test automated battery) was applied. The students showed significantly improved attention (+52.9% vs +4.7% in the control group) and increased memory skills (+35.8% vs +11.6% for picture recall, +6.7% vs. 2.6% for spatial recognition memory and +4.4% vs +3.5% for pattern recognition memory). Consequently, the test results of the supplemented students were better by 7.6% compared the ones from the control group. Pycnogenol was shown to have beneficial effects on the mental performance in healthy students.

Advanced cognitive function in healthy professionals

Another study, including 60 subjects between 35 and 55 years evaluated the effects of Pycnogenol 150 mg a day on cognitive function, attention and mental performance in healthy professionals [5]. For this, cognitive battery tests, similar to those of the previous study with students were used, determining, among other things, improvements in spatial working memory (+13.5%), planning (+16%), mental flexibility (ID/ED) (+9.8%) and general cognitive function (10%). No significant changes were found in the control group. Additionally, the plasma oxidative stress levels were measured (as plasma free radicals in Carr units) and showed to be elevated at the beginning of the study, probably due to negative daily stress. After 12 weeks of supplementation with Pycnogenol, a significant decrease of 30.4% to normal levels compared to a slight increase in the control group of 0.8% was measured.

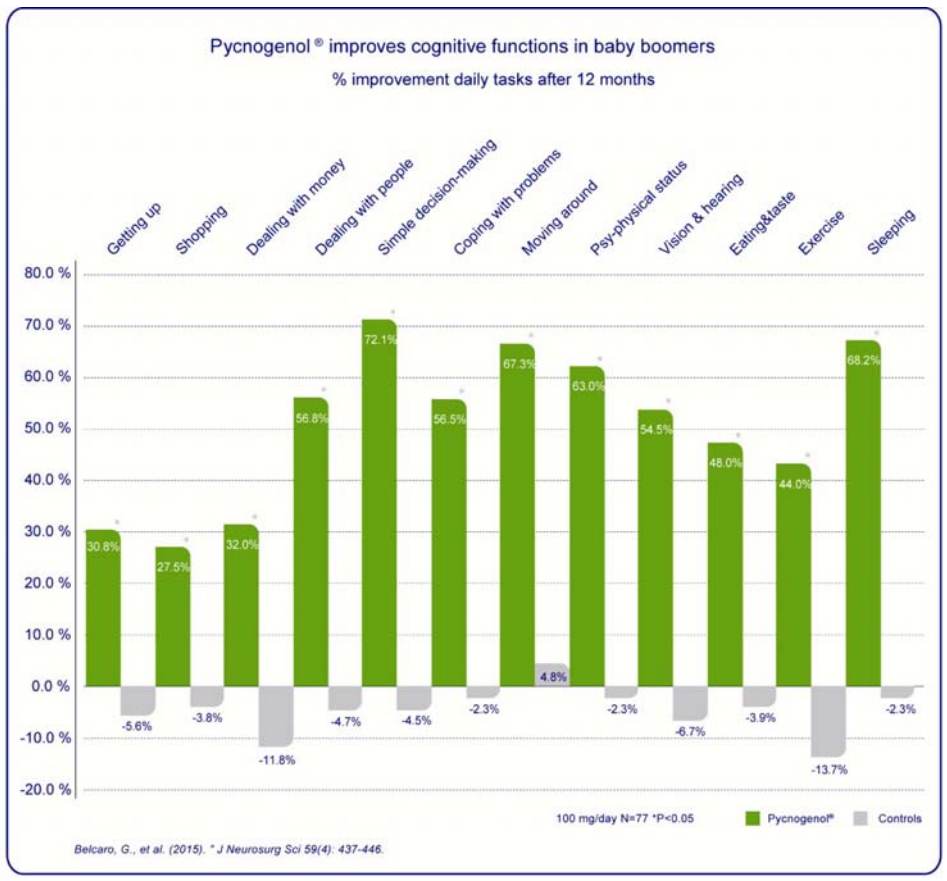




Improvement of cognitive function in the aging baby boomer generation

Neurological hypoactivity – the decline of brain activity – usually mainly affects aged or elderly people. This can result in senility, dementia or in diseases like Alzheimer's or Parkinson's disease. Here, the abilities to remember, recall, combine and orientate are deteriorating. A few studies have shown that Pycnogenol can help to keep a good mental performance and to manage mild cognitive impairment [6-9]. A study with 150 healthy subjects from 55 to 70 years, who were supplemented with 100 mg Pycnogenol per day for 12 months confirms the beneficial effects of Pycnogenol on healthy aging and the maintenance of good cognitive function (6). The tested parameters included cognitive impairment, attention,

mental performance, memory, and daily tasks (like making decisions or coping with problems), all of which improved significantly in the supplementation group, in contrast to the control group. Another similar study with 87 subjects (55 to 75 years) with mild cognitive impairment showed several positive effects of Pycnogenol supplementation (150 mg per day) for two months [7]. The improvements were assessed using cognitive tests, as described before (regarding memory, attention, and daily tasks), as well as the MMSE (mini-mental state examination), which helps to evaluate borderline cognitive impairments for apparently unaffected individuals. The MMSE score increased significantly by 18.5% for the Pycnogenol supplemented subjects, in contrast to an increase of 2.5% in the control group, bringing the MMSE score back to a normal level in the Pycnogenol group. In a recent study on the effect of Pycnogenol (150 mg per day) in patients with Parkinson's Disease, in addition to the standard medication with carbidopa/levodopa, beneficial effects could be observed in the supplement group after four weeks [8]. The subjects, between 60 and 67 years old, described mild to moderate symptoms, including tremor, bradykinesia, alterations in cognitive function, rigidity, and speech changes. Using a scoring system, it was found that the cognitive function in these patients, supplemented with Pycnogenol improved by 18.8% compared to inclusion. A double blind, placebo-controlled trial with 101 subjects, between 60 and 85 with moderate decline of their cognitive function investigated the effects of 150 mg Pycnogenol per day for three months on mental performance [9]. The Australian study not only followed the cognitive abilities of the subjects but also the blood profiles, including the serum lipid profile and growth hormones. Statistically significant improvements, as compared to the placebo group could be found for memory-based cognitive functions, more precisely the spatial and numeric working memory, and lipid peroxidation products, confirming Pycnogenol's role as a potent antioxidant. As an impairment of the memory skills was connected to increased age and oxidative stress [19]. These findings further support a beneficial effect of Pycnogenol on cognitive functions in elderly people.



Population aging generates a number of health concerns and maintaining a healthy cognitive function is of the utmost importance. Research shows Pycnogenol and its unique properties can help improve cognitive health at all ages.

Pycnogenol French maritime pine bark extract is a safe, natural, and evidence-based solution to support a healthy cognitive function at any age. For a complete list of scientific research and for further information, please visit www.pycnogenol.com

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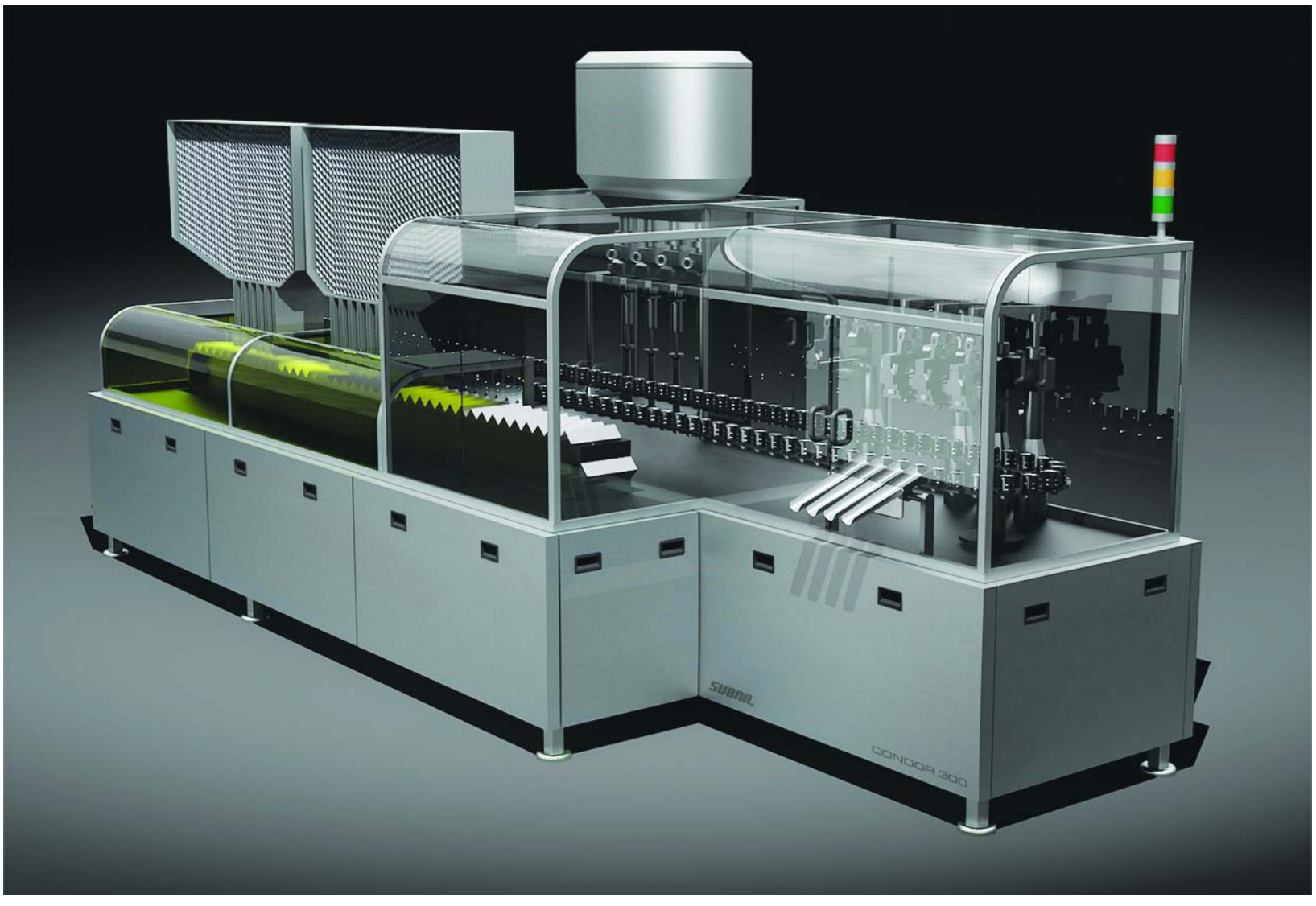
CONDOR 300: Contemporary, high-speed tube filler

As the fastest tube filler in SUBNIL's range, it has the capacity to produce about 100,000 tubes per shift

The CONDOR 300 is high-speed tube filler with a capacity to produce about 100,000 tubes per shift. This is the fastest tube filler in Subnil's range.



The tubes have to be first manually transferred from the tube box to the cassette provided on the machine. In turn the cassette transfers them, through multiple chutes, to a servo-driven pocketed conveyor. From the conveyor, multiple tubes are picked up by a rotary pick-up device, driven by servo, and loaded into the tube holders. First the tubes are centered and oriented and then filled. They are then closed depending on the type of tube. In case of metal tubes, the tubes are flattened and crimped twice (or even thrice). In case of laminate/plastic tubes, they are first heated on the inside periphery and then sealed. Batch details are then coded on the crimp (or seal) with metal stereos and the tubes are ejected out either into a collection container or to a tube-transfer system to link to the downstream MERLIN 300XC cartoner.

Features

- Easy changeover
- Bottom-up filling with shut-off nozzle. Blow-off for string-like characteristic
- Vertical dosing for ease in suction
- Standard features include product level sensor, detection of reverse tubes, jammed tubes and un-oriented tubes
- All-around guarding, with minimum access to moving parts
- Saddle fold
- Multi-colour filling
- Profiled sealing / Euro-slot
- Heating from hopper to nozzle, for balm-like products
- Adjustment with bare minimum tools
- Vision systems for checks like right packaging for SKU, illegible printing by ink-jet, bad seal, etc.
- Nitrogen flushing

For more details contact:
AVISH MACHINES PVT LTD
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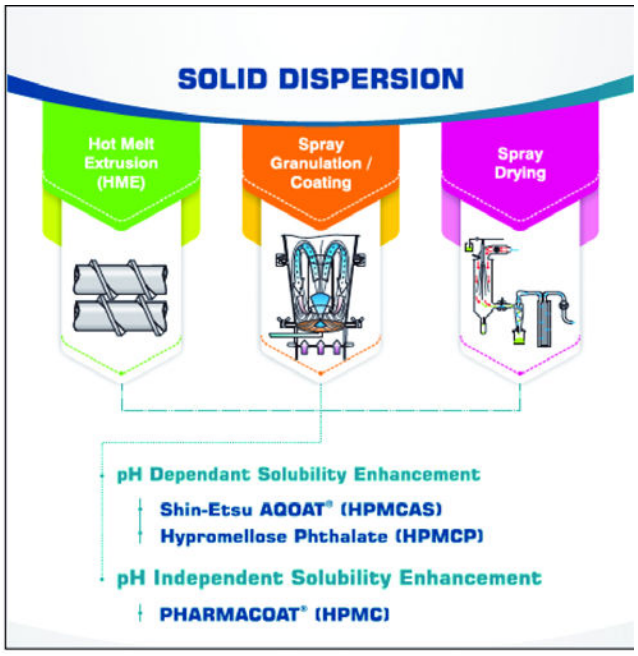
Tel: 96079 40379
E: sales@avishmachine.com

Solid dispersion technology: A tool for solubility enhancement

Shin-Etsu Chemicals offers a selection of suitable polymers in solubility enhancement

The oral route of drug administration is the most common and preferred method of delivery due to convenience and ease of ingestion. From a patient's perspective, swallowing a dosage form is a comfortable and a familiar means of taking medication. Although the oral route of administration is preferred, for many drugs it can be a problematic and inefficient mode of delivery for a number of reasons. Limited drug absorption resulting in poor bioavailability is paramount amongst the potential problems that can be encountered when delivering an active agent via the oral route.



Hence, two areas of pharma research that focus on improving the oral bioavailability of active agents include:

(i) enhancing solubility and dissolution rate of poorly water-soluble drugs and

(ii) enhancing permeability of poorly permeable drugs. And solid dispersion is the technique to improve the dissolution characteristics of poorly water-soluble drugs and in turntheir oral bioavailability.

Numerous solid dispersion systems have been demonstrated in the pharma industry to improve the dissolution properties of poorly water-soluble drugs like co-precipitation, spray drying, spray coating/granulation and hot melt extrusion (HME). Solid dispersion technologies are particularly promising for improving the oral absorption and bioavailability of BCS Class II drugs.

The term solid dispersion refers to a group of solid products consisting of at least two different components, generally a hydrophilic matrix and a hydrophobic drug. The matrix can be either crystalline or amorphous. The drug can be dispersed molecularly, in amorphous particles (clusters) or in crystalline particles. Various polymers are used in solid dispersions like PVP base, HPMC based and further derivatives like HPMCP, HPMCAS. HPMCAS (Hypromellose Acetate Succinate, commercially known as Shin-Etsu AQOAT) has been found to be an excellent polymer for the carrier for solid dispersions to increase solubility of poorly-soluble drugs.

The suitability of a polymer as a carrier in solid dispersion has been reported to depend on a drug's characteristics and chemical structure, however HPMCAS is known to be suitable polymer that prevents recrystallisation, improves solubility of poorly soluble drugs and maintains higher solubility. Additionally, due to polymer's low hygroscopicity, higher solubility is maintained even after long-term storage.

Thermal Characteristics of HPMCAS

Glass Transition Temperature (Tg): The Tg of HPMCAS measured with DSC and it was found tobe 115°C, which was lower compared to other cellulose derivatives that have been used for pharmaceutical applications. There was nodependency by grade, while other polymers showed some grade dependency.

Melt Viscosity: Using a capillary rheometer (Capilograph Model E3B, Toyo-Seiki, Japan), melt viscosity of HPMCAS without API was measured under various conditions. This was compared with HPMCP which is another enteric polymer that has been used commercially for along time. A grade-dependency was observed, especially for the temperature at which the polymer was able to melt and be extruded, and the overall viscosity was lower than HPMCP. Between 150 and 180°C, the viscosity was relatively stable (except AS-LF at 150°C).

HPMCAS (Hypromellose Acetate Succinate) was first commercialised by Shin-Etsu Chemical in Japan in 1986 as an enteric coating agent, with a commercial name of Shin-Etsu AQOAT. Currently nine grades of Shin-Etsu AQOAT (HPMCAS) are commercially available as shown in table below differentiated as per physical properties and chemical substitution. F grades are used for aqueous enteric coating; G grades are usually used in solvent methods for spray drying/enteric coating while MP grades are used mainly for melt extrusion techniques.

Comparative performance of different polymers checked which shows that HPMCAS performs better to enhance the solubility as well keeps drug in a supersaturated state for a longer period of time. HPMCAS shows higher Tg even at higher humidity. However, all reported studies were conducted in pH 6.8 buffer or in simulated intestinal fluids. This

Grade	Viscosity* (mPa·s)	Methoxy content (%)	Hydroxypropoxy content (%)	Acetyl content (%)	Succinoyl content (%)	Particle	pH Solubility
AS-LF	2.4-3.6	20.0-24.0	5.0-9.0	5.0-9.0	14.0-18.0	Fine**	≥ 5.5
AS-LMP						Medium***	
AS-LG						Coarse	
AS-MF		21.0-25.0	5.0-9.0	7.0-11.0	10.0-14.0	Fine**	≥ 6.0
AS-MMP						Medium***	
AS-MG						Coarse	
AS-HF		22.0-26.0	6.0-10.0	10.0-14.0	4.0-8.0	Fine**	≥ 6.5
AS-HMP						Medium***	
AS-HG						Coarse	

**Viscosity of 2% w/w solution of sodium hydroxide aqueous solution at 20°C. **D50: NMT 10µm, D90: NMT 20µm by laser diffraction method. ***D50: 70-300µm by laser diffraction method*

Continued on Page 63

How balanced is Budget 2021?

Amit Jain, Director, Erawat Pharma shares his views and insight on the Union Budget 2021 and its focus on healthcare

Budget 2021 on the surface looks like quite a balanced budget focusing on all the right places. But is the focus sufficient?

Three key areas which were demanding urgent and immediate attention were Healthcare, Education, and Infrastructure. Apparently, they were focused on well.

But there are still concerns that are unaddressed and which are quite capable to derail the government's plans.

COVID-19 uncovered serious shortcomings in the healthcare sector. Whether it is the healthcare infrastructure, support, or healthcare human assets. This obviously reconfirmed India's low spending on healthcare. Even with Indian healthcare cost at around 1.29 per cent of GDP in FY20 (increased from approximately one per cent since last many years), India stood with the bottom few countries of the world who are spending meagre amount on healthcare. If we compare with the top few countries who are spending the most on healthcare, the percentage would be anywhere around five per cent of GDP.

Even though the budget allocation on healthcare has been increased by 137 per cent as compared to last year, I believe it is still insufficient. It may look that there is a jump of 137 per cent but if we see it as a percentage of GDP it is a very marginal few points' increase. We have hardly touched per cent. So, I would say we are still too short of what is required, but yes, the allocation is certainly better than earlier.

Considering a population of approximately 138 crore people, budget allocation on healthcare translates to Rs 1622 per person per year. Better than earlier? Definitely, yes. Is it sufficient? That remains a question mark.

Concerns are always there but if executed and implemented properly, the government's good intent would be translated into a better future for the country

Another key concern is that our healthcare system is already short of a skilled workforce. Plans of laying almost 28,000 new health and wellness centres in the country will require an additional workforce, the lack of which might derail the ambitious plan. So, this plan should be complemented with very robust skill development and education plan specifically for the healthcare sector. If handled properly, it will suffice the required skill and people gap and will generate quite good employment opportunities.

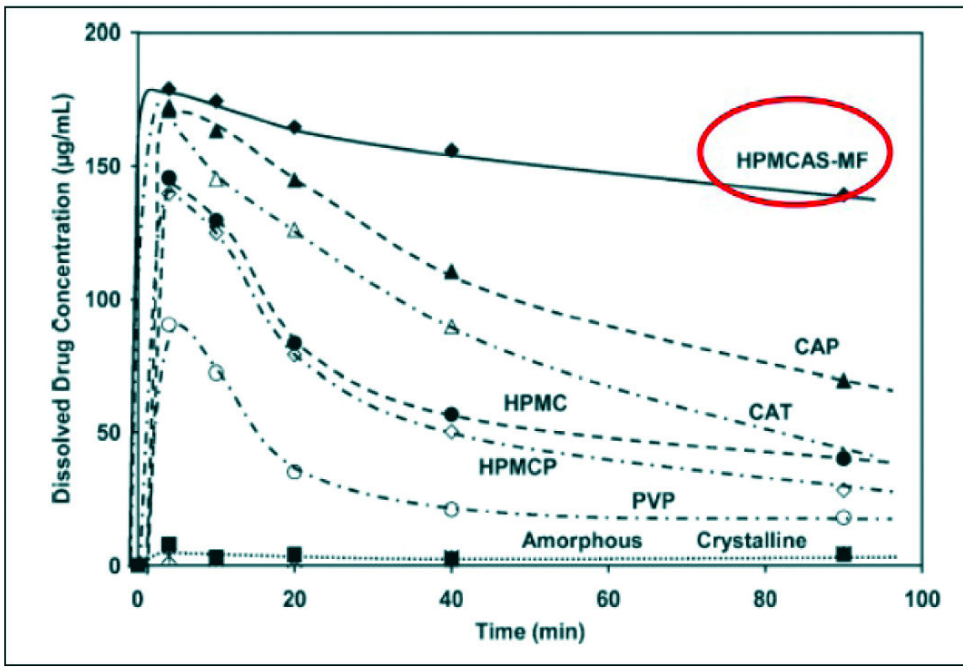
So overall, the right strings are being pulled and things are looking better. Concerns are always there but if executed and implemented properly, the government's good intent would be translated into a better future for the country. Obviously, healthcare spending cannot be increased exorbitantly overnight. It must be a slow and steady process and with a constrained budget. No doubt that it is a tough balancing act for the government.

Solid dispersion technology: A tool for...

Continued from Page 62

study was conducted for spray dried dispersions (SDD's) with various polymers at 10% drug loading.

As of 2019, more than 35 pharma products have been marketed throughout the world using this polymer as anenteric coating agent and solid-dispersion carrier. The first commercial solid dispersion product using HPMCAS was brought into the Japanese market in 1994 using Efonidipine Hydrochloride Ethanolate as an active pharma ingredient (API). The product was producedby a method using organic solvents. During 2011 - 2012, three block buster drugs, Telaprevir, Vemurafenib, and Ivacaftor were marketed using HPMCAS as solubility enhancement carrier. Spray drying or co-precipitation process were applied to create amorphous solid dispersions. Inlate 2013, the first commercial solid-dispersion product using HPMCAS by the melt extrusionprocess was marketed for Posaconazole DR tablets.

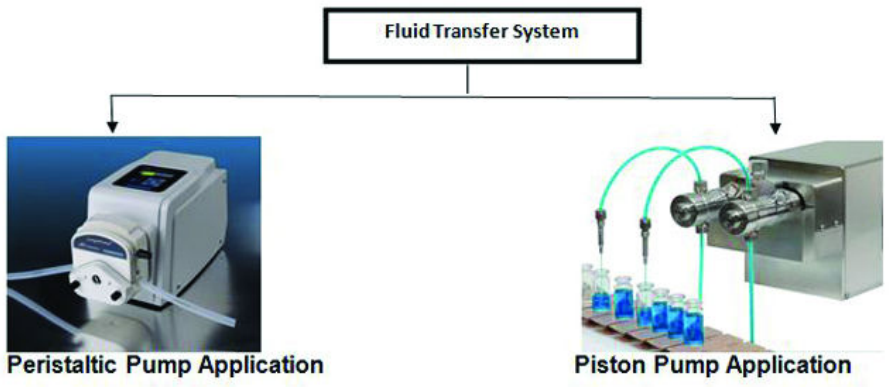


- Shin-Etsu AQOAT (HPMCAS) shows excellent performance as a carrier in various solid dispersions.
- Shin-Etsu AQOAT can greatly enhance drug solubility and it requires small polymer ratio for amorphous drug.
- Shin-Etsu AQOAT can greatly inhibits recrystallization of the drugs and maintain supersaturated state.
- Higher glass transition temperature (Tg) even at higher humidity.

Polymers and their solutions for pharma and biopharma industries

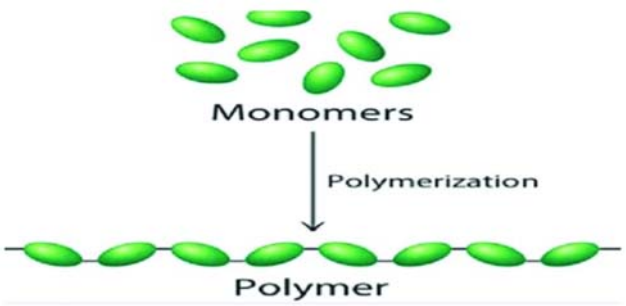
Anuj Singh, Sr Executive, Business Development, Ami Polymers, highlights that polymers have unique properties that can be tailored for different uses in pharma and biomedical applications

Nowadays, synthetic and natural-based polymers have found their way into the pharma and biomedical industries and their applications are growing at a fast pace. The role of polymers as in ingredients and a medium in a form of food-grade plastic or rubber products help to form several types of drug dosage (tablets, capsules, creams, ointments, solutions, injections, and aerosols). Polymers in pharma and biomedical applications are water-soluble synthetic polymers, cellulose-based polymers, hydrocolloids, starch-based polymers, water-insoluble biodegradable polymers, food-grade plastics and rubbers products.



Introduction

A polymer is a chemical compound with molecules bonded together in long, repeating chains. (Poly- "many" + -mer, "part") is a large molecule, or macromolecule, composed of



many repeated subunits. Because of their structure, polymers have unique properties that can be tailored for different uses. Polymers are extremely large molecules that are formed by monomers with the help of polymerization.

Properties of polymers: Depending on the desired use, polymers can be fine-tuned to leverage certain advantageous properties. These include:

Reflectivity: Some polymers are used to produce a reflective film, which is used in a variety of light-related technologies.

Impact resistance: Sturdy plastics that can withstand rough handling are perfect for luggage, protective cases, car bumpers, and more.

Brittleness: Some forms of polystyrene are hard and brittle and easy to deform using heat.

Translucence: See-through polymers, including polymer clay, are often used in arts and crafts.

Ductility: Unlike brittle polymers, ductile polymers can be deformed without falling apart. Metals such as gold, aluminium, and steel are known for their ductility. Ductile polymers, while not as strong as other polymers, are useful for many purposes.

Elasticity: Natural and synthetic rubbers have elastic properties that make them ideal for car tires and similar products.

Selecting the right polymer for end-use: Selecting the right polymer for a finished product's intended end use is important, regardless of the end use. Factors that are typically taken into consideration include:

- Service temperature range of the finished product
- Compatibility with contacting chemicals
- Compatibility with contacting plastics
- Required mechanical properties (tensile strength, modulus, ultimate elongation) of the finished product.
- Impact resistance, clarity and opacity, permeability to gases
- Ease of connecting system components. Additional specific requirements for certain end

Uses can include:

- Electrical resistivity (e.g., for wire insulation or antistatic flooring)
- Stain resistance (e.g., for household goods), flame resistance (e.g., for children's apparel)
- UV resistance (e.g., for roofing membranes), water-resistance (e.g., for submersible cables).
- Microbial resistance (e.g., for products susceptible to mould or mildew attack)

Polymers are a solution for fluid transfer application in pharma and biopharma:-

It's very necessary to understand what are the parameters and things required while we manufacture liquid injectable drugs or the type of drug which are in liquid form. These drugs are formed through the transfer and filling application using a Peristaltic pump.

Two types of peristaltic pump are used in pharma and biopharma industries:

Both pump applications are for the transfer of the fluid from one end to the other end.

But, the main thing is that in the peristaltic pump we can use only elastomer tubing and not plastic tubing, but in the piston pump, we can use both polymer tubings.

Now we have to understand the factors responsible for selecting the right polymer for fluid transfer application in the pharma and biopharma industries:

Chemical compatibility: It's compatibility between any chemicals or organic solvents

Temperature: It is a measure of how hot or cold something is. The degree or intensity of heat present in a substance or object. Temperature is different for different polymeric materials. On that basis, we can select the right polymer for the right temperature.

Pump compatibility: It is the compatibility of the pump with the polymeric tubing. Pump life depends on the type of polymer based on their structure and compounding.

Compliances: It means the authority to manufacture food and pharma grade products under regulatory compliance. There are several kinds of certifications on products such as food and pharma grade compliances and biological reactivity test on the product.

For further information, check https://www.amipolymer.com

A new era of manufacturing

B&R heralds the beginning of multidimensional manufacturing with ACOPOS 6D, which is ideal for small-batch production with frequent changeover between products of different designs and dimensions

With ACOPOS 6D, B&R heralds a new era of manufacturing. Magnetic levitating shuttles move individual products freely through the machine. Gone are the days when conventional transport systems imposed rigidly defined timing on the production process. ACOPOS 6D is ideal for small-batch production with frequent changeover between products of different designs and dimensions.

ACOPOS 6D is based on the principle of magnetic levitation: Shuttles with integrated permanent magnets float over the surface of electromagnetic motor segments. The modular motor segments are 240 x 240 millimetres in size and can be arranged freely in any shape. A variety of shuttle sizes carry payloads of 0.6 to 14 kilograms and reach speeds of up to 2 meters per second. They can move freely in two-dimensional space, rotate and tilt along three axes and offer precise control over the height of levitation. All together, that gives them six degrees of motion control freedom.

Space savings

ACOPOS 6D offers up to four times the shuttle density of other systems on the market through the unique ability to control four shuttles on the same motor segment simultaneously. The shuttles can also be used as axes in processing stations. An ACOPOS 6D shuttle carrying a workpiece could follow a CNC path, for example, allowing the processing tool to be mounted rigidly. Weighing stations can be eliminated entirely, since each shuttle can also serve as a high-precision scale. This makes it possible to design a more compact machine.

Zero wear

ACOPOS 6D shuttles levitate freely without any contact or friction. With no abrasive wear, there are no parts to be maintained. If a stainless steel cover is placed over the motor segments, ACOPOS 6D offers IP69K protection – making it ideally suited for cleanrooms or food and beverage production.

Fully integrated

ACOPOS 6D is fully integrated in the B&R ecosystem. That allows the shuttles to be synchronized with servo axes, robots, track systems and machine vision cameras with microsecond precision. Path planning for the shuttles occurs in a dedicated controller, connected to the machine network via POWERLINK – which means it has no impact on the performance of the network or machine control system. For systems with more than 200 segments or 50 shuttles, multiple controllers can be synchronized with each other.

Intelligent shuttles

Unlike comparable systems, each ACOPOS 6D shuttle is assigned a globally unique ID. At startup, the controller immediately knows the location of each shuttle on the motor segments, and production can begin without time-consuming homing sequences or manual input by an operator. The shuttles offer positioning repeatability of ffl5 ❄m, making ACOPOS 6D perfectly suited for applications with strict positioning requirements, like those in the electronics industry and in the assembly of mechanical and electronic components.

Easy setup

ACOPOS 6D offers nearly limitless possibilities in machine design, yet is remarkably easy to set up.

Sophisticated algorithms ensure the shuttles follow an optimal path while avoiding collisions and minimising energy consumption. Developers are free to concentrate on their primary task: developing optimal machine processes that deliver maximum productivity.

ACOPOS 6D was developed in cooperation with Planar Motors, a company with more than 15 years of research and development in the field of magnetic levitation technology for industrial manufacturing. B&R is a shareholder in Planar Motors.

High Speed Doors from Gandhi Automations

Gandhi designed and manufactured High Speed Doors are versatile and solid, ensuring long-lasting reliability

Gandhi Automations - India's No.1 Entrance Automation and Loading Bay Equipment Company offers High Speed Doors.

High Speed Doors designed and manufactured by Gandhi Automations are sturdy, dependable and are the ideal solution for medium and large entrances. The doors are manufactured with European collaboration and technology with innovative and creative engineering.

Fast moving functional and reliable doors are needed in industrial and commercial contexts. Gandhi designed and manufactured High Speed Doors are versatile and solid ensuring long-lasting reliability. The modular structure of the curtains, assembled and joined by anodized aluminium extrusions, provides for a wide range of polyester sections available in a variety of colours. Wide, full-width window panels ensure a safer traffic and allow more light in. Their fast and easy replacement, in case of accidental tearing, saves money and time. The alternating metal tubular structure there inserted ensures high wind-resistance.

PrimeHigh Speed Doors are the ideal solution for internal and external entrances and effectively operate in any situation, even when strong winds are blowing and in rooms with high volume traffic. Sturdy and dependable, Prime is the intelligent door for medium and large entrances.

High Speed Doors for external entrance are equipped with spring steel wind lock in curtain pocket that ensures silent door travel, higher wind loads and curtain stability.

High Speed Door - Prime Reset

It is an unique High Speed Self-Repairing Door with the latest technology that prevents downtime of the door system. In case, the curtain is impacted accidentally it will cause the curtain to move out of the guides without damage. The movement of the door is designed in such a way it can be recovered with a simple opening and closing operation. Gandhi Automations manufactures doors of the highest quality that meet the issue for greater flexibility desired by clients. High Speed Self-Repairing Door in PVC is the most suitable solution in the field industries, it lowers the time of transition from one facility to another, avoiding any human error which can cause damage to the High Speed Door and all this can be achieved due to the innovative ANTI CRASH SYSTEM. Gandhi Automations provides a world class product with great security.

Below are the features of self-repairing high speed doors offered by Gandhi Automations:-

- Flexible and Self-Repairing Door
- Functional, safe, quick and resistant
- Innovative anti-crash system
- Can be equipped with PVC vision windows
- Self-Lubricating maintenance free guide
- Smooth and silent opening and closing
- Protects traction unit, enables rapid wiring and safety photocell
- Flexible curtain in self-extinguishing material
- Self-resetting without intervention
- Quickly back to operation
- Control panel designed for an intensive continuous service

Contact

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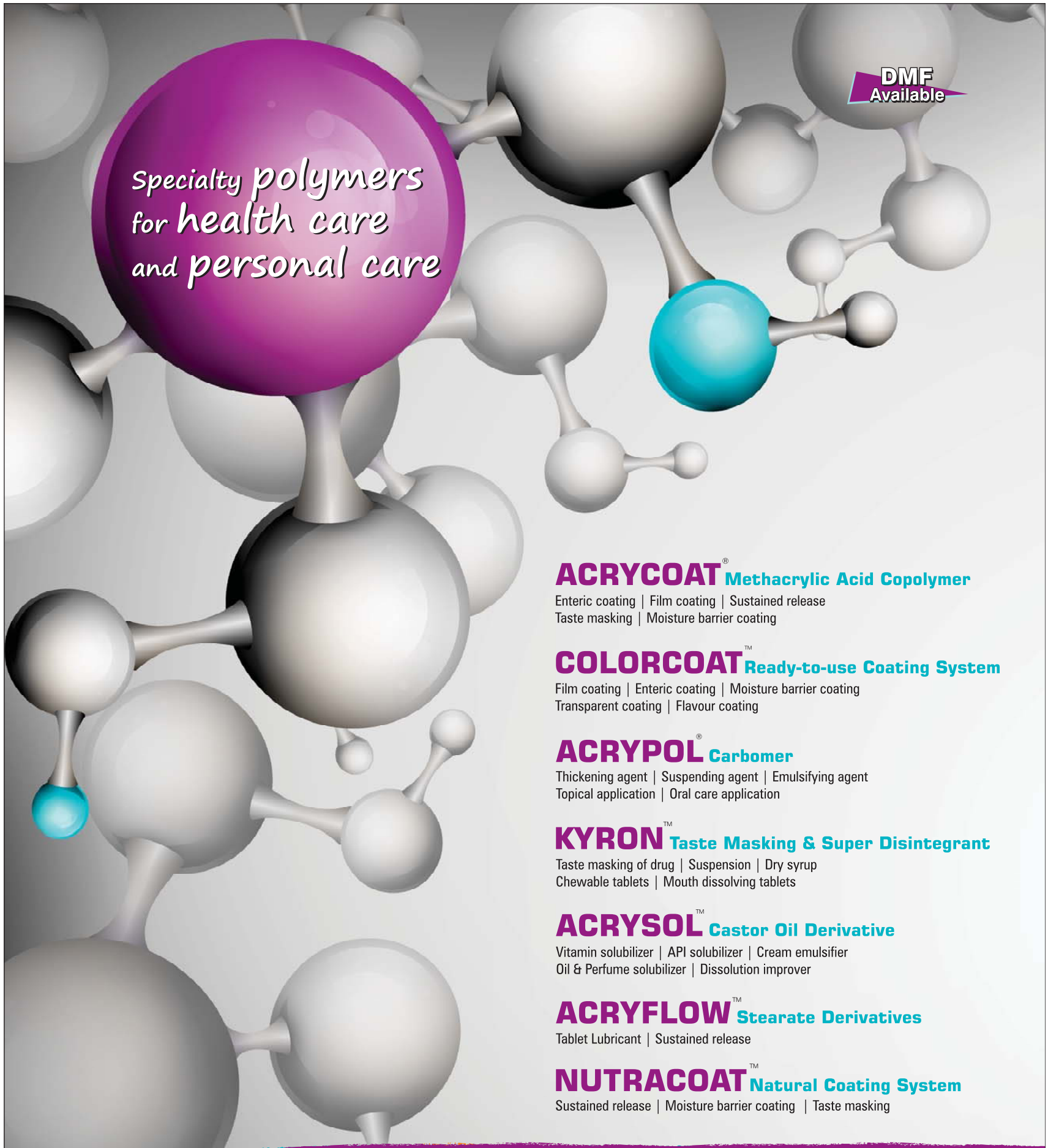

ACRYCOAT® Methacrylic Acid Copolymer
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Taste masking | Moisture barrier coating

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Transparent coating | Flavour coating

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Thickening agent | Suspending agent | Emulsifying agent
Topical application | Oral care application

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Taste masking of drug | Suspension | Dry syrup
Chewable tablets | Mouth dissolving tablets

ACRYSOL™ Castor Oil Derivative
Vitamin solubilizer | API solubilizer | Cream emulsifier
Oil & Perfume solubilizer | Dissolution improver

ACRYFLOW™ Stearate Derivatives
Tablet Lubricant | Sustained release

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